Gmail Francis Collins (b) (6) >

FW: Confidential, new case

7 messages

Jane Goodall (b) (6) Thu, May 1, 2014 at 12:06 PM
To: Francis Collins (b) (6)

Dear Francis,
Below is the email I got from Dan – after I received the first I called him, and that is always better than asking difficult questions via email.
So all the correspondence is below, and I outlined the phone conversation.
Would be great if this was a turning point in all our relations with PETA and we could get all that good energy working in a way that helps everyone.
You won't enjoy the videos!
Lots of love and thank you for listening
Jane

From: Jane Goodall (b) (6)
Date: Sunday, 27 April 2014 12:08
To: <JANE>, <PETA>
Subject: FW: Confidential, new case

From: Dan Mathews <DANM@peta.org>
Date: Friday, 25 April 2014 23:19
To: Jane Goodall (b) (6)
Subject: Re: Confidential, new case

Hi Jane,

I'm very pleased we spoke today. PETA's plan for the monkey case doesn't involve protests, rather sharing the video online and urging people to ask NIH to end the project. But we'd much prefer to begin with private discussions with Dr. Collins. We'd be much obliged if you called him, shared the footage, and asked for a meeting with us in hopes of making headway behind the scenes. One of PETA's researchers is a human neuroscientist who just left NIH after 8 years; she knows the issue in and out and can speak authoritatively to the science of this issue. We have other experts who could join too. And if you are able to join via Skype even better! But I know you'll be on the road again soon. We are at the disposal of both you and Dr. Collins, please advise.

THANK YOU!

Dan

PS Regarding Air France, we will draft a letter for you to send them and get it to you later today. We're happy to help with media to promote that, as well.

From: Dan Mathews
Sent: Wednesday, April 23, 2014 7:18 PM
To: Jane Goodall
Subject: Confidential, new case

Hi Jane,

Greetings from Virginia - I hope you are well wherever you are. I'm writing to ask if you'd consider offering your professional opinion on a highly confidential new case we have related to the use of infant monkeys in maternal deprivation and psychopathology experiments at a government laboratory. Your expertise would be invaluable to helping us draw attention to and put an end these cruel studies that the experimenters themselves recently acknowledged are not relevant to humans.

PETA has obtained hundreds of photographs, and more than 500 hours of high-definition videos, taken between 2009 and 2012 depicting continuing maternal deprivation and depression experiments on hundreds of baby monkeys conducted in the laboratory of psychologist Stephen Suomi (a protégé of Harry Harlow's) and his colleagues at a National Institutes of Health (NIH) facility in Poolesville, Maryland.

Each year, 40 to 60 monkeys—many bred to be genetically predisposed to mental illness—are born in Suomi's laboratory. The monkeys undergo years of terrifying, distressing and sometimes painful experiments designed to exacerbate and measure their anxiety, depression, fear, social withdrawal and physical illness.

The videos PETA has obtained show experiments in which newborn infants are restrained inside tiny mesh cages and placed in "startle chambers." The infants are then startled by loud noises from which they struggle hide and escape. In other tests, newborns are separated from their mothers or social groups, placed alone in a small cage, and then repeatedly scared by a human presence. In other experiments, the infant monkeys are caged with their mothers, who are chemically-sedated so as to be unresponsive, and placed in a car seat. The terrified and confused infants scream and cry, climbing onto and frantically shaking their mothers. In at least one case, experimenters can be heard laughing while a mother tries to remain awake to comfort her upset child. In some trials, an electronic snake is released into the cage with the baby monkeys, who innately fear the reptiles.

A confidential 9 min. video representative of the complete footage is viewable here: http://www.petapreview.com/4preview/monkey_experiments_rc.asp

I have also attached a fact sheet that describes the project in greater detail.

Please do not share or forward this information just yet. Might you be able to share your professional opinion on the short-term and long-term distress being caused to the monkeys, as well as your feelings on the ethics, especially given the experimenters' acknowledgements that the experiments aren't useful to humans? Your expertise could be a game-changer n this case.

Please let me know if you have any questions, and thanks as always!

Dan

Francis Collins <(b) (6) Thu, May 1, 2014 at 1:47 PM
To: Kathy Hudson <(b) (6)>

Have a look at this. It will trouble you a lot. Then we will need to strategize about what to do.

FC

---------- Forwarded message ----------
From: **Jane Goodall** <(b) (6)>
Date: Thu, May 1, 2014 at 12:06 PM
Subject: FW: Confidential, new case
[Quoted text hidden]

Kathy Hudson <(b) (6) Thu, May 1, 2014 at 9:39 PM
To: Francis Collins (b) (6)

okay. this is complicated.

I have a new set of hsus videos of really gross conditions at texas biomed which you might remember i visited on one of my trips to be with my dad last spring. I think i described the place as a death camp. it was markedly different than any of the other places i have visited. i don't really understand how usda and nih regs permit such wide variance in the care of these animals.

anyway, the nichd researcher is of special concern because he is our own intramural researcher. Anything we do will be seen as precedent for all nih research and that is dangerous for you. that caused overexpresson of my bulldog protective instincts. How about i explore it discreetl with alan and maybe go up for a site visit? You need to stay at a distance.

Lets figure out how to very carefully explore this reseracher (who is pretty prolific in publications....)

The number one thing I think we need to do right now is put the final peice in the chimp puzzle. Turn alamagordo into a sancturary, move all our remaining chimps that won't fit at chimp haven there, and - as a bonus- have dod pick up the tab for the alamagordo sancturary since the chimps there that we have been paying for for years were origianlly airforce chimps.

[Quoted text hidden]

Francis Collins <(b) (6)> Fri, May 2, 2014 at 5:30 AM

To: Kathy Hudson <(b) (6)

Yes, please discuss discreetly with Alan. But meanwhile, we probably need to touch base with this Dan Mathews soon, or he will assume that we are deflecting Jane's proposal and PETA will go public with the videos.

Can we discuss how that contact should be made?

FC
[Quoted text hidden]

Kathy Hudson <(b) (6) Fri, May 2, 2014 at 8:49 PM
To: Francis Collins (b) (6)

i am talking with alan and going to go look at the poolsville facility next week. I do not think you should meet with peta - certainly not before we collect the facts and we have some sense of what the options are and their ramifications.

[Quoted text hidden]

Francis Collins <f(b) (6) Sun, May 4, 2014 at 8:32 PM
To: Kathy Hudson (b) (6)

Even though Poolesville is intramural, would it be good to bring Jim along, since DPCPSI oversees ORIP, and extramural projects of this sort are in their wheelhouse?

FC
[Quoted text hidden]

Kathy Hudson <(b) (6) Sun, May 4, 2014 at 8:36 PM
To: Francis Collins <(b) (6)

Yes. Good thinking.
[Quoted text hidden]

Gmail **Francis Collins <(b) (6)**

Sensitive and confidential question

5 messages

Francis Collins <(b) (6) Sun, May 4, 2014 at 8:31 PM
To: (b) (6)

Hi (b) (6)

I could use your advice. My new friend Jane Goodall has contacted me to alert me to videos obtained by PETA that show behavioral research on newborn rhesus macaques (see below). I was pretty troubled by the video -- but the investigator Stephen Suomi (NICHD intramural) is apparently well respected by his peers, and I haven't yet done the due diligence to see what useful data might be derived from these experiments.

Of course most of our colleagues view PETA as evil, or even as a terrorist organization. Getting into any serious public negotiation with them would likely lose the confidence of the research community in a hurry. But as I wrestle with what to do here, your own observations, based on study section service, about the pointlessness of much of the research being conducted on non-human primates is ringing in my ears.

How would you view Suomi's research efforts?

Any other advice here? Please keep all of this COMPLETELY confidential.

Thanks, Francis

Jane Goodall May 1 (3 days ago)

to me

Dear Francis,
Below is the email I got from Dan – after I received the first I called him, and that is always better than asking difficult questions via email.
So all the correspondence is below, and I outlined the phone conversation.
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remain awake to comfort her upset child. In some trials, an electronic snake is released into the cage with the baby monkeys, who innately fear the reptiles.

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Please let me know if you have any questions, and thanks as always!

Dan

(b) (6)
(b) (6)

Mon, May 5, 2014 at 4:11 AM

To: Francis Collins <(b) (6)

Hi Francis,
Thanks for thinking of me in these matters. I have followed some of Steve Suomi's research from a distance after reading Deborah Blum's "Monkey Wars" book. I think you may have seen it. (b) (6)
(b) (6)
(b) (6)
I've wrestled with my opinion on Steve's research and will be as unbiased as I can be. Yes, he was a doctoral student of Harry Harlow at the University of Wisconsin (National Medal of Science winner). While there, he was involved in the notorious "pit of despair" - term coined by Harry Harlow to describe the apparatus for keeping rhesus macaques socially isolated for prolonged periods of time to investigate aberrant behaviors and generate animal models of induced depression. Harry also liked to coin other volatile phrases such as the "rape rack" to describe devices where socially isolated females were subject to forced matings to determine how well these females would rear their offspring. As I recall, the there has an increased rate of infanticide. As such, while Harry is well know for his far more benign 'wire cloth model' monkey models of maternal love, there were seriously dark experiments conducted that would not pass today's ethical standards.
As such, Harry Harlow and his most famous scientific trainee Steve Suomi have become rallying points for anti-vivisectionist groups (for want of a better term since their tactics and philosophies are all over the map) and individuals. Case in point, the Primate Research blogspot highlights the concerns and anger of a subset of such individuals.
http://primateresearch.blogspot.com/search?q=suomi
Let's just scan some of the titles of the entries:
"Stephen John Suomi: A Lifetime of Sadism" (Thursday, June 28, 2007)
"Monsters: Harry Harlow and Stephen Suomi" (Sunday, August 29, 2010)
Needless to say, for many many years, Steve has been a major target on the radar screen of animal rights activists. Many people still resent his participation in Harry Harlow's early experiments. Nevertheless, the question is, what about the here and now? That is, are the experiments that are currently being undertaken as extreme? Obviously not, however, the general theme of generating rhesus macaque models of "early life social adversity" (title of one of Steve's 2012 PNAS papers) persists. Just how severe is the psychological stress these animals that are reared apart from their

their parental groups? I would need to see this in person (verbal descriptions are insufficient), but obviously the goal of the experiment is to put the animals under conditions that affect their behavior as a model of childhood neglect, isolation, or bullying, in crude terms. The other experiments highlighted in the e-mail exchange frankly sound pretty severe. I did not download the video. However, I can say that it would not surprise me if at one point in time at least animal handler would laugh at one of these situations. The issue is desensitization and the lack of maturity of a limited subset of the animal handler group. Over the years, I've heard enough comments from a limited number of such individuals that would indicate this could happen.

The next question arises, "what practical benefit is all this to human and non-human primate health?" Many times I am left scratching my head. The conclusions tend to be simplistic, such as social adversity compromises the primate immune system. Gene expression and DNA methylation profiles of blood samples change. Obviously there is the next generation experiments of ChiP-Seq and other genomics technologies that will be brought to bear. Predictable progression of experiments.

Is this line of research going to help a person addicted to drugs or subject to child abuse or other traumas? I can't think of anything practical that could not be studied simply using human subjects. Yes, the human work is less controlled, but the animals also show extreme behavioral diversity. That is highlighted by varying degrees of self-injurious behavior in captive non-human primate populations. The rhesus experiments are less controlled than one might think at first blush.

Given this diversity, could Steve's projects help minimize self-injurious behavior in captive non-human primates? That would be a laudable goal. Well, the problem in my opinion is that we already know that this behavior is strongly influenced by their social isolation, which is unavoidable in some vaccine trials. Also, drugs similar to valium have been used to treat such animals. However, this compromises the vaccine development trials because it introduces another variable. In other words, I do not believe there is a reasonable chance that such studies could be used to improve dramatically the health of captive non-human primates. Perhaps one could identify the animals most likely to develop self-injurious behavior through genetic testing (laudable goal), but all the data I have seen so far indicates that these studies are severely under-powered and highlight small effect sizes that make such selective breeding for more 'adversity robust' animals impractical. Certainly not theorectically impossible, but not probable in my opinion.

In his own words, here are two NIH grants attributed to Steve

http://projectreporter.nih.gov/project_info_description.cfm?aid=8736837&icde=20243398

http://projectreporter.nih.gov/project_info_description.cfm?aid=8736838&icde=20243398&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC

I think the PETA involvement will cause many in the scientific community to circle their bandwagons without much critical thought. Steve has to be a world expert in defending himself since he has heard these complaints his entire scientific career. He has an avid circle of scientific defenders. Harry Harlow did as well at the time, but look at Harry's long-term legacy.

I would hope that this general subject matter could be handled without directly dragging PETA into the discussion. Too much convoluted history and too many complicated personalities to engage in a rational discussion - at least in my opinion. I believe one would need to involve unbiased behavioral scientists who solely focus on humans and ask them, does any of this rhesus macaque work have any real impact on your research? This has to go way beyond citing a few papers here and there. The rhesus experiments should have a practical impact on experimental design and data interpretation that can be cataloged. In my humble opinion, Steve's studies do not have a truly significant practical impact on human life. Knowledge is gained by a world expert, but I'm not seeing how human beings who experienced any of a wide variety of social abuses benefit to any appreciable extent. I really wish they could, but I'm not seeing it.

My apologies for the long e-mail. I simply want to be fair to everyone involved. I'm happy to clarify or provide any additional opinions at any time.

Best wishes - (b) (6)

[Quoted text hidden]

Francis Collins (b) (6) Mon, May 5, 2014 at 5:30 AM

To: Kathy Hudson (b) (6)

Hi Kathy,

(b) (6)

He has spent countless hours in study sections reviewing non-human primate research, and has had reservations about how much of it is scientifically useful and ethically justifiable. I asked him to provide some insight into Suomi's work. His comments are below, in case they are of use in sizing up this situation. He is 100% trustworthy in keeping confidence.

FC

(b) (6) 4:11 AM (1 hour ago)

to me

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My apologies for the long e-mail. I simply want to be fair to everyone involved. I'm happy to clarify or provide any additional opinions at any time.

Best wishes - (b) (6)

Francis Collins <(b) (6) Mon, May 5, 2014 at 5:41 AM

To: (b) (6)

Thanks for this thoughtful and detailed response (b) (6) It gives me a lot to think about. I may come back to you with more questions after doing some more digging.

Francis

[Quoted text hidden]

Kathy Hudson <(b) (6) [redacted]> Mon, May 5, 2014 at 12:11 PM
To: Francis Collins <(b) (6) [redacted]>

Remarkably helpful
[Quoted text hidden]

Gmail **Francis Collins** <(b) (6)

Rhesus experiments in Poolesville

8 messages

Francis Collins <(b) (6) Sun, May 4, 2014 at 9:57 AM
To: Jane Goodall <(b) (6), DANM@peta.org

Hi Jane and Dan,

I appreciate Jane having brought to my attention the experiments in Poolesville on baby rhesus monkeys. I am looking into this situation with high level members of my team, but it will take a little time to understand how such experiments have been considered scientifically justified.

Please allow me to do some discrete investigating, and then I will get back to you. I welcome the chance to pursue this discussion in a thoughtful and private way.

Francis

Jane Goodall <(b) (6) Sun, May 4, 2014 at 10:10 AM
To: Francis Collins <(b) (6)

Dear Francis,
I imagine you were shocked by the video?
PETA has worked very hard on this – so I hope that you can investigate fairly quickly – or they may go public. I cannot stop them
It would seem sensible to at least talk with their guy who was working with NIH??
The monkey people have admitted it does not help people.
I my mind the whole thing is inhumane and unethical. And, as I said to you before, I have already written protesting these continuations of the Harlow type experiments. It seems extraordinary such cruel and valueless research is still being funded, when so many really important things are being cut.
Am just off to (b) (6) am on email though out.
Sending much love,
Jane

From: Francis Collins (b) (6)
Date: Sunday, 4 May 2014 14:57
To: Jane Goodall (b) (6), <DANM@peta.org>
Subject: Rhesus experiments in Poolesville
[Quoted text hidden]

Francis Collins <(b) (6) Sun, May 4, 2014 at 10:22 AM
To: Jane Goodall <(b) (6)

Hi Jane,

Yes, I was utterly taken aback by the video. I have to move carefully here, however. PETA is seen by most biomedical researchers as utterly unscrupulous -- some would even identify them as a terrorist organization. In order to make real progress, I can't risk the precipitous loss of the confidence of my own community. I will try my best to move this discussion quickly in the right direction, but I may need your help!

Francis
[Quoted text hidden]

Dan Mathews <DANM@peta.org> Mon, May 5, 2014 at 9:53 AM
To: Francis Collins [redacted]
Cc: Jane Goodall [redacted]

Hi Francis,

Thanks for your note. We'd like to offer to meet privately in order to present some materials to help as you investigate. Please let me know if/when that might be possible. We very much appreciate your attention to this matter.

Kindest regards,

Dan Mathews

Senior VP, PETA

From: Francis Collins [redacted]
Sent: Sunday, May 04, 2014 9:58 AM
To: Jane Goodall; Dan Mathews
Subject: Rhesus experiments in Poolesville

Hi Jane and Dan,

[Quoted text hidden]

Dan Mathews <DANM@peta.org> Thu, May 15, 2014 at 10:09 PM
To: Francis Collins [redacted]

Hi Francis,

Might there be any update on the Poolesville case in the past few weeks? I'd like to reiterate my offer of a private, confidential meeting with myself and our advising

[redacted]

neuroscientist, who spent 8 years at NIMH. I'm very thankful that Jane connected us, and look forward to hearing from you again soon. Have a good weekend,

Dan

PS As someone who works with both faith-based and non-religious leaders, I really appreciated your message in *Language of God*. It's the moral voice within, I always say, and it was heartening to see you articulate that. My degree is in ancient history and I studied the western world's fascinating conversion to Christianity when I lived in Rome, before joining PETA in '85.

From: Francis Collins [(b) (6)]
Sent: Sunday, May 04, 2014 9:58 AM
To: Jane Goodall; Dan Mathews
Subject: Rhesus experiments in Poolesville

Hi Jane and Dan,

[Quoted text hidden]

Francis Collins <(b) (6)> Tue, May 20, 2014 at 12:39 PM
To: Kathy Hudson <(b) (6)>

complete thread with PETA guy below....
[Quoted text hidden]

Francis Collins <(b) (6)> Tue, May 20, 2014 at 12:40 PM
To: Dan Mathews <DANM@peta.org>

Hi Dan,

It's been quite a month, and I am currently in Brazil, but I have asked Kathy Hudson, the NIH Deputy Director for Science, Outreach, and Policy, to contact you about this important issue.

Best, Francis
[Quoted text hidden]

Dan Mathews <DANM@peta.org> Tue, May 20, 2014 at 3:13 PM
To: Francis Collins <(b) (6)>

Thank you Francis, all the best in Brazil, and I'll look forward to hearing from Kathy.

Dan

From: Francis Collins (b) (6) [redacted]
Sent: Tuesday, May 20, 2014 12:40 PM
To: Dan Mathews
Subject: Re: Rhesus experiments in Poolesville

[Quoted text hidden]

Gmail **Francis Collins** <(b) (6) [redacted]

Field trip

4 messages

Kathy Hudson <(b) (6) [redacted] Thu, May 8, 2014 at 12:02 AM
To: Francis Collins (b) (6) [redacted]

Field trip scheduled for next Friday. Alan will go with me. I am in on going discussions with michael and Jim.

Will keep you posted.

Have my suitcase packed for (b) (6) [redacted]. Very bittersweet trip.

Francis Collins <(b) (6) [redacted] Thu, May 8, 2014 at 5:21 AM
To: Kathy Hudson <(b) (6) [redacted]

Sounds like a good plan -- so far no follow up from PETA.

(b) (6) [redacted].

FC

[Quoted text hidden]

Kathy Hudson (b) (6) [redacted] Thu, May 8, 2014 at 7:19 PM
To: Francis Collins <(b) (6) [redacted]

I am going to have a bottle of champagne sent to their room from you!! Cause that is just what a great deputy I am !

[Quoted text hidden]

Francis Collins (b) (6) [redacted] Fri, May 9, 2014 at 7:22 AM
To: Kathy Hudson (b) (6) [redacted]

Excellent plan!!!! Thanks!!!!

[Quoted text hidden]

Gmail **Francis Collins** [redacted]

PETA AND THE MONKEY EXPERIMENTS.

9 messages

Jane Goodall <[redacted] Tue, May 20, 2014 at 11:17 AM
To: Francis Collins [redacted]

Dear Francis,
I suspect that PETA will be planning a release of some sort about the footage they have gained.
I don't think I can stop them. Nor do I know if you contacted them at all.
I have to say that the footage sickened me. As did the information we received about this quite some time ago.
You remember, I told you I had already written a letter, or signed a letter, opposing the research.
Perhaps you have found out something that justifies it?
Sorry I'm writing in staccato phrases – its not meant to sound like it probably does, but I am [redacted],
about to get on a plane.
And got a letter from Dan Matthews asking if I'd heard from you. No more than that.
Here we are b attling with [redacted]. It never stops!!
Sending lots of love to make up for fierce sounding letter!
Jane

Francis Collins <[redacted] Tue, May 20, 2014 at 11:28 AM
To: Kathy Hudson [redacted]

Just what we need right now, a threat that PETA is going to release videos.

I'd like to be able to tell Dan that we are taking these concerns seriously, and that public release would not be productive right now. When is the field trip to Poolesville?

FC
[Quoted text hidden]

Kathy Hudson <[redacted] Tue, May 20, 2014 at 12:35 PM
To: Francis Collins [redacted]

Field trip to poolesville was friday in the monsoon and we hit flooded roads repeatedly (5x i think) so we ultimately turned around. in the meantime, i have talked to tom insel about the researcher. He says that he (tom) hired soumi when he ran poolesville (before he went to Emory). Tom said that he has always been annoyed that suomi's work is basically doing in macaques what has already been shown in humans. He called it third rate and said it is time for soumi to retire.

I am working with alan to figure out if he is up for review.... I think we can fix this administratively

Tom agreed you need to stay a million miles away from peta. If you talk to them, they will tell the world and then you will have the entire reserach community thinking badly of you.

[redacted]

How about if i reach out to him?

[Quoted text hidden]

Francis Collins <(b) (6) > Tue, May 20, 2014 at 12:37 PM
To: Kathy Hudson <(b) (6) >

Having you reach out to Dan would be great. I'll send you the most recent correspondence, in case you don't already have it.

Just one more fun topic for a fun day in DDSOP land.....

FC
[Quoted text hidden]

Francis Collins <(b) (6) > Tue, May 20, 2014 at 12:49 PM
To: Jane Goodall (b) (6)
Bcc: Kathy Hudson (b) (6)

Hi Jane,

Thanks for the heads up, and no need to apologize for sounding fierce! E-mail sometimes defeats one's best efforts to convey nuance, but you and I know each other well enough that I couldn't imagine you being harsh. Passionate, yes! Principled, yes!

We have indeed been looking into this, but haven't yet arrived at a concrete plan. Meanwhile, I'm in Brazil working on scientific collaborations -- they have terrific students here. In my absence I have asked Dr. Kathy Hudson, who I think you have met in the context of the chimpanzee efforts, to contact Dan Matthews. I continue to hope that we can arrive at a good outcome here without PETA having to resort to a big press event. That might raise consciousness for the public, but it will thoroughly alienate the scientific community, who will then lock arms, making it hard for Kathy and me to negotiate a good outcome.

We're hoping for a bit more time...

(b) (6)

Love, Francis
[Quoted text hidden]

Kathy Hudson <(b) (6) > Fri, May 23, 2014 at 8:02 PM

To: Francis Collins <(b) (6)

dear FC
major news on this. Video is old and largely from nimh investigators who are dead or gone. Look forward to updating you.
Best,
CEO
monkey biz

[Quoted text hidden]

Francis Collins <(b) (6) Sat, May 24, 2014 at 5:13 AM
To: Kathy Hudson <(b) (6)

That is indeed major news! Did you connect with Dan, or do we need to powwow first?
[Quoted text hidden]

Kathy Hudson (b) (6) Sat, May 24, 2014 at 4:42 PM
To: Francis C(b) (6)

I need more info to have complete response and will meet with relevant folks this week. Will go to poolsville on Friday. The story line is that I got this video. You are not connected.

Yes, I told dan I would meet. He said ok and he would get back to me. I am sure they are scheming.
[Quoted text hidden]

Francis Collins <(b) (6) Sun, May 25, 2014 at 7:41 AM
To: Kathy Hudson (b) (6)

Great, thanks!
[Quoted text hidden]

Gmail **Francis Collins** (b) (6) [redacted]

monkeys

2 messages

Hudson, Kathy (NIH/OD) [E] <Kathy.Hudson@nih.gov> Thu, Jun 12, 2014 at 10:51 PM
To: Francis Collins (b) (6) [redacted]

Fyi and not at all urgent so when you have down time, read from bottom up but message is that I am moving this ahead, slowly - carefully.

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 12, 2014 10:46 PM
To: Insel, Thomas (NIH/NIMH) [E]; Guttmacher, Alan (NIH/NICHD) [E]
Cc: Schulke, Hilda (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: FW: meeting

Please see delicate dance emails below. I think we need to have our big-ish meeting with our team and then maybe have the three of us meet with dan and his two colleagues.

Not sure where this is going but it is a conversation we were asked to have so we shall have it.

I have actually been pretty impressed with Dan's diplomacy.

Look forward to talking to you guys about this.

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 12, 2014 10:35 PM
To: 'Dan Mathews'
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: RE: meeting

Appreciate very much the consideration. I will get back to you in next day or two with time and place and folks from my end who will attend. My inclination is to keep it small. I am heading out of town for the next week to help clean out my folk's house after my

(b) (6) earlier this year but will be checking email.

Best,
kathy

-----Original Message-----
From: Dan Mathews [mailto:DANM@peta.org]
Sent: Thursday, June 12, 2014 10:14 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: RE: meeting

Thanks Kathy,
I'll postpone my trip to be there July 2. I'll bring, as originally discussed with Jane and Francis, our scientific advisor Katherine Roe (post-doctoral/research fellow at NIMH & experimental psychologist) and Justin Goodman (MA, PETA's director of laboratory investigations). We're all professionals, just tell me the time and office location.
Looking forward!
Dan

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]
Sent: Thursday, June 12, 2014 3:10 PM
To: Dan Mathews
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: Re: meeting

I would prefer to have a one on one with you or postpone till you can join.

I trust you recognize that this meeting was agreed to based on trust relationships.

Jane apparently trusts you, Francis trusts jane, Jane and Francis trust me.

Let's build on that and get on the phone to see if there is common ground and common understanding. If there is some glimmer of that, then we can have a bigger confab.

Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy NIH
301 496 1455
kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>

On Jun 12, 2014, at 5:08 PM, "Dan Mathews" <DANM@peta.org<mailto:DANM@peta.org>> wrote:

Hey Kathy, sorry it's been difficult to gather everyone with busy travel schedules. I hoped we'd have been able to do this in May or June as I am away the first 2 weeks of July. Might you have the first meeting with our team but without me, then I can join for a follow-up meeting later in July? As you know we've been very keen to get this moving since April.

Thanks!

Dan

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]
Sent: Thursday, June 12, 2014 1:26 PM
To: Dan Mathews
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: Re: meeting

Hmmm. I thought I agreed to meet with you.

Let's push the restart button here.

Kathy Hudson, Ph.D.

Deputy Director for Science, Outreach, and Policy NIH

301 496 1455

kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>

> On Jun 12, 2014, at 4:23 PM, "Dan Mathews" <DANM@peta.org<mailto:DANM@peta.org>> wrote:

>

> Hi Kathy,

(b) (6) [redacted]

> I will be unavailable to attend the July 2 meeting but hope to attend

> a subsequent meeting. But you'll be in good hands with our reps who

> include the following. Thanks again, Dan

>

>

> 1. John Gluck, Ph.D., Emeritus Professor of Psychology at the

> University of New Mexico and affiliate faculty of the Kennedy

> Institute of Ethics, Georgetown University

>

> 2. Justin Goodman, M.A., Director, Laboratory Investigations

> Department, People for the Ethical Treatment of Animals

>

> 3. Katherine Roe, Ph.D., Research Associate, Laboratory Investigations

> Department, People for the Ethical Treatment of Animals

>

> 4. (Tentative) Lawrence Hansen, MD, Professor, Departments of

> Neurosciences and Pathology, University of California, San Diego

>

>

> -----Original Message-----

> From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]

> Sent: Thursday, June 12, 2014 2:58 PM

> To: Dan Mathews

> Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]

> Subject: Re: meeting

>

> I am putting together list of folks but likely leadership from nichd and nimh. And who will come with you?

>

>

>

> Kathy Hudson, Ph.D.

> Deputy Director for Science, Outreach, and Policy NIH

> 301 496 1455

> kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov<mailto:kathy.hudson@n
> ih.gov%3cmailto:kathy.hudson@nih.gov>>

>

> On Jun 12, 2014, at 1:02 PM, "Dan Mathews" <DANM@peta.org<mailto:DANM@
peta.org<mailto:DANM@peta.org%3cmailto:DANM@peta.org>>> wrote:

>

> Dear Kathy,

>

> Thanks for your email. I've checked with my colleagues and it appears that Wednesday, July 2, would work for us. Could you please clarify who from NIH will be attending the meeting?

>

> Thank you,

> Dan

>

>

> From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]

> Sent: Wednesday, June 11, 2014 10:02 AM

> To: Dan Mathews

> Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]

> Subject: meeting

>

> Dan,

> You asked about the week of June 23 for a possible meeting. That wont work for me but the following week could work. What is your availability that week?

>

> Thanks

> Kathy

Francis Collins (b) (6) [redacted] Fri, Jun 13, 2014 at 5:38 AM
To: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>

Certainly appreciate the delicacy here -- talk about trying to balance benefits and risks! You are right to hold Dan accountable.

FC
[Quoted text hidden]

Gmail **Francis Collins** (b) (6) [redacted]

Jane

1 message

Kathy Hudson (b) (6) [redacted] Tue, Jul 1, 2014 at 11:16 PM
To: Francis Collins (b) (6) [redacted]

Met with PETA today. Went fine. John Burklow joined me. Will fill you I later.

Do not engage in emails on this with jane or PETA.

More later

Gmail **Francis Collins** <(b) (6)

Follow-up after NIH meeting

10 messages

Dan Mathews <DANM@peta.org> Thu, Jul 3, 2014 at 2:59 PM
To: Francis Collins (b) (6) Jane Goodall (b) (6)

Greetings Francis and Jane,

On Tuesday, a pair of PETA's scientific advisors and I met with NIH's Dr. Kathy Hudson about the decades-old maternal deprivation monkey experiments that continue in Poolesville. It was a very friendly exchange; thanks to both of you for setting it up.

We presented documents from experts and publications showing that the scientific objectives of these monkey experiments are better achieved using human-based research methods. Kathy asked good questions and seemed to recognize systemic problems in oversight and the general benefits of research modernization. NIH's Dr. Lyric Jorgensen, who we expected to attend, was a no-show. Dr. Hudson mentioned a general, forthcoming review of all intramural projects because of reduced funding, but made no suggestion that the project we are concerned about would get any special attention now or later. We were happy to be heard, but disappointed that it wasn't more of a 2-way conversation and that nothing was brought to the table.

Today, the neuroscientist who led the discussion (she worked at NIH for years before coming to PETA) sent the follow-up letter below with the attached overview that elaborates on the concerns we brought up in person. Francis, we'd very much appreciate you taking a look and making sure that it gets circulated and prompts more critical thought and discussion.

In a nutshell, our formal request to the NIH is twofold:

1) end the maternal deprivation and depression experiments in question

2) during upcoming budgetary reviews, seriously consider cutting those animal experiments classified as "column E" (those involving the most excruciating pain and distress); this would fall in line with policies enacted in Switzerland and the Netherlands, and would create an enormous amount of goodwill with the public

Thanks again! Please let me know your thoughts on this; we're keen to resolve the Poolesville monkey matter as soon as possible.

Dan Mathews

Senior VP, PETA

From: Katherine Roe
Sent: Thursday, July 03, 2014 12:00 PM
To: 'kathy.hudson@nih.gov'
Subject: Follow-up from PETA

July 3, 2014

Dr. Kathy Hudson

Deputy Director for Science, Outreach, and Policy

Building 1, Room 109

1 Center Drive

Bethesda, MD 20892

Dear Kathy,

Thank you for meeting with us to discuss concerns about NIH's maternal deprivation and depression experiments on monkeys.

As promised, I have attached a critical review of these studies prepared in consultation with subject matter experts. You'll see that the document elaborates on the points we spoke about on Tuesday, with extensive evidence of the inapplicability of these studies to human health, the availability of existing data and superior human-based research methodologies, and the problematic lack of oversight of these studies which cause suffering and harm to primates.

Having conducted research with human subjects at NIMH, I have always lauded the Intramural Research Program as one that dedicates itself to using the most innovative and humane methodology available in the interest of science and human health. So, as you might imagine, learning about the existence and details of these projects came as

quite a surprise to me, as I hope it did for you, and I have no doubt it will to others inside and outside the research community.

As we brought up Tuesday, the NIH's own analysis of experiments on chimpanzees confirmed that it is possible for practices that are cruel and scientifically unnecessary to be reviewed, approved, funded and conducted within the NIH's intramural program for a long time without question. At the same time, the NIH's decision to suspend, review and ultimately end experiments on chimpanzees demonstrates how additional, objective scrutiny of a deeply-embedded practice can serve to benefit the agency, animals, researchers and taxpayers and acknowledge evolving public opinion. **We believe that the same process can and should be applied here, and we hope to hear from you soon about plans to end these experiments.**

Also, in light of the NIH's forthcoming review of intramural projects that you mentioned are to occur due to budget cuts, we urge that close attention be paid to all experiments on animals that involve pain and distress, particularly those in what NIH refers to as "USDA Column E," where suffering is unmitigated. I think you will find that the mother/infant deprivation experiments we discussed are wrongly categorized as Column C, and belong in Column E because of the intentional, prolonged and unrelieved distress caused during experimental trials and the studies overall. As you know, other countries have put in place more stringent regulations governing the use of animals in experiments that cause considerable, unrelieved suffering to animals (known here as "USDA Column E").

I hope we will hear from you regarding the status of your inquiry into the maternal deprivation and depression experiments on monkeys that we discussed before you leave for your bike trip next month.

Please contact me with any questions.

Sincerely,

Katherine Roe, Ph.D.

Research Associate

Laboratory Investigations Department

KatherineR@peta.org

240-355-6656

PETA review of NIH primate experiments July 2014.pdf
545K

Francis Collins <(b) (6) Thu, Jul 3, 2014 at 8:10 PM
To: Kathy Hudson (b) (6)

Something to discuss next week.....
[Quoted text hidden]

PETA review of NIH primate experiments July 2014.pdf
545K

Kathy Hudson (b) (6) Fri, Jul 4, 2014 at 3:51 PM
To: Francis Collins (b) (6)

Sure. But we need to bring the chat with PETA to an end.
[Quoted text hidden]

Kathy Hudson (b) (6) Mon, Jul 14, 2014 at 10:18 AM
To: Francis Collins (b) (6)

Sure. But we need to bring the chat with PETA to an end.

On Thursday, July 3, 2014, Francis Collins (b) (6) wrote:
[Quoted text hidden]

Francis Collins <(b) (6) > Mon, Jul 14, 2014 at 12:12 PM
To: Kathy Hudson (b) (6)

Was there supposed to be a message here?
[Quoted text hidden]

Kathy Hudson <(b) (6) Mon, Jul 14, 2014 at 11:24 PM
To: Francis Collins (b) (6)

I dont think there was earlier message. Operator error. Sorry

I will however share about today's tour that monkey's were watching "finding nemo" when we walking in. Hilarious.

Animals well cared for and protocols - to novice eye - scientifically sound. Interesting studies of malarial pathogen being sequestered in placenta and using baboos to test pig heart trNsplants (though adequate human organ donation should solve that perhaps).

More tours later in the week
[Quoted text hidden]

Dan Mathews <DANM@peta.org> Mon, Jul 21, 2014 at 5:09 PM
To: Francis Collins (b) (6)
Cc: Jane Goodall <(b) (6)

Hi Francis,

I wanted to follow-up on my email of 3 weeks ago to learn of any progress since our meeting at NIH about the maternal deprivation experiments on monkeys in Poolesville. We are anxious to move forward but haven't heard a peep. Please advise ASAP, and thanks.

Dan

From: Dan Mathews
Sent: Thursday, July 03, 2014 3:00 PM
To: 'Francis Collins'; 'Jane Goodall'
Subject: Follow-up after NIH meeting
Importance: High
[Quoted text hidden]

Francis Collins <(b) (6) Mon, Jul 21, 2014 at 5:10 PM
To: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>

My call with Jane Goodall didn't go through -- hard to make contact in (b) (6). We are trying for another date.

Meanwhile, here comes Dan again. How do you suggest I respond, if at all?

FC

---------- Forwarded message ----------
From: **Dan Mathews** <DANM@peta.org>
Date: Mon, Jul 21, 2014 at 5:09 PM
Subject: RE: Follow-up after NIH meeting
To: Francis Collins (b) (6)
[Quoted text hidden]

Hudson, Kathy (NIH/OD) [E] <Kathy.Hudson@nih.gov> Mon, Jul 21, 2014 at 5:43 PM
To: Francis Collins (b) (6)

You don't respond.

If you want, I can send a note saying thanks for the meeting and materials. Then we go dark. There is no benefit to continued discussion unless u want to start ww3.

We don't negotiate. We listened. That is all

Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy
NIH
301 496 1455
kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>

On Jul 21, 2014, at 5:10 PM, "Francis Collins" <(b) (6) (b) (6) wrote:

My call with Jane Goodall didn't go through -- hard to make contact in (b) (6). We are trying for another date.

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Date: Mon, Jul 21, 2014 at 5:09 PM
Subject: RE: Follow-up after NIH meeting
[Quoted text hidden]
To: 'kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>'
Subject: Follow-up from PETA

July 3, 2014

Dr. Kathy Hudson
Deputy Director for Science, Outreach, and Policy
Building 1, Room 109
1 Center Drive
Bethesda, MD 20892

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Having conducted research with human subjects at NIMH, I have always lauded the Intramural Research Program as one that dedicates itself to using the most innovative and humane methodology available in the interest of science and human health. So, as you might imagine, learning about the existence and details of these projects came as quite a surprise to me, as I hope it did for you, and I have no doubt it will to others inside and outside the research community.

As we brought up Tuesday, the NIH's own analysis of experiments on chimpanzees confirmed that it is possible for practices that are cruel and scientifically unnecessary to be reviewed, approved, funded and conducted within the NIH's intramural program for a long time without question. At the same time, the NIH's decision to suspend, review and ultimately end experiments on chimpanzees demonstrates how additional, objective scrutiny of a deeply-embedded practice can serve to benefit the agency, animals, researchers and taxpayers and acknowledge evolving public opinion. We believe that the same process can and should be applied here, and we hope to hear from you soon about plans to end these experiments.

Also, in light of the NIH's forthcoming review of intramural projects that you mentioned are to occur due to budget cuts, we urge that close attention be paid to all experiments on animals that involve pain and distress, particularly those in what NIH refers to as "USDA Column E," where suffering is unmitigated. I think you will find that the mother/infant deprivation experiments we discussed are wrongly categorized as Column C, and belong in Column E because of the intentional, prolonged and unrelieved distress caused during experimental trials and the studies overall. As you know, other countries have put in place more stringent regulations governing the use of animals in experiments that cause considerable, unrelieved suffering to animals (known here as "USDA Column E").

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Please contact me with any questions.

Sincerely,

Katherine Roe, Ph.D.
Research Associate
Laboratory Investigations Department

KatherineR@peta.org<mailto:KatherineR@peta.org>
240-355-6656<tel:240-355-6656>

Francis Collins <(b) (6) [redacted] Mon, Jul 21, 2014 at 5:56 PM
To: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>

Yep, please send a note, I will remain silent.
[Quoted text hidden]

Bordine, Roger (NIH/OD) [E]

From:	Kathy Hudson <(b) (6) [redacted]>
Sent:	Wednesday, July 13, 2016 4:05 PM
To:	Abel, Kathy (NIH/OD) [E]
Subject:	Fwd: Follow-up after NIH meeting
Attachments:	PETA review of NIH primate experiments July 2014.pdf

KH GMails
45267 Seber

Forwarded conversation

Subject: **Fwd: Follow-up after NIH meeting**

From: **Francis Collins** (b) (6) [redacted]
Date: Thu, Jul 3, 2014 at 8:10 PM
To: Kathy Hudson <(b) (6) [redacted]>

Something to discuss next week.....

---------- Forwarded message ----------
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Date: Thu, Jul 3, 2014 at 2:59 PM
Subject: Follow-up after NIH meeting
To: Francis Collins (b) (6) [redacted], Jane Goodall <(b) (6) [redacted]>

Greetings Francis and Jane,

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We presented documents from experts and publications showing that the scientific objectives of these monkey experiments are better achieved using human-based research methods. Kathy asked good questions and seemed to recognize systemic problems in oversight and the general benefits of research modernization. NIH's Dr. Lyric Jorgensen, who we expected to attend, was a no-show. Dr. Hudson mentioned a general, forthcoming review of all intramural projects because of reduced funding, but made no suggestion that the project we are concerned about would get any special attention now or later. We were happy to be heard, but disappointed that it wasn't more of a 2-way conversation and that nothing was brought to the table.

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Thanks again! Please let me know your thoughts on this; we're keen to resolve the Poolesville monkey matter as soon as possible.

Dan Mathews

Senior VP, PETA

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Sent: Thursday, July 03, 2014 12:00 PM
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Subject: Follow-up from PETA

July 3, 2014

Dr. Kathy Hudson

Deputy Director for Science, Outreach, and Policy

Building 1, Room 109

1 Center Drive

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Research Associate

Laboratory Investigations Department

KatherineR@peta.org

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From: **Kathy Hudson** <(b) (6)
Date: Fri, Jul 4, 2014 at 3:51 PM
To: Francis Collins <(b) (6)

Sure. But we need to bring the chat with PETA to an end.

From: **Kathy Hudson** <(b) (6)
Date: Mon, Jul 14, 2014 at 10:18 AM
To: Francis Collins <(b) (6)

Sure. But we need to bring the chat with PETA to an end.

On Thursday, July 3, 2014, Francis Collins <(b) (6) wrote:

From: **Francis Collins** (b) (6)
Date: Mon, Jul 14, 2014 at 12:12 PM
To: Kathy Hudson <(b) (6)

Was there supposed to be a message here?

From: **Kathy Hudson** <(b) (6)
Date: Mon, Jul 14, 2014 at 11:24 PM
To: Francis Collins (b) (6)

I dont think there was earlier message. Operator error. Sorry

I will however share about today's tour that monkey's were watching "finding nemo" when we walking in. Hilarious.

Animals well cared for and protocols - to novice eye - scientifically sound. Interesting studies of malarial pathogen being sequestered in placenta and using baboos to test pig heart trNsplants (though adequate human organ donation should solve that perhaps).

More tours later in the week

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Review of Maternal Deprivation Experiments on Primates at the National Institutes of Health

Prepared by

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People for the Ethical Treatment of Animals

July 2014

This document provides a critical scientific review and assessment of continuing maternal deprivation and psychopathology studies on nonhuman primates conducted within the National Institutes of Health (NIH) Intramural Research Program. A careful analysis of Animal Study Proposals, Board of Scientific Counselors reviews, scientific publications, photographs, and videos related to these projects casts doubt on the worth of these experiments in light of advancements in the field, and offers several examples of human-based studies that successfully address precisely the questions asked by these NIH investigators. Moreover, after consulting numerous experts in the fields of anthropology, primatology. medicine, and mental health, we conclude **that given the harm caused to animals, the experiments' limited relevance to humans, the substantial financial cost, and the existence of superior nonanimal research methods that the continued use of animals in this work is scientifically and ethically unjustifiable.**

Project title: "Biobehavioral Reactivity in Monkeys"
Institute: National Institute Of Child Health And Development (NICHD)
Principal Investigator: Stephen J. Suomi
Intramural Animal Study Proposal: 11-043
Project Number: 1ZIAHD001106
Start/end: 2007–present
Funding: $907,723 in 2013 ($7,786,372 total)

At the foundation of all of the studies in question are maternal deprivation experiments conducted by Stephen J. Suomi and the Laboratory of Cognitive Ethology (LCE) at NICHD. For the past three decades, Suomi's group has utilized a maternal deprivation model of psychopathology, depriving hundreds of infant macaques of maternal contact and resulting in animals with an array of cognitive, social, emotional, and physical deficits that persist throughout their lifetimes. According to the approved Animal Study Proposal (ASP), approximately 45 macaques are selectively bred each year to carry different alleles of the 5H-TTT and MAO-1 genes, known to be risk factors for psychopathology in humans. Half of these captive-born infants are separated

from their mothers within 24 hours of birth, causing great distress to mother and baby, and are hand-reared by humans in a nursery for one month and then put into a nursery with other like-reared peers, sometimes with a terrycloth-covered water bottle. Starting on their first day of birth, all infants are subject to numerous fear, stress, and pain-inducing tests. Day-old infants are forcibly restrained by experimenters for behavioral tests, such as facial imitation or head-orientation bias trials. Other experiments entail the infants being isolated in small cages, placed in unfamiliar locations, and deliberately startled by threatening human strangers, unfamiliar objects (including realistic-looking snakes, which are innately frightening to monkeys), and unfamiliar conspecifics. In one such procedure designed to measure infants' auditory startle response, newborn infants are restrained inside tiny mesh cages and placed in "startle chambers" where they are presented with unexpected loud noises. During their first few months of life, the infants are repeatedly subjected to blood draws and cerebral spinal fluid taps; hair and saliva samples are also taken. Additionally, in a project funded by the NICHD (Project 5P01HD064653; $877,229 of funding in 2013), Nathan A. Fox from the University of Maryland takes infants as young as one day old from Suomi's colony, shaves their heads, and physically restrains them for electroencephalogram testing.[1,2]

The approved ASP for the breeding and experimentation regimen (11-043) in Suomi's laboratory does not explain the scientific relevance of the single nucleotide polymorphisms that animals are bred to carry, their methods for selective breeding of these animals, the exact conditions they classify as "mother-rearing," the scientific purpose for numerous cognitive and biological tests being conducted, or any risk factors associated with capture, restraint, and biological or behavioral testing that they perform repeatedly on the animals.

The NIH Policy Manual for Animal Care and Use in the Intramural Research Program clearly states that the Principal/Responsible Investigator is accountable for assuring that the "proposed studies are not unnecessarily duplicative" (p. 7).[3] Several of the experiments currently being conducted have already been performed using the same procedures and the results published.[4,5,6,7,8,9,10,11,12] The rearing procedures described have been in place for decades, and behavioral and biological data from these animals have also been collected for decades.[13,14,15,16] Repeating these test batteries and causing suffering to additional infant monkeys is required by law to be justified; however, given the limited information contained in the ASP, it is virtually impossible for a review committee to adequately evaluate the project's design or scientific merit. The LCE's approved ASP emphasizes that the purpose of the study is to model the genetic and environmental contributions to abnormal human behavior and to develop interventions for at-risk individuals. However, a comprehensive review shows that none of the aforementioned studies have resulted in the development or modification of treatments for the human mental illnesses they are purported to model.

In addition to the study designed to create and quantify mental illness in infant macaques, the LCE has also received $6,289,327 since 2007 to assess whether the laboratory-reared, mentally ill animals they created can adapt to a nonlaboratory environment (Project 1ZIAHD001107). According to the approved ASP associated with this project (11-105), the purpose of the study is to understand "how humans of all ages and backgrounds adapt to new physical and social settings, as well as what aspects of their immediate environment might be affecting their psychological well-being." However, in their 2013 annual NIH Intramural Database report, the experimenters describe several findings related to infant-mother

communication, facial processing in infants, the effect of oxytocin on monkey-human interactions, and cortisol levels in nursing mothers' milk. The discrepancy between the procedures and purposes outlined in the ASP and the reported findings from those procedures makes it difficult to evaluate the value of this study in understanding human health and behavior.

Though the ASPs for these projects claim the protocols are designed to elucidate genetic and environmental influences on pathological behavior unattainable with human participants, many resultant publications from these projects merely address whether macaques exhibit visual preferences, facial asymmetries, facial preferences, imitative behaviors, or similar hand- and head-orientation biases as those already well documented in human infants.[17,18,19,20,21] Given the wealth of knowledge about human behaviors of this sort—and the non-invasive research with humans available to further explore these same issues—these studies are gratuitous.

Project title: "Assessment of Neural and Behavioral Alterations Associated with Chronic Fluoxetine Administration in Adolescence"
Institute: National Institute of Mental Health (NIMH)
Principal Investigator: Bruno Averbeck
Intramural Animal Study Proposal: IPC-01-09
Project Number: MH002902
Start/end: 2007–present
Funding: $9,034,371 total

At NIMH, the Non-Human Primate Core purchases many of the maternally deprived, at-risk for illness animals created in Suomi's laboratory for its own battery of experiments. Some of these studies expose the animals to additional acute startle and isolation[22] in hopes of eliciting a pathological response to stress as a function of their early-adverse rearing conditions. For example, infants and juveniles are restrained inside tiny mesh cages or in restraint chairs and placed into startle chambers where they are deliberately startled by the presence of a human, loud auditory stimuli, or powerful bursts of air. To acclimate them to the chair restraint, the older animals spend up to an hour a day, every day, strapped to a chair for weeks *prior* to testing. In other experiments, the infant monkeys are caged with their mothers—who are chemically sedated so as to be unresponsive—and placed in a car seat.[23] Videos of these experiments indicate that infants are terrified and confused while they try to revive their mothers.

In addition to various oral, subcutaneous, and intramuscular administrations of drugs, some animals are surgically implanted with devices that allow intracranial administration of pharmaceuticals, requiring multiple surgeries, weeks of recovery and pain management, and constant monitoring for infection. According to the ASP, the purpose of this pharmaceutical treatment is to "define specific neural pathways important to the expression of emotional, social, or cognitive deficits associated with differential rearing histories." However, the exact drugs administered intracranially are not specified but described as "substances of interest [that] are likely to include NM concentrations of the neuropeptides oxytocin, vasopressin, CRH, MEK inhibitor PD98592, or GABA agonists such as muscimo and bicuculine, as well

as genes attached to viral vectors (AAV-P11)." Without including this critical information in the ASP, there is no way for reviewers to evaluate the merits of the proposed experiments.

Some animals are injected with Interferon-alpha, which creates depressive-like symptoms in the monkeys and causes heightened sensitivity to pain, ahedonia, and anorexia. This procedure is classified as causing unrelieved pain and/or distress to those animals to whom it is administered. An unspecified number of animals in this project will be killed following pharmaceutical administration.

In their approved ASP to conduct these experiments (IPC-01-09), the experimenters argue that "these experiments could provide important insights about the pathoetiology as well as potential, novel treatments for human syndromes with social detachment." In their 2010 annual NIH Intramural Database report, they write, "A major public health concern has emerged regarding the treatment of children with psychotherapeutic drugs. This study seeks to inform this important concern." However, these statements seem to contradict other claims from this same project in a subsequent publication in *The American Journal of Psychiatry* in which the authors themselves conclude the following:

"...[M]any findings from behavioral and biochemical studies in monkeys and other animals are not replicated in humans. Accordingly, this study cannot directly address the safety and efficacy of SSRIs in children and adolescents with psychiatric disorders. ... [T]his animal model of maternal separation has never been validated as a measure of drug efficacy in humans[.] ... The only way to know definitively whether SSRIs persistently upregulate SERT in humans would be to study our species"(p. 7-8).[24]

In addition to the projects and procedures described above, many animals from Suomi's LCE have been used for additional testing with the NIAAA. One project (Project Number: 1ZIAAA000214), which received $4 million dollars between 2007 and 2010, studied juvenile monkeys' response to acute social separation,[25] spontaneous alcohol consumption,[26] and even acute ethanol exposure,[27] which requires the animals to be restrained while high concentrations of ethanol are administered intravenously. These alcohol exposure studies often result in alcohol addiction, increased aggression, and increased susceptibility to depression in macaques.[28,29,30,31] Other animals are transported to Wake Forest University to be used in Project 5U01AA014106 where they undergo additional alcohol exposure testing before being killed and dissected.[32,33,34] The Wake Forest study received $3,931,858 in funding from 2003 and 2011.

Inapplicability to human mental illness

The experimenters that are discussed above seek to justify the use of animals by positing that maternally deprived macaques model the effect of early-life stress on the development of mood and anxiety disorders in humans. In addition to fundamental differences in gene expression,[35,36,37,38] brain anatomy and physiology,[39,40,41,42] and development[43,44] among humans and other primates, these adverse environments *do not* adequately represent the type of early social and physical stressors that precipitate mental illness in human children and adults. In reality, sexual abuse, physical abuse, prenatal stress, parental drug abuse, parental mental illness and/or criminal behavior, and economic stress are more common early life traumas affiliated with later mental illness and often co-occur in affected individuals.[45,46,47] However, details regarding infants' *in utero* environment are not described in these studies,

nor are details regarding the mothers' genetic makeup, rearing history, or mental health status—all of which are far likely more important contributors to the development of mental illness than the postnatal manipulations imposed by these researchers. Additionally, while macaque social structure may be as complex as human social structure, it is decidedly different from that of most modern human societies. For example, it is typical for infant macaques to stay in *constant* physical contact with their mothers for their first month of life,[48] making even the briefest separation stressful for infants as well as chronic separation more detrimental than can be expected in humans in most cultures. Therefore, any applicability of this nonhuman primate model is likely to vary dramatically across different human cultures with different social structures and traditional rearing practices. Even the "typical" mother-reared infants who are used as a control group in most of these experiments spend much of their time in barren, metal cages, and are subject to constant experimental testing, requiring multiple separations from their mother, and involving stress and/or fear-inducing tests.[22,49] These living conditions and frequent maternal separations likely impact the natural infant-mother behavior that would occur in the wild, and as reviewed below, increase the stress levels and mental health of all animals included in the study. The mother-reared infants cannot provide an accurate example of "typical" or "healthy" development for any species, and the additional stress of laboratory conditions confound the experimental stressors introduced in maternally deprived animals. Therefore, these studies using a "well controlled" nonhuman primate model fail to properly model the complex relationship between genes, early life experience, and mental illness in the human population. The evidence of this fact is that, collectively, the project has not resulted in any new treatments for human mental illness.

Existing clinical research and nonanimal methodologies readily available

The principal investigators on the aforementioned projects contend that controlled studies of gene-environment interactions in humans are ethically and practically untenable. However, this contention is inaccurate. Numerous large-scale epidemiological studies in humans have documented the effects of early life stress,[50,51,52] genetic risk,[53,54,55] and gene-environment interactions,[56,57,58,59,60,61] on abnormal social, emotional, and behavioral development. These studies include investigating the contribution of both genes and the environment in the development of mood disorders,[57,58] addiction,[62] depression,[63] and altered brain structure and function[64,65,66] in humans.

Recent human studies have also begun to unlock the complex biological and molecular mechanisms that underlie these gene and environmental interactions.[62,67,68,69] For example, McGowan et al.[62] and Klengel et al.[69] studied the interaction between early childhood trauma and genetic variation on gene transcription in the brains of humans. Similarly, in a large-scale study of nearly 200 individuals, Buchman et al.[68] tested the interaction between early-life psychosocial adversity, genetic make-up, and plasma levels of brain-derived neurotrophic factor, critical for brain development and plasticity. DNA methylation, studied in the brain tissue of monkeys killed in the NIH studies, can be non-invasively measured in monocytes and T-cells and correlated with neurotransmitter synthesis using positron emission tomography *in vivo* in humans, a technique recently used to determine the relationship between childhood aggression, DNA methylation, and serotonergic function in humans.[67] Postmortem studies using brain tissue from humans at different stages of development[70] as well as those from individuals suffering from or carrying genes associated with autism,[71,72] depression,[73] and schizophrenia[74,75] have identified critical differences in gene expression

across age, species, and clinical populations. These groundbreaking studies have already begun detailing genetic *and* epigenetic effects on human brain structure, function, and development in humans suffering from mental illness—details not attainable from animal models.

Additionally, the mood-altering effects of the type of drugs being tested by the NIMH Non-Human Primate Core, including fluoxetine,[76] oxytocin,[77] diazepam,[78] and dopamanergic and serotonergic drugs such as raclopride and buspirone,[79,80] are already well documented in humans suffering from mental illness. These studies have been conducted with healthy volunteers,[81,82,83] children,[75,84,85] and patients with mental illness.[86,87] The impact that these drugs have on brain structure and function have also been evaluated in human volunteers,[78,88,89] and their neural mechanisms in healthy and ill children and adults are already well delineated.[90,91,92,93]

Impact on animal welfare

The physical and psychological harms of confining primates and other animals in laboratories and subjecting them to routine and experimental procedures are well established.[94,95] Primates experience increased stress from common laboratory procedures such as cage cleaning,[96] physical examination,[97] blood draws,[98] and restraint.[99] The mere physical presence of human experimenters and technicians increases stress in primates.[100,101] Numerous studies have demonstrated that even minor changes in primates' captive environment, including temporary changes in cage size or location, increase stress levels.[102,103] It is not surprising that decreased immune system functioning[104] and increased self-injurious behavior are common in primates in laboratories.[105,106]

Specific to the experiments in question, the intention of these projects is to create, psychological illness in primates. Maternal deprivation, repeated restraint and social isolation, repeated exposure to startling sounds and frightening situations, and repeated blood draws, spinal taps, drug injections, and brain imaging procedures take an enormous toll on the psychological well being of these animals.

The numerous long-term negative outcomes of these motherless rearing conditions on monkeys have been well established for decades: mother-deprived infants exhibit excessive fearfulness and/or aggression,[48] produce excess stress hormones,[107] and frequently rank at the bottom of the social dominance hierarchy.[48] They exhibit motor stereotypies indicative of frustration and stress,[108] abnormal sleep patterns,[109] increased susceptibility to alcohol abuse,[110] and increased startle and stress responses to threatening stimuli.[111] Maternal deprivation affects serotonin pathway function[112,113] and cerebral blood flow[114] and alters levels of brain-derived neurotrophic factor and nerve growth factor critical for normal brain function[115] and has long-term effects on brain morphology.[116] Both spontaneous and selectively bred genetic variations in the macaques interact with adverse rearing conditions, often exacerbating the already profoundly negative effects of adverse rearing.[117,118,119]

Additional independent review

To extend the depth of our analysis of these experiments, we have consulted with independent subject matter experts in the fields of mental health, medicine, anthropology, and primatology (they were not compensated in any way by PETA). Concerns of several of these specialists, which they have provided to PETA in writing, are as follows:

- *"Given the current status and progress of the research (as assessed via the published literature), I can no longer see a potential benefit from such experimentation as is ongoing currently. I cannot consider the depicted experiments, designed to create and study psychopathology in monkeys, to be a valuable undertaking that will likely contribute to the health and well being of humans..... From the methodologies described in the proposals and articles and the written and visual documentation provided by PETA of actual laboratory procedures and activities, it is my assessment that the monkeys used in these experiments experience substantial psychological (and likely physiological) harm and that there is no current evidence that there will be any results from the studies that move our understanding of human psychopathology forward."*

  Agustìn Fuentes, PhD
  Chair of Anthropology
  University of Notre Dame

- *"The cause of mental illness in humans is unknown, but it is clearly complex and multifactorial. Some genetic studies are promising. Abusing monkeys, however, won't get us any closer to that understanding."*

  Jaymie Shanker, MD
  Board-certified psychiatrist

- *"Taken as a group and without exception, these experiments are cruel, plunging infant monkeys into hellish conditions that they can neither control nor escape from. Ethically and morally, they have no place in science today. The cost to these animals is far too high. As we have seen, it is not as if the experiments lead to an earth-shattering breakthrough that could, in some moral calculus (though not PETA's and not mine), give us reason to think the cost was remotely worth it. This lack of justification is particularly true given the myriad of human-based research methodologies available to study the environmental, genetic, and social causes of mental illness as well as the fact that these experiments on monkeys often seek to replicate knowledge already ascertained in humans."*

  Barbara J. King, PhD
  Chancellor Professor of
  Anthropology
  College of William and Mary

- *"The scientific objections to continuing this research are immediately obvious. If the goal is to model neuropathologic/neurophysiologic substrates of human psychiatric diseases, then these efforts are hopelessly crude and antiquated, having long been superseded by in vivo neuroimaging studies of human patients with the psychiatric diseases of interest. Simply conduct a search in PubMed on any psychiatric diagnosis, such as psychopathic personality disorder, depression, schizophrenia, and a host of others, and you will find dozens of current, sophisticated, state-of-the-art neuroimaging studies comparing brain structure and function in patients and controls, clearly delineating structural and functional abnormalities in human patients. These patients, along with their early life experiences, genetic make-up, and medical histories, can be followed longitudinally to*

evaluate illness etiology and treatment efficacy. Modern research methodology has also allowed investigators to measure the separate and interacting contribution of genes and early environmental stress in the development and neural substrates of mental illnesses in humans. Postmortem studies of human brain tissue from individuals with mental illnesses or individuals carrying risk-alleles associated with psychiatric diseases are far better methods for clarifying the molecular etiologies of these complex ailments. , , If the goal of the infant monkey psychological trauma experiments is not to eventually improve our understanding of human psychiatric diseases—as the above cited imaging, genetic, and epidemiological studies are already doing—then in the zero sum game of research funding, the National Institutes of Health (presumably referring to human health) should have nothing to do with them."

Lawrence A. Hansen, MD
Professor of Neuroscience
and Pathology
University of California-San
Diego School of Medicine

- *"It is not surprising that monkeys reared under such adverse conditions at the NIH are physically, mentally, and emotionally unwell. However, despite the outcome being known, it is surprising that experiments in which these animals are deliberately subjected to extreme stress are allowed to continue. Moreover, monkeys are not humans, so any experimental findings that are true of monkeys would not necessarily be true of humans. If the researchers who are performing these experiments wish to argue that the monkeys are similar enough to humans in terms of emotional development that studies done on them can be applied to human development, then they must acknowledge that they are performing studies that cause intense pain and terror to their subjects, much as any human would experience intense pain and terror were these experiments performed on humans... .... The American Psychological Association should not permit these experiments, which I believe are in violation of several sections of the APA Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research. Specifically, Guideline I (2) states that "[T]he scientific purpose of the research should be of sufficient potential significance to justify the use of nonhuman animals" and notes that "psychologists should act on the assumption that procedures that are likely to produce pain in humans may also do so in other animals." Yet, in a 2014 paper published in The American Journal of Psychiatry, the experimenters acknowledge that their anti-depressant experiments on monkeys cannot be applied to humans, that maternal deprivation studies on monkeys have never been confirmed as an effective way to test the efficacy of drug treatments for human mental illness, and that the only way to test treatments for human psychological disorders is in humans."*

Michael Radkowsky, PsyD
Clinical psychologist

- *"If these experiments are meant to parallel or predict the psychopathy and mental illness of human infants in the care of negligent, absent, and/or abusive mothers, they fail profoundly. Contrived maternal deprivation, chronic exposure to stressful experimental paradigms, confinement, and social isolation in laboratory settings do not parallel the*

types of early stressors experienced by most human mental illness sufferers. These laboratory versions of early-life adversity are too routinized and methodical to be representative of any real-world experiences faced by humans. The circumstances surrounding physical, social, emotional, and cognitive development in human beings is multifaceted and more complicated than those that can be imposed on infant monkeys reared in a laboratory. Good, creative research either cleverly sets up situations that allow behavioral and biological responses of interest to occur naturally, or it takes the form of field studies to observe real-world dynamics in a natural setting. The NIH experiments depicted on video include constraining infants in small cages and startling them with loud noises, trapping infants and then threatening them with human experimenters, or caging them with a drugged, unresponsive mother. These procedures do not accurately or creatively replicate the stressful situations believed to precipitate mental illness in humans."

Nora J. Johnson, PsyD
Clinical psychologist
University of Pennsylvania
Health System

- *"I do not consider the depicted experiments, designed to create and study psychopathology in monkeys, to be a valuable undertaking that will likely contribute to the health and well-being of humans. Rather, the causes and manifestations of mental illness in humans are most effectively researched without the use of animals."*

Tara West, PhD
Adjunct Associate Professor
of Psychology
CUNY School of
Professional Studies

Conclusion

In a recent paper discussing the inadequacy of regulations governing experimentation on animals, bioethicist Dr. David Wendler of the NIH's Clinical Center called for greater restrictions on the use of primates in experiments, noting that existing regulations "do not mandate that the risks to which nonhuman primates are exposed must be justified by the value of the study in question."[120]

For decades the NIH has continued to review, approve, fund, and conduct the aforementioned studies that deliberately and repeatedly inflict severe and chronic harm to monkeys, are often not at all designed to help humans, or have extremely limited potential to elucidate the complex etiology of human mental illness and have not improved our treatments of these illnesses or human health in general.

These experiments represent an enormous financial burden to taxpayers, particularly as there are a myriad of accessible, humane research methodologies that are more directly applicable to mental illness and its treatment. Continuing to fund this suite of projects appears to be both scientifically and ethically unjustifiable.

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Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)>
Sent: Wednesday, July 13, 2016 4:09 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: Jane

---------- Forwarded message ----------
From: **Kathy Hudson** (b) (6)
Date: Tue, Jul 1, 2014 at 11:16 PM
Subject: Jane
To: Francis Collins <(b) (6)

Met with PETA today. Went fine. John Burklow joined me. Will fill you I later.

Do not engage in emails on this with jane or PETA.

More later

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson (b) (6)
Sent: Wednesday, July 13, 2016 4:11 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: confidential meeting date

---------- Forwarded message ----------
From: **Dan Mathews** <DANM@peta.org>
Date: Fri, May 30, 2014 at 12:14 PM
Subject: confidential meeting date
To: Kathy Hudson <(b) (6)

Hi Kathy,

Regarding the private meeting, what's your availability the week of June 23?

Thanks and have a great weekend,

Dan

From: Kathy Hudson [mailto(b) (6)
Sent: Wednesday, May 21, 2014 3:57 PM
To: Dan Mathews
Subject: Connecting

Hello,

I am deputy director for science, outreach, and policy at the NIH and I have been deeply involved in chimpanzee issues over the last couple of years. Francis asked that I reach out to you because he is on extended travel and because he always hands me the difficult and complicated issues!

I have been looking into this - though my efforts to actually look carefully at the facility were stymied last friday due to floods (see below). I tried five different routes to get there and had to turn back due to rivers over the roads.

You had offered to meet confidentially and to provide additional information along with your advising neuroscientist. I would like to take you up on that offer and I would like to include two other senior folks from NIH who are in a better position than me to help chart the path forward. Shall we try to set that up?

Thanks

Kathy

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)
Sent: Wednesday, July 13, 2016 4:11 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: movies

---------- Forwarded message ----------
From: **Thomas Insel** (b) (6)
Date: Wed, May 28, 2014 at 8:34 PM
Subject: Re: movies
To: Kathy Hudson (b) (6)

Yes, I would bring in Jim Raber, Eric Nelson, and the NICHD folks including Steve Suomi. The facts are pretty consistent at this point. Strategy not so much. Suspect we will hear from PETA when they make this public. So would plot our response now. I am in NYC late tomorrow and Fri but can join by phone if you want to meet this week.

On Wed, May 28, 2014 at 5:08 PM, Kathy Hudson <(b) (6) wrote:
Thanks tom.

What is your view about meeting with all related folks with goal of clarifying all the facts and plotting strategy forward. I am pleased - but suspicious - that PETA has not gotten back to me.

On Wednesday, May 28, 2014, Thomas Insel <(b) (6) wrote:
Spoke w NIMH vet, Jim Raber, today. He knows studies well. He suggested and I agree that would be good to plan the communications strategy, assuming that PETA goes forward without meeting w NIH. He volunteered to assist w this and reminded me that the IACUC has two public members who would be effective. Since the focus may be on Suomi, we need to figure out how NICHD wants to deal w this as well,

On Sat, May 24, 2014 at 4:40 PM, Kathy Hudson <(b) (6) wrote:
Tom
Was same investigator responsible for the experiments where the mom monkeys are knocked out and the babies freak out?

I think we need some pretty solid info for each of the clips and then to develop our respknse to PETA and Jane (and subsequently the media).

Would it make sense to meet with Danny, Steve, poolsville manager woman who's name I can remember, Constantine, you, Alan, Burklow, and others that are central. Bi think we can probably then wrap this up.

I do not want fc connected to this. Story line should be that I received video...

On Saturday, May 24, 2014, Thomas Insel <(b) (6)> wrote:

OK -- the startle test -- which is the most dramatic of these videos - is likely from experiments done on juvenile monkeys separated from their mothers at birth and raised in peer groups in a study at the NIMH Poolesville lab beginning in about 2004 or 2005. The PI was Jim Winslow, a staff scientist with Dennis Charney at first and later with Husseini Manji. The control animals in this case were mother raised. Half of each group received fluoxetine (prozac) for 1 year beginning at age 2 to create a 2 x 2 design. All monkeys received PET scans 1.5 years after drug was discontinued. The study looked at 32 monkeys across 4.5 years. The idea was to model drug effects in kids receiving this class of drugs. The relevant paper published in March in the American Journal of Psychiatry was provocative because it suggested that juveniles treated with fluoxetine showed lasting changes in serotonin receptors -- there was no effect of rearing condition or drug on startle. Because of the implications for the use of fluoxetine in children (SSRIs are broadly prescribed for kids with mood or anxiety problems), the paper concludes:

"Fluoxetine administered to juvenile monkeys upregulates SERT into young adulthood. Implications regarding the efficacy or potential adverse effects of SSRIs in patients cannot be directly drawn from this study. Its purpose was to investigate effects of SSRIs on brain development in nonhuman primates using an experimental approach that randomly assigned long-term SSRI treatment or placebo."

(b) (6). The lab was closed soon after and NIMH left Poolesville completely. I believe all of the monkeys have been killed, but I need to check on that because some were transferred to Bethesda. Some of the co-authors remain at NIMH. I can check on the details with those who remain but need some guidance about how much I can share about the reason for my inquiry. I suspect the videos come from a disgruntled employee -- (b) (6) (b) (6) (b) (6) (Really -- I am not making this up.) One of the senior authors, Danny Pine, is a good resource here who would know current status of monkeys, data, etc.

Tom

On Sat, May 24, 2014 at 11:45 AM, Kathy Hudson <(b) (6)> wrote:

(b) (5)

The first clip is from steve's lab but the others we understand are not. Steve and his lab manager think these are from NIMH researchers who are gone or dead. Can you help us figure out the origins?

Thanks

Kathy

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson (b) (6)
Sent: Wednesday, July 13, 2016 4:12 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: monkey stuff

---------- Forwarded message ----------
From: **Kathy Hudson** <(b) (6)>
Date: Mon, May 26, 2014 at 3:13 PM
Subject: monkey stuff
To: Brigid Guttmacher (b) (6)

Alan,

Below is an email string between me and tom. somehow header of first got cut off. do you think meeting of all involved woudl be helpful?

so nice to see you yesterday! we totally lucked out with weather.

from kathy to tom------

here is the email dan from peta sent to jane.

The first clip is from steve's lab but the others we understand are not. Steve and his lab manager think these are from NIMH researchers who are gone or dead. Can you help us figure out the origins?

Thanks

Kathy

Hi Jane,

Greetings from Virginia - I hope you are well wherever you are. I'm writing to ask if you'd consider offering your professional opinion on a highly confidential new case we have related to the use of infant monkeys in maternal deprivation and psychopathology experiments at a government laboratory. Your expertise would be invaluable to helping us draw attention to and put an end these cruel studies that the experimenters themselves recently acknowledged are not relevant to humans.

PETA has obtained hundreds of photographs, and more than 500 hours of high-definition videos, taken between 2009 and 2012 depicting continuing maternal deprivation and depression experiments on hundreds of baby monkeys conducted in the laboratory of psychologist Stephen Suomi (a protégé of Harry Harlow's) and his colleagues at a National Institutes of Health (NIH) facility in Poolesville, Maryland.

Each year, 40 to 60 monkeys—many bred to be genetically predisposed to mental illness—are born in Suomi's laboratory. The monkeys undergo years of terrifying, distressing and sometimes painful experiments designed to exacerbate and measure their anxiety, depression, fear, social withdrawal and physical illness.

The videos PETA has obtained show experiments in which newborn infants are restrained inside tiny mesh cages and placed in "startle chambers." The infants are then startled by loud noises from which they struggle hide and escape. In other tests, newborns are separated from their mothers or social groups, placed alone in a small cage, and then repeatedly scared by a human presence. In other experiments, the infant monkeys are caged with their mothers, who are chemically-sedated so as to be unresponsive, and placed in a car seat. The terrified and confused infants scream and cry, climbing onto and frantically shaking their mothers. In at least one case, experimenters can be heard laughing while a mother tries to remain awake to comfort her upset child. In some trials, an electronic snake is released into the cage with the baby monkeys, who innately fear the reptiles.

A confidential 9 min. video representative of the complete footage is viewable here: http://www.petapreview.com/4preview/monkey_experiments_rc.asp

I have also attached a fact sheet that describes the project in greater detail.

Please do not share or forward this information just yet. Might you be able to share your professional opinion on the short-term and long-term distress being caused to the monkeys, as well as your feelings on the ethics, especially given the experimenters' acknowledgements that the experiments aren't useful to humans? Your expertise could be a game-changer n this case.

Please let me know if you have any questions, and thanks as always!

Dan

Thomas Insel

May 2
days a

to me

OK -- the startle test -- which is the most dramatic of these videos - is likely from experiments done on juvenile monkeys separated from their mothers at birth and raised in peer groups in a study at the NIMH Poolesville lab beginning in about 2004 or 2005. The PI was Jim Winslow, a staff scientist with Dennis Charney at first and later with Husseini Manji. The control animals in this case were mother raised. Half of each group received fluoxetine (prozac) for 1 year beginning at age 2 to create a 2 x 2 design. All monkeys received PET scans 1.5 years after drug was discontinued. The study looked at 32 monkeys across 4.5 years. The idea was to model drug effects in kids receiving this class of drugs. The relevant paper published in March in the American Journal of Psychiatry was provocative because it suggested that juveniles treated with fluoxetine showed lasting changes in serotonin receptors -- there was no effect of rearing condition or drug on startle. Because of the implications for the use of fluoxetine in children (SSRIs are broadly prescribed for kids with mood or anxiety problems), the paper concludes: "Fluoxetine administered to juvenile monkeys upregulates SERT into young adulthood. Implications regarding the efficacy or potential adverse effects of SSRIs in patients cannot be directly drawn from this study. Its purpose was to investigate effects of SSRIs on brain development in nonhuman primates using an experimental approach that randomly assigned long-term SSRI treatment or placebo."
(b) (6) The lab was closed soon after and NIMH left Poolesville completely. I believe all of the monkeys have been killed, but I need to check on that because some were transferred to Bethesda. Some of the co-authors remain at NIMH. I can check on the details with those who remain but need some guidance about how much I can share about the reason for my inquiry. I suspect the videos come from a disgruntled employee -- (b) (6)
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Tom

Kathy Hudson <(b) (6)>

May 2
days a

to Thomas

Tom
Was same investigator responsible for the experiments where the mom monkeys are knocked out and the babies freak out?

I think we need some pretty solid info for each of the clips and then to develop our respknse to PETA and Jane (and subsequently the media).

Would it make sense to meet with Danny, Steve, poolsville manager woman who's name I can remember, Constantine, you, Alan, Burklow, and others that are central. Bi think we can probably then wrap this up.

I do not want fc connected to this. Story line should be that I received video...

Thomas Insel

May
days ago)

to me

I spoke w Danny. The good news is that the fluoxetine study is really in the past. And he states there is no active research involving what you see in the videos. He did not know if the IACUC protocol was terminated -- we need to check on that on Tuesday. But the section was closed, the monkeys euthanized, and the staff dispersed at least 2 years ago. The complication is that there were two different studies involving startle tests or babies on anesthetized mothers. The fluoxetine study used startle in juvenile monkeys in large cages, so the video is from a different study. The second study was an NIMH study using Suomi's monkeys. That study was also in the past, but the NICHD monkeys are still around and still part of Suomi's colony. Suomi was a co-author on the paper (see attached). The remaining key person at NIMH is Eric Nelson. He no longer is involved in non-human primate research, as far as I know. I can check w him on Tuesday. Danny mentioned that Eric was contacted by PETA about a year ago and that the NIMH vet dealt w FOIA requests from PETA about that time. Some of the personnel continue to work w non-human primates in other labs at NIMH, but I am pretty sure no one at NIMH studies infant monkeys. I will check on this on Tues.
Tom

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)
Sent: Wednesday, July 13, 2016 4:13 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: Connecting

---------- Forwarded message ----------
From: **Dan Mathews** <DANM@peta.org>
Date: Wed, May 21, 2014 at 6:18 PM
Subject: RE: Connecting
To: Kathy Hudson <(b) (6)

Thanks Kate, I appreciate this and we'd love to meet. Back to you in a day or so with a few options!

Kind regards,

Dan

From: Kathy Hudson [(b) (6)
Sent: Wednesday, May 21, 2014 3:57 PM
To: Dan Mathews
Subject: Connecting

Hello,

I am deputy director for science, outreach, and policy at the NIH and I have been deeply involved in chimpanzee issues over the last couple of years. Francis asked that I reach out to you because he is on extended travel and because he always hands me the difficult and complicated issues!

I have been looking into this - though my efforts to actually look carefully at the facility were stymied last friday due to floods (see below). I tried five different routes to get there and had to turn back due to rivers over the roads.

You had offered to meet confidentially and to provide additional information along with your advising neuroscientist. I would like to take you up on that offer and I would like to include two other senior folks from NIH who are in a better position than me to help chart the path forward. Shall we try to set that up?

Thanks

Kathy

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)
Sent: Wednesday, July 13, 2016 4:14 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: Field trip

---------- Forwarded message ----------
From: **Francis Collins** <(b) (6)
Date: Fri, May 9, 2014 at 7:22 AM
Subject: Re: Field trip
To: Kathy Hudson <(b) (6)

Excellent plan!!!! Thanks!!!!

On Thursday, May 8, 2014, Kathy Hudson <(b) (6) wrote:
I am going to have a bottle of champagne sent to their room from you!! Cause that is just what a great deputy I am !

On Thursday, May 8, 2014, Francis Collins <(b) (6) > wrote:
Sounds like a good plan -- so far no follow up from PETA.

(b) (6)

FC

On Thu, May 8, 2014 at 12:02 AM, Kathy Hudson <(b) (6) wrote:
Field trip scheduled for next Friday. Alan will go with me. I am in on going discussions with michael and Jim.

Will keep you posted.

Have my suitcase packed for (b) (6) Very bittersweet trip.

Hello,

I am deputy director for science, outreach, and policy at the NIH and I have been deeply involved in chimpanzee issues over the last couple of years. Francis asked that I reach out to you because he is on extended travel and because he always hands me the difficult and complicated issues!

I have been looking into this - though my efforts to actually look carefully at the facility were stymied last friday due to floods (see below). I tried five different routes to get there and had to turn back due to rivers over the roads.

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Thanks

Kathy

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)>
Sent: Wednesday, July 13, 2016 4:13 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: PETA AND THE MONKEY EXPERIMENTS.

---------- Forwarded message ----------
From: **Francis Collins** (b) (6)
Date: Sun, May 25, 2014 at 7:41 AM
Subject: Re: PETA AND THE MONKEY EXPERIMENTS.
To: Kathy Hudson <(b) (6)

Great, thanks!

On Sat, May 24, 2014 at 4:42 PM, Kathy Hudson (b) (6) wrote:
I need more info to have complete response and will meet with relevant folks this week. Will go to poolsville on Friday. The story line is that I got this video. You are not connected.

Yes, I told dan I would meet. He said ok and he would get back to me. I am sure they are scheming.

On Saturday, May 24, 2014, Francis Collins <(b) (6) wrote:
That is indeed major news! Did you connect with Dan, or do we need to powwow first?

On Fri, May 23, 2014 at 8:02 PM, Kathy Hudson (b) (6) wrote:
dear FC
major news on this. Video is old and largely from nimh investigators who are dead or gone. Look forward to updating you.
Best,
CEO
monkey biz

On Tue, May 20, 2014 at 12:49 PM, Francis Collins <(b) (6) wrote:
Hi Jane,

Thanks for the heads up, and no need to apologize for sounding fierce! E-mail sometimes defeats one's best efforts to convey nuance, but you and I know each other well enough that I couldn't imagine you being harsh. Passionate, yes! Principled, yes!

We have indeed been looking into this, but haven't yet arrived at a concrete plan. Meanwhile, I'm in Brazil working on scientific collaborations -- they have terrific students here. In my absence I have asked Dr. Kathy Hudson, who I think you have met in the context of the chimpanzee efforts, to contact Dan

Matthews. I continue to hope that we can arrive at a good outcome here without PETA having to resort to a big press event. That might raise consciousness for the public, but it will thoroughly alienate the scientific community, who will then lock arms, making it hard for Kathy and me to negotiate a good outcome.

We're hoping for a bit more time...

(b) (6) [redacted]

Love, Francis

On Tue, May 20, 2014 at 11:17 AM, Jane Goodall <(b) (6) [redacted]> wrote:

Dear Francis,
I suspect that PETA will be planning a release of some sort about the footage they have gained.
I don't think I can stop them. Nor do I know if you contacted them at all.
I have to say that the footage sickened me. As did the information we received about this quite some time ago. You remember, I told you I had already written a letter, or signed a letter, opposing the research.
Perhaps you have found out something that justifies it?
Sorry I'm writing in staccato phrases – its not meant to sound like it probably does, but I am in (b) (6) [redacted], about to get on a plane.
And got a letter from Dan Matthews asking if I'd heard from you. No more than that.
Here we are b attling with (b) (6) [redacted]. It never stops!!
Sending lots of love to make up for fierce sounding letter!
Jane

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)>
Sent: Wednesday, July 13, 2016 4:14 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: Rhesus experiments in Poolesville

---------- Forwarded message ----------
From: **Francis Collins** <(b) (6)>
Date: Tue, May 20, 2014 at 12:39 PM
Subject: Fwd: Rhesus experiments in Poolesville
To: Kathy Hudson <(b) (6)>

complete thread with PETA guy below....

---------- Forwarded message ----------
From: **Dan Mathews** <DANM@peta.org>
Date: Thu, May 15, 2014 at 10:09 PM
Subject: RE: Rhesus experiments in Poolesville
To: Francis Collins <(b) (6)>

Hi Francis,

Might there be any update on the Poolesville case in the past few weeks? I'd like to reiterate my offer of a private, confidential meeting with myself and our advising neuroscientist, who spent 8 years at NIMH. I'm very thankful that Jane connected us, and look forward to hearing from you again soon. Have a good weekend,

Dan

PS As someone who works with both faith-based and non-religious leaders, I really appreciated your message in *Language of God*. It's the moral voice within, I always say, and it was heartening to see you articulate that. My degree is in ancient history and I studied the western world's fascinating conversion to Christianity when I lived in Rome, before joining PETA in '85.

From: Francis Collins [mailto:(b) (6)]
Sent: Sunday, May 04, 2014 9:58 AM
To: Jane Goodall; Dan Mathews
Subject: Rhesus experiments in Poolesville

Hi Jane and Dan,

I appreciate Jane having brought to my attention the experiments in Poolesville on baby rhesus monkeys. I am looking into this situation with high level members of my team, but it will take a little time to understand how such experiments have been considered scientifically justified.

Please allow me to do some discrete investigating, and then I will get back to you. I welcome the chance to pursue this discussion in a thoughtful and private way.

Francis

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)
Sent: Wednesday, July 13, 2016 4:16 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: Sensitive and confidential question

---------- Forwarded message ----------
From: **Kathy Hudson** <(b) (6)
Date: Mon, May 5, 2014 at 9:05 PM
Subject: Re: Sensitive and confidential question
To: Brigid Guttmacher <(b) (6)

fyi

On Mon, May 5, 2014 at 5:30 AM, Francis Collins <(b) (6) > wrote:
Hi Kathy,

(b) (6) He has spent countless hours in study sections reviewing non-human primate research, and has had reservations about how much of it is scientifically useful and ethically justifiable. I asked him to provide some insight into Suomi's work. His comments are below, in case they are of use in sizing up this situation. He is 100% trustworthy in keeping confidence.

FC

(b) (6) 4:11 AM (1 hour ago)

to me

Hi Francis,
Thanks for thinking of me in these matters. I have followed some of Steve Suomi's research from a distance after reading Deborah Blum's "Monkey Wars" book. I think you may have seen it. (b) (6)
(b) (6)
(b) (6)
I've wrestled with my opinion on Steve's research and will be as unbiased as I can be. Yes, he was a doctoral student of Harry Harlow at the University of Wisconsin (National Medal of Science winner). While there, he was involved in the notorious "pit of despair" - term coined by Harry Harlow to describe the apparatus for keeping rhesus macaques socially isolated for prolonged periods of time to investigate aberrant behaviors and generate animal models of induced depression. Harry also liked to coin other volatile phrases such as the "rape rack" to describe devices where socially isolated females were subject to forced matings to determine how well these females would rear

their offspring. As I recall, the there has an increased rate of infanticide. As such, while Harry is well know for his far more benign 'wire cloth model' monkey models of maternal love, there were seriously dark experiments conducted that would not pass today's ethical standards.
As such, Harry Harlow and his most famous scientific trainee Steve Suomi have become rallying points for anti-vivisectionist groups (for want of a better term since their tactics and philosophies are all over the map) and individuals. Case in point, the Primate Research blogspot highlights the concerns and anger of a subset of such individuals.
http://primateresearch.blogspot.com/search?q=suomi
Let's just scan some of the titles of the entries:
"Stephen John Suomi: A Lifetime of Sadism" (Thursday, June 28, 2007)
"Monsters: Harry Harlow and Stephen Suomi" (Sunday, August 29, 2010)
Needless to say, for many many years, Steve has been a major target on the radar screen of animal rights activists. Many people still resent his participation in Harry Harlow's early experiments. Nevertheless, the question is, what about the here and now? That is, are the experiments that are currently being undertaken as extreme? Obviously not, however, the general theme of generating rhesus macaque models of "early life social adversity" (title of one of Steve's 2012 PNAS papers) persists. Just how severe is the psychological stress these animals that are reared apart from their their parental groups? I would need to see this in person (verbal descriptions are insufficient), but obviously the goal of the experiment is to put the animals under conditions that affect their behavior as a model of childhood neglect, isolation, or bullying, in crude terms. The other experiments highlighted in the e-mail exchange frankly sound pretty severe. I did not download the video. However, I can say that it would not surprise me if at one point in time at least animal handler would laugh at one of these situations. The issue is desensitization and the lack of maturity of a limited subset of the animal handler group. Over the years, I've heard enough comments from a limited number of such individuals that would indicate this could happen.
The next question arises, "what practical benefit is all this to human and non-human primate health?" Many times I am left scratching my head. The conclusions tend to be simplistic, such as social adversity compromises the primate immune system. Gene expression and DNA methylation profiles of blood samples change. Obviously there is the next generation experiments of ChiP-Seq and other genomics technologies that will be brought to bear. Predictable progression of experiments.
Is this line of research going to help a person addicted to drugs or subject to child abuse or other traumas? I can't think of anything practical that could not be studied simply using human subjects. Yes, the human work is less controlled, but the animals also show extreme behavioral diversity. That is highlighted by varying degrees of self-injurious behavior in captive non-human primate populations. The rhesus experiments are less controlled than one might think at first blush. Given this diversity, could Steve's projects help minimize self-injurious behavior in captive non-human primates? That would be a laudable goal. Well, the problem in my opinion is that we already know that this behavior is strongly influenced by their social isolation, which is unavoidable in some vaccine trials. Also, drugs similar to valium have been used to treat such animals. However, this compromises the vaccine development trials because it introduces another variable. In other words, I do not believe there is a reasonable chance that such studies could be used to improve dramatically the health of captive non-human primates. Perhaps one could identify the animals most likely to develop self-injurious behavior through genetic testing (laudable goal), but all the data I have seen so far indicates that these studies are severely under-powered and highlight small effect sizes that make such selective breeding for more 'adversity robust' animals impractical. Certainly not theorectically impossible, but not probable in my opinion.
In his own words, here are two NIH grants attributed to Steve
http://projectreporter.nih.gov/project_info_description.cfm?aid=8736837&icde=20243398
http://projectreporter.nih.gov/project_info_description.cfm?aid=8736838&icde=20243398&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC

I think the PETA involvement will cause many in the scientific community to circle their bandwagons without much critical thought. Steve has to be a world expert in defending himself since he has heard these complaints his entire scientific career. He has an avid circle of scientific defenders. Harry Harlow did as well at the time, but look at Harry's long-term legacy.

I would hope that this general subject matter could be handled without directly dragging PETA into the discussion. Too much convoluted history and too many complicated personalities to engage in a rational discussion - at least in my opinion. I believe one would need to involve unbiased behavioral scientists who solely focus on humans and ask them, does any of this rhesus macaque work have any real impact on your research? This has to go way beyond citing a few papers here and there. The rhesus experiments should have a practical impact on experimental design and data interpretation that can be cataloged. In my humble opinion, Steve's studies do not have a truly significant practical impact on human life. Knowledge is gained by a world expert, but I'm not seeing how human beings who experienced any of a wide variety of social abuses benefit to any appreciable extent. I really wish they could, but I'm not seeing it.

My apologies for the long e-mail. I simply want to be fair to everyone involved. I'm happy to clarify or provide any additional opinions at any time.

Best wishes - (b)

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)
Sent: Wednesday, July 13, 2016 4:21 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: video

---------- Forwarded message ----------
From: **Kathy Hudson** <(b) (6)>
Date: Mon, May 5, 2014 at 9:08 PM
Subject: video
To: Brigid Guttmacher <(b) (6)

i am not a primatologist (but did do dog experiments in college at mayo) and i did not find the holding of the baby monkeys troubling. they look clean and well cared for. I found the startle boxes and knocked out moms of concern. how long have we been doing these experiments and how much have they contributed to our ability to treat humans? just being a cynic.

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)>
Sent: Wednesday, July 13, 2016 4:15 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Re: FW: Confidential, new case

On Mon, May 5, 2014 at 9:06 PM, Kathy Hudson <(b) (6)> wrote:
fyi

On Thu, May 1, 2014 at 1:47 PM, Francis Collins <(b) (6)> wrote:
Have a look at this. It will trouble you a lot. Then we will need to strategize about what to do.

FC

---------- Forwarded message ----------
From: **Jane Goodall** <(b) (6)>
Date: Thu, May 1, 2014 at 12:06 PM
Subject: FW: Confidential, new case
To: Francis Collins <(b) (6)>

Dear Francis,
Below is the email I got from Dan – after I received the first I called him, and that is always better than asking difficult questions via email.
So all the correspondence is below, and I outlined the phone conversation.
Would be great if this was a turning point in all our relations with PETA and we could get all that good energy working in a way that helps everyone.
You won't enjoy the videos!
Lots of love and thank you for listening
Jane

From: Jane Goodall <(b) (6)>
Date: Sunday, 27 April 2014 12:08
To: <JANE>, <PETA>
Subject: FW: Confidential, new case

From: Dan Mathews <DANM@peta.org>
Date: Friday, 25 April 2014 23:19
To: Jane Goodall <(b) (6)>
Subject: Re: Confidential, new case

Hi Jane,

I'm very pleased we spoke today. PETA's plan for the monkey case doesn't involve protests, rather sharing the video online and urging people to ask NIH to end the project. But we'd much prefer to begin with private discussions with Dr. Collins. We'd be much obliged if you called him, shared the footage, and asked for a meeting with us in hopes of making headway behind the scenes. One of PETA's researchers is a human neuroscientist who just left NIH after 8 years; she knows the issue in and out and can speak authoritatively to the science of this issue. We have other experts who could join too. And if you are able to join via Skype even better! But I know you'll be on the road again soon. We are at the disposal of both you and Dr. Collins, please advise.

THANK YOU!

Dan

PS Regarding Air France, we will draft a letter for you to send them and get it to you later today. We're happy to help with media to promote that, as well.

From: Dan Mathews
Sent: Wednesday, April 23, 2014 7:18 PM
To: Jane Goodall
Subject: Confidential, new case

Hi Jane,

Greetings from Virginia - I hope you are well wherever you are. I'm writing to ask if you'd consider offering your professional opinion on a highly confidential new case we have related to the use of infant monkeys in maternal deprivation and psychopathology experiments at a government laboratory. Your expertise would be invaluable to helping us draw attention to and put an end these cruel studies that the experimenters themselves recently acknowledged are not relevant to humans.

PETA has obtained hundreds of photographs, and more than 500 hours of high-definition videos, taken between 2009 and 2012 depicting continuing maternal deprivation and depression experiments on hundreds of baby monkeys conducted in the laboratory of psychologist Stephen Suomi (a protégé of Harry Harlow's) and his colleagues at a National Institutes of Health (NIH) facility in Poolesville, Maryland.

Each year, 40 to 60 monkeys—many bred to be genetically predisposed to mental illness—are born in Suomi's laboratory. The monkeys undergo years of terrifying, distressing and sometimes painful experiments designed to exacerbate and measure their anxiety, depression, fear, social withdrawal and physical illness.

The videos PETA has obtained show experiments in which newborn infants are restrained inside tiny mesh cages and placed in "startle chambers." The infants are then startled by loud noises from which they struggle hide and escape. In other tests, newborns are separated from their mothers or social groups, placed alone in a small cage, and then repeatedly scared by a human presence. In other experiments, the infant monkeys are caged with their mothers, who are chemically-sedated so as to be unresponsive, and placed in a car seat. The terrified and confused infants scream and cry, climbing onto and frantically shaking their mothers. In at least one case, experimenters can be heard laughing while a mother tries to remain awake to comfort her upset child. In some trials, an electronic snake is released into the cage with the baby monkeys, who innately fear the reptiles.

A confidential 9 min. video representative of the complete footage is viewable here:
http://www.petapreview.com/4preview/monkey_experiments_rc.asp

I have also attached a fact sheet that describes the project in greater detail.

Please do not share or forward this information just yet. Might you be able to share your professional opinion on the short-term and long-term distress being caused to the monkeys, as well as your feelings on the ethics, especially given the experimenters' acknowledgements that the experiments aren't useful to humans? Your expertise could be a game-changer n this case.

Please let me know if you have any questions, and thanks as always!

Dan

Bordine, Roger (NIH/OD) [E]

From: Anderson, James (NIH/OD) [E]
Sent: Tuesday, May 06, 2014 5:44 AM
To: Hudson, Kathy (NIH/OD) [E]
Subject: monkeys

Jack is senior, has directed the center program for more than 15 years and knows the science and monkey facilities cold.
We are fortunate to have him.

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, May 5, 2014 8:57 PM
To: Anderson, James (NIH/OD) [E]
Subject: RE: monkeys

(b) (6) [redacted]

I would prefer to keep the monkey discussion very senior level for now so I will sally forth alone and loop you in as we go.

I don't know jack... I guess I should meet him?

-----Original Message-----
From: Anderson, James (NIH/OD) [E]
Sent: Monday, May 05, 2014 8:52 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: RE: monkeys

Our expert is Jack Harding. He will be at the Primate Center Directors meeting tomorrow where we were today. I really would take Jack.

(b) (6) [redacted]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, May 05, 2014 8:21 PM
To: Anderson, James (NIH/OD) [E]
Subject: monkeys

Can we talk tonight or tomorrow about interest in looking into irp monkey resources and how it would be useful to hae you along for the ride given your oversight for extramural?

(b) (6) [redacted] We are looking at a field trip to Poolesville next Friday a.m.

Bordine, Roger (NIH/OD) [E]

From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Thursday, May 08, 2014 12:40 PM
To: Suomi, Stephen (NIH/NICHD) [E]
Subject: Visit to Poolesville

Should be a fun road trip...

See you next Friday,

Alan

From: Suomi, Stephen (NIH/NICHD) [E]
Sent: Thursday, May 08, 2014 12:37 PM
To: Guttmacher, Alan (NIH/NICHD) [E]
Subject: RE: Visit to Poolesville

Alan,

We will certainly be ready for you guys – hopefully with some brand-new babies in the neonatal nursery. We already have 10 new babies down at the field station...

Steve

Stephen J. Suomi, Ph.D.
Chief, Laboratory of Comparative Ethology
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health, DHHS
Bethesda, MD 20892-7971
Phone: 301-496-9550
Fax: 301-496-0630
e-mail: ss148k@nih.gov

From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Thursday, May 08, 2014 12:30 PM
To: Suomi, Stephen (NIH/NICHD) [E]; Woodward, Ruth (NIH/NICHD) [E]; Schech, Joseph (NIH/NICHD) [E]
Cc: NICHDsd; Stratakis, Constantine (NIH/NICHD) [E]; Hanning, Brenda (NIH/NICHD) [E]; Kitzmiller, Francie (NIH/NICHD) [E]
Subject: RE: Visit to Poolesville

And my apologies to all for any imposition on your schedules by not first consulting about possible times to visit. The IRP review is on very compressed time schedule, and figuring out a time that both Dr. Hudson and I were available proved challenging, to say the least.

I look forward to the re-visit and I know she looks forward to her first visit.

Thanks in advance for hosting us, Alan

Alan E. Guttmacher, M.D.
Director
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health

Cc: Burklow, John (NIH/OD) [E]
Subject: monkeys

(I found this stuck in my outbox. Sorry if dup)

Can you three work to pull together list of folks recommended for meeting on monkeys? Tom insel, alan g., Constantine, nichd researcher whose name I am spacing out, mike gottesmans, Others?. To meet early in week of 23. Then I need a time I can provide to meet with peta folks off campus late that week. I would like to discuss whether observers are needed and who should be in this meeting.

Lyric, I think you get to catch this ball for us and move it ahead.

Bordine, Roger (NIH/OD) [E]

From: Jorgenson, Lyric (NIH/OD) [E]
Sent: Wednesday, June 11, 2014 10:11 AM
To: Schulke, Hilda (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Abel, Kathy (NIH/OD) [E]
Subject: monkeys

Hilda,

Please see the list below for this meeting. For right now, let's change the subject heading to "IRP and animal research". I would think a full hour is needed:

1. Mike Gottesman
2. John Burklow
3. Lyric Jorgenson
4. Tom Insel
5. Alan Guttmacher
6. Stephen Suomi
7. Constantine Stratakis
8. Pat White
9. Lauren Higgins
10. James Raber (NEI)
11. Eric Nelson (NIMH)

From: Hudson, Kathy (NIH/OD) [E]
Sent: Tuesday, June 10, 2014 1:20 PM
To: Schulke, Hilda (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Abel, Kathy (NIH/OD) [E]
Cc: Burklow, John (NIH/OD) [E]
Subject: monkeys

(I found this stuck in my outbox. Sorry if dup)

Can you three work to pull together list of folks recommended for meeting on monkeys? Tom insel, alan g., Constantine, nichd researcher whose name I am spacing out, mike gottesmans, Others?. To meet early in week of 23. Then I need a time I can provide to meet with peta folks off campus late that week. I would like to discuss whether observers are needed and who should be in this meeting.

Lyric, I think you get to catch this ball for us and move it ahead.

Bordine, Roger (NIH/OD) [E]

From: Francis Collins (b) (6) >
Sent: Friday, June 13, 2014 5:38 AM
To: Hudson, Kathy (NIH/OD) [E]
Subject: monkeys

Certainly appreciate the delicacy here -- talk about trying to balance benefits and risks! You are right to hold Dan accountable.

FC

On Thu, Jun 12, 2014 at 10:51 PM, Hudson, Kathy (NIH/OD) [E] <Kathy.Hudson@nih.gov> wrote:

Fyi and not at all urgent so when you have down time, read from bottom up but message is that I am moving this ahead, slowly - carefully.

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 12, 2014 10:46 PM
To: Insel, Thomas (NIH/NIMH) [E]; Guttmacher, Alan (NIH/NICHD) [E]
Cc: Schulke, Hilda (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: FW: meeting

Please see delicate dance emails below. I think we need to have our big-ish meeting with our team and then maybe have the three of us meet with dan and his two colleagues.

Not sure where this is going but it is a conversation we were asked to have so we shall have it.

I have actually been pretty impressed with Dan's diplomacy.

Look forward to talking to you guys about this.

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 12, 2014 10:35 PM
To: 'Dan Mathews'
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: RE: meeting

Appreciate very much the consideration. I will get back to you in next day or two with time and place and folks from my end who will attend. My inclination is to keep it small. I am heading out of town for the next week to help clean out my folk's house after my (b) (6) earlier this year but will be checking email.

Best,
kathy

-----Original Message-----
From: Dan Mathews [mailto:DANM@peta.org]
Sent: Thursday, June 12, 2014 10:14 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: RE: meeting

Thanks Kathy,
I'll postpone my trip to be there July 2. I'll bring, as originally discussed with Jane and Francis, our scientific advisor Katherine Roe (post-doctoral/research fellow at NIMH & experimental psychologist) and Justin Goodman (MA, PETA's director of laboratory investigations). We're all professionals, just tell me the time and office location.
Looking forward!
Dan

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]
Sent: Thursday, June 12, 2014 3:10 PM
To: Dan Mathews
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: Re: meeting

I would prefer to have a one on one with you or postpone till you can join.

I trust you recognize that this meeting was agreed to based on trust relationships.

Jane apparently trusts you, Francis trusts jane, Jane and Francis trust me.

Let's build on that and get on the phone to see if there is common ground and common understanding. If there is some glimmer of that, then we can have a bigger confab.

Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy NIH
301 496 1455
kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>

On Jun 12, 2014, at 5:08 PM, "Dan Mathews" <DANM@peta.org<mailto:DANM@peta.org>> wrote:

Hey Kathy, sorry it's been difficult to gather everyone with busy travel schedules. I hoped we'd have been able to do this in May or June as I am away the first 2 weeks of July. Might you have the first meeting with our team but without me, then I can join for a follow-up meeting later in July? As you know we've been very keen to get this moving since April.

Thanks!

Dan

-----Original Message-----
From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]
Sent: Thursday, June 12, 2014 1:26 PM
To: Dan Mathews
Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]
Subject: Re: meeting

Hmmm. I thought I agreed to meet with you.

Let's push the restart button here.

Kathy Hudson, Ph.D.

Deputy Director for Science, Outreach, and Policy NIH

301 496 1455

kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>

> On Jun 12, 2014, at 4:23 PM, "Dan Mathews" <DANM@peta.org<mailto:DANM@peta.org>> wrote:

>

> Hi Kathy,

> I will be unavailable to attend the July 2 meeting but hope to attend

> a subsequent meeting. But you'll be in good hands with our reps who

> include the following. Thanks again, Dan

>

>

> 1. John Gluck, Ph.D., Emeritus Professor of Psychology at the

> University of New Mexico and affiliate faculty of the Kennedy

> Institute of Ethics, Georgetown University

>

> 2. Justin Goodman, M.A., Director, Laboratory Investigations

> Department, People for the Ethical Treatment of Animals

>

> 3. Katherine Roe, Ph.D., Research Associate, Laboratory Investigations

> Department, People for the Ethical Treatment of Animals

>

> 4. (Tentative) Lawrence Hansen, MD, Professor, Departments of

> Neurosciences and Pathology, University of California, San Diego

>

>

> -----Original Message-----

> From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]

> Sent: Thursday, June 12, 2014 2:58 PM

> To: Dan Mathews

> Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]

> Subject: Re: meeting

>

> I am putting together list of folks but likely leadership from nichd and nimh. And who will come with you?

>

>

>

> Kathy Hudson, Ph.D.

> Deputy Director for Science, Outreach, and Policy NIH

> 301 496 1455

> kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov<mailto:kathy.hudson@n
> ih.gov%3cmailto:kathy.hudson@nih.gov>>

>

> On Jun 12, 2014, at 1:02 PM, "Dan Mathews"
<DANM@peta.org<mailto:DANM@peta.org<mailto:DANM@peta.org%3cmailto:DANM@peta.org>>>
wrote:

>

> Dear Kathy,

>

> Thanks for your email. I've checked with my colleagues and it appears that Wednesday, July 2, would work for us. Could you please clarify who from NIH will be attending the meeting?

>

> Thank you,

> Dan

>

>

> From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]

> Sent: Wednesday, June 11, 2014 10:02 AM

> To: Dan Mathews

> Cc: Jorgenson, Lyric (NIH/OD) [E]; Schulke, Hilda (NIH/OD) [E]

> Subject: meeting

>

> Dan,

> You asked about the week of June 23 for a possible meeting. That wont work for me but the following week could work. What is your availability that week?

>

> Thanks

> Kathy

Bordine, Roger (NIH/OD) [E]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, June 23, 2014 4:31 PM
To: Jorgenson, Lyric (NIH/OD) [E]
Subject: Video

A confidential 9 min. video representative of the complete footage is viewable here:http://www.petapreview.com/4preview/monkey_experiments_rc.asp

Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy
NIH
301 496 1455
kathy.hudson@nih.gov

Bordine, Roger (NIH/OD) [E]

From: Quinn, Kevin (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 5:27 PM
To: Hudson, Kathy (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [V]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA

I'll coordinate with John Burklow tomorrow on this. I understand the concern and the decision to stick with being responsive vs. proactive and completely agree that any video that we would generate would not change the perception of PETA on this issue.

The only reason to consider generating our own video, if we would choose to do this, would be to reach the American public who are not animal activists but who might be alarmed by seeing the PETA version of how we do research. We have the ability to present our own "9 min" story showing both how NHPs actually spend the majority of their days in Poolesville and secondly, why this work is directly relevant to human studies. There are videos that we might be able to borrow from extramural investigators who have shown side by side the similarities in the behavioral paradigms used in human studies and animal studies, exploring the same research questions currently under consideration. If this is considered worthwhile to pursue, we could pull this together.

Kevin

From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 26, 2014 4:15 PM
To: Quinn, Kevin (NIH/NIMH) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

Thanks. Burklow will work with nichd and nimh comms to reach out to FBR. I do not think video will change reception of peta so I would not make that investment for this purpose. In fact, most folks are unaware that NIH has a bunch of primates and we might just be raising awareness that does not need to be raised....

I think we do responsive, rather than proactive, communications on this but will defer to Burklow.

From: Quinn, Kevin (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 11:31 AM
To: Insel, Thomas (NIH/NIMH) [E]; Hudson, Kathy (NIH/OD) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

I concur with Tom's suggestion – FBR is really effective in messaging about the value of animals in biomedical research. Frankie Trull, the FBR CEO is very adept at this. Within NIH, I recommend that we engage Maggie Snyder from

OER who is our lead on dealing with animal activists and has a lot of experience dealing with these organizations and defending the use of animals in research. I also suspect Pat Brown from OLAW would have a lot to say in developing good talking points on the value of animals in research and NHPs in particular.

I will coordinate development of talking points from my shop with John Burklow (we have plans to follow up) but I'd also suggest that we preemptively shoot some video ourselves that more accurately portrays the daily lives of NHPs in Poolesville. We could send someone from my Communications Branch to do a shoot tomorrow if people thought that might be useful to have in our back pocket.

Kevin

From: Insel, Thomas (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 11:18 AM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Quinn, Kevin (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Re: Meeting with PETA

Thanks for follow up note - sorry to miss this meeting. Concur re plans for July 2nd. Since this is likely a communications battle that is brewing, do you want to reach out to FBR? They are real pros on these issues.
Tom

On Jun 26, 2014, at 3:27 PM, "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov> wrote:

> Thank you all for joining me the other day to discuss the use of non-human primates in research. In line with our discussions, I have decided that it would be best if I meet with the folks from PETA on my own, especially to show that while I am willing to listen, NIH is not debating the scientific merits of this research with this organization.
>
> What would be helpful is if you folks could work with Lyric to generate the 3-4 salient points that articulate why NHPs are so invaluable to research, especially the behavioral research depicted in the video stream we discussed. I would like to concisely and firmly emphasize (and repeat as needed) NIH's position about the value of these animal models and highlight some of the advances they have enabled that have had a critical impact on human and animal health.
>
> Can we guys work with Lyric to pull something together by tomorrow, COB?
>
> Thanks so much,
>
> Kathy

Bordine, Roger (NIH/OD) [E]

From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Friday, June 27, 2014 10:02 AM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Stratakis, Constantine (NIH/NICHD) [E]; Suomi, Stephen (NIH/NICHD) [E]
Subject: Non-human primate research

Kathy –

Steve Suomi reached out to a respected colleague to ask why he sees non-human primate research as important. I thought the reply might be of interest...

Alan

Research on primates is essential because

1) It makes it possible to visualize phenomena that cannot be identified or tracked in human studies
2) It makes it possible to draw firm causal conclusions about the origins of health and disease where human studies leave many doubts and
3) It permits the study of effects of interventions that rid sources of bias that are inevitable in human studies where these biases weaken conclusions about results.

Essential observations. Three features of a well-run behavioral primate laboratory provide a unique vantage for observations. First, the life span of rhesus macaques is a quarter of that of humans but macaques go through the same developmental stages and their genetic similarity to humans, as well as years of observation, suggest remarkable similarities between rhesus developmental process--including the evolution of disease syndromes--between humans and macaques. Additionally, comprehensive observations of the social ecology of these developmental process have highlighted phenomena in macaques before human observations have, but, when applied to humans, produced results of utmost importance. For example, the fate of aggressive males in the wild--after extrusion by matrilineal colonies--anticipated and clarified the fate of aggressive human children and adolescents. Additionally, the clear cut dominance hierarchies in rhesus colonies first clarified the substantial effects of dominance hierarchies on both upper and lower members and, only subsequently, were those effects detected in school settings in human studies. Finally, the temporal detail of observations in primate facilities (daily, hourly, minute-by-minute) cannot be duplicated in human studies and is crtical for determining "on and off" boundaires for for crtical developmental phenomena such as infant imitation and changes in social hierarchies.

Causal conclusions. Proofs of causality in human studies are very hard to come by--sometimes impossible in the most critical situations. For example, child abuse--in human studies--**appears** to be related to subsequent deterioration in health when these children become adults. However, parents who abuse children are genetically quite distinct from those who do not and this apparent effect of their abusive treatment of the child may be due more to the transmission of these genes to children where they may not only produce aggression in the children but directly or indirectly lead to their poor health. In this case billions of dollars devoted to policy or therapeutic interventions would be wasted. Primate research allows newborns to be randomly assigned to different rearing conditions and, where health consequences follow from these assignments, the causal connections between early rearing conditions and later health can be proved. Because of the already-demonstrated similarity in developmental processes between macaques and humans these animal result buttress--in essential ways--the

human correlational findings and make it much more certain that investments in developing and applying corrective policy and therapeutic techniques will have a high yield.

Interventions. The problems in evaluating the effects of behavioral--and even medical--interventions in human studies are not widely appreciated and it important to give these enormous emphasis in underscoring the importance of primate research. First, intervention studies can only be carried out on volunteers and there are reams of data suggesting a profound bias in such studies as volunteers differ from non-volunteers on many measures critical to the outcome of most interventions. Second, interventions are heavily sensitive to contextual effects that are beyond the control of human investigators. For examples, antidepressants are relatively ineffective (or absolutely ineffective in some studies) where there is serous marital conflict. Further, without enormous expense, interventions must be relatively brief, and followups of even a year are very difficult to achieve. In addition, interventions can have unanticipated and at time disastrous unintended consequences that are better recognized first in animal models. Whereas rodents help screen such effects in simple pharmaceutical interventions they are relatively useless for more sophisticated behavioral interventions. Finally, the evaluation of interventions are subject to network effects. Any intervention conducted in a community where there is some spatial or relational contiguity (such has hospitals, towns, occupational settings (etc) may operate by the contagion of the therapeutic results achieved with one or two key individuals to others in the community, confounding all statistical analyses of efficacy. The intervenetion would be useless in a community without this contiguity. Primate colonies--specifically designed for intervention studies--can definitively deal with all these threats to the validity of human intervention studied.

A final word on PETA and the stance of NIH. The name PETA stands for the ethical treatment of animals and there is no mature way to combat the manifest concerns of this group, or others like it, that we can conduct with full integrity. If a group focuses exclusively on the ethical treatment of animals they, understandably, can determine the range, intensity and applicability of the ethical standard they develop; they can use all legal means possible to defend them. Within this frame they are unlikely to be convinced by four talking points or fourteen or forty four. NIH cannot get itself in a position of disputing those ethical commitments or trying to persuade these advocates of the importance of the research. The position of NIH must be entirely of a different frame (and one I have used above). WE at NIH are ethically committed to the health of human fetuses, infants, children, adolescents, adults and the aging. Where this health can be promoted by research based on the altruism and informed consent of human subjects we choose those methods because we are equally committed to support adult humans in their ethical commitment to advance health research. Where we **absolutely cannot advance a research project with high potential to assure human health with the use of human volunteers we must turn then to animals to rigorously evaluate their potential in solving riddles that would otherwise remain.** This carries with it a secondary commitment to provide the most favorable circumstances for the maintenance of animals and animal facilities and to minimize the risks and discomfort to animal subjects. The execution of this commitment is already rigorously reviewed for every animal study. However when it comes to the balance between assuming human health versus causing pain or discomfort to animals--including primates where only primates will suffice--our own ethical commitment is to humans. If NIH leadership is not crystal clear on this point we are all in trouble. We cannot draw lines on the level of sentience or the amount of discomfort in our research animals. *Our ethics* draw a firm boundary around the health of humans from conception to death. The fundamental question, within this ethical frame, becomes: **is this animal study indispensable for assuring human health?**

I see NIH leadership, not PETA, as the main target here. They need to understand the science of human development clearly and have a firm grasp of why the work at LCE provides the **only** avenue to assure critical advances in the application of this research to human health. I cannot imagine anything more important than to assure that Francis Collins sees this with a clarity that rivals his grasp of the structure and function of the human genome.

Bordine, Roger (NIH/OD) [E]

From: Raber, James (NIH/NEI) [E]
Sent: Friday, June 27, 2014 11:20 AM
To: Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Nelson, Eric (NIH/NIMH) [V]; Quinn, Kevin (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA
Attachments: Proposed Talking Points 6-27-2014.docx

Per request. Please let me know if you have any questions.

Jim

James M. Raber, DVM, PhD
Animal Program Director, NEI & NIMH

From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 26, 2014 10:27 AM
To: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Quinn, Kevin (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA

Thank you all for joining me the other day to discuss the use of non-human primates in research. In line with our discussions, I have decided that it would be best if I meet with the folks from PETA on my own, especially to show that while I am willing to listen, NIH is not debating the scientific merits of this research with this organization.

What would be helpful is if you folks could work with Lyric to generate the 3-4 salient points that articulate why NHPs are so invaluable to research, especially the behavioral research depicted in the video stream we discussed. I would like to concisely and firmly emphasize (and repeat as needed) NIH's position about the value of these animal models and highlight some of the advances they have enabled that have had a critical impact on human and animal health.

Can we guys work with Lyric to pull something together by tomorrow, COB?

Thanks so much,

Kathy

1. Animal Housing, Care, and Testing:
    a. Conducted in compliance with the Animal Welfare Act, Public Health Service Policy, and *The Guide for the Care and Use of Laboratory Animals (2011)*
    b. Program Accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC)
    c. All husbandry and research procedures were reviewed and approved by the Institutional Animal Care and Use Committee
    d. All housing, care, and testing conducted and/or overseen by trained, experienced investigators, animal care staff, and veterinarians
    e. Testing procedures produced a range of animal responses, mirroring human traits and attributes, ranging from no response to momentary and transient anxiety
    f. Each animal's well-being was closely monitored during and after testing by experienced and train animal care staff and veterinarians
    g. The procedures under questions resulted in no harm to any of the animals tested

2. Importance of non-human primate research to human/animal health and development:

    a. Non-human primate research has contributed to Nobel-prize-winning research: development of yellow fever vaccine (1951); culturing of poliovirus that ultimately led to a polio vaccine (1954); and in neuroscience the significant discoveries in visual processing in the brain (1981).
    b. Recovery from Stroke: Non-human primates are helping scientists study rehabilitation of stroke patients. Specifically, scientists are investigating whether other neurons can be trained to take over functions of the cells that died. Researchers studying monkeys found that by restricting the monkey's use of its stronger arm, the animal will use its weaker arm. Increased use pushes surviving nerve cells to take on new functions. Follow-up studies in human stroke patients have confirmed the value of this approach.
    c. Post-Traumatic Stress Disorder: Animal research including rodents and primates has led to a deeper understanding of PTSD, enabling scientists to develop therapeutics that lessen the number or intensity of a person's flashbacks.
    d. Parkinson's disease: Once scientists understood the role of cell death in the basal ganglia in Parkinson's, they were able to replicate the disease in monkeys. After giving monkeys drugs (MPTP) that cause cells in the basal ganglia to die, scientists found that other regions of the brain – the subthalamic nucleus and globus pallidus – became overactive in response to lowered signals from dopamine. Scientists realized that by stimulating these areas of the brain they could quiet the overactivity and relieve symptoms of Parkinson's disease. As a result Deep Brain Stimulation was developed to counteract the overactivity. Deep Brain Stimulation involves the implantation of a brain pacemaker, which sends electrical impulses to specific parts of the brain. This procedure was approved for Parkinson's disease in 2002. It has the benefit of being reversible and adjustable to the needs of the patient.
    e. Deep brain stimulation studies in monkeys are now also being applied to the treatment of obsessive-compulsive disorder and depression.
    f. Brain-Machine Interfaces for controlling prostheses. Signals from electrodes in the brain can now be used control prosthetic limbs. A paraplegic patient of Dr. M. Nicolelis stood and kicked a soccer ball with prosthetic limbs at the opening ceremony of the 2014 World Cup.
    g. Prefrontal cortical function (PFC): Many cognitive disorders involve impairments of the PFC. A series of studies on the anatomy, physiology and function of the PFC in laboratory

animals, including monkeys, have led to the identification of therapeutic treatments to treat cognitive disorders. Guanfacine, a noradrenergic α2A agonist is now being used to treat a variety of PFC cognitive disorders, including Tourette's Syndrome and Attention Deficit Hyperactivity Disorder (ADHD).

h. Application of neural interfaces: The interface is a system operating at the intersection of the nervous system and an internal or external device. Neural interfaces (electrode arrays implanted in the motor cortex) include neural prosthetics, which are artificial extensions to the body that restore or supplement function of the nervous system lost during disease or injury, and implantable neural stimulators that provide therapy have been studies and developed in laboratory animals, including monkeys. Neural interfaces are used to allow disabled individuals the ability to control their own bodies and lead fuller and more productive lives.

i. Additional non-human primate research successes:

Early 1900s

Components of blood and plasma discovered. Treatment of pellagra.

1920s

Ability to diagnose and treat typhoid fever.

1930s

Modern anesthesia and neuromuscular blocking agents. Mumps virus discovered.

1940s

Treatment of rheumatoid arthritis. Discovery of the Rh factor, blood-typing knowledge critical for safe blood transfusions.

1950s

Development of polio vaccine. Chlorpromazine and its tranquilizing derivatives. Cancer chemotherapy. Development of yellow fever vaccine.

1960s

Mapping of the heart's connections to arteries. Development of German measles vaccine. Therapeutic use of cortisone. Corneal transplants.

1970s

Treatment of leprosy. Procedures to restore blood supply in the brain. Interaction between tumor viruses and genetic material. Understanding of slow viruses, which linger in the nervous system.

1980s

Development of cyclosporine and anti-rejection drugs. Processing of visual information by the brain. Identification of psychophysiological co-factors in depression, anxiety, and phobias. Treatment of malnutrition caused by food aversion following chemotherapy. Treatment of congenital cataracts and "lazy eye" in children. First animal model for research on Parkinson's Disease, enabling doctors to more accurately research human Parkinson's Disease. Heart and lung transplant to treat cardiopulmonary hypertension. First Hepatitis B vaccine. Rhesus monkey model for AIDS used to establish the effectiveness of early administration of AZT in cases of diagnosed infection. Addition of taurine to infant formulas. An amino acid in breast milk, taurine is necessary for normal retinal development.

1990s

Estrogen discovered to control an enzyme key to making serotonin, the brain chemical that regulates mood. Represents first step to providing effective medications for depression at the end of the menstrual cycle, and postpartum and postmenopausal depression. Lead toxicity studies help U.S. fight childhood lead exposure. Ongoing development of a one-dose transplant drug to prevent organ rejection. First controlled study to reveal that even moderate levels of alcohol are dangerous in pregnancy. Breakthroughs in understanding the mechanisms of puberty and disorders of puberty. Primate embryonic stem cells studied extensively for the first time, advancing efforts to better understand reproduction and genetic disorders. Control of intimal hyperplasia. Parent to child lung transplants for cystic fibrosis. Monkey model developed for curing diabetes. Naturally regenerative mechanism discovered in the mature primate brain, spurring new research toward curing Alzheimer's, other degenerative brain disorders. Wild primate species help characterize emerging infectious diseases. Rhesus and cynomolgus monkey kidneys developed for use in diagnosing influenza. Development of anthrax vaccine.

2000s

Gene that boosts dopamine production and strengthens brain cells used to successfully treat monkeys showing symptoms of Parkinson's Disease, a neurodegenerative disorder. Monkey model developed to study the effects of malaria in pregnant women and their offspring. Cyclospora, a food-borne pathogen, is characterized in primates. Dietary restriction without malnutrition provides major health benefits and may extend maximum lifespan. Rhesus monkeys are now prime model for development of human immunodeficiency virus (HIV) treatments and potential vaccines. There are 14 licensed anti-viral drugs for treatment of HIV infection alone. Human embryonic stem cell work based on research in monkeys makes dramatic advances.

Acquired Immune Deficiency Syndrome (AIDS)

Researchers depend heavily on monkeys for the development of promising strategies to protect people from this disease. Vaccines containing various strains of a simian immunodeficiency virus (SIV), a closely related virus that follows a disease course similar to HIV, or a hybrid human/simian immunodeficiency virus (SHIV) are being tested in macaque monkeys, and several research groups have successfully vaccinated monkeys with viral preparations that reduce viral load and halt disease progression. If these results can be generalized to humans, the vaccines may be used to treat HIV-infected humans. Due to primate studies, significant strides have been made, especially in maternal transmission of HIV/AIDS to fetuses and infants.

Hepatitis B and C

Research with chimpanzees has virtually eradicated Hepatitis B and C infections acquired through blood transfusions. Commercially available Hepatitis B vaccines have prevented the development of cirrhosis and liver cancer in millions of people. Because no vaccine for hepatitis C infections is yet available, scientists continue to study the pathogenesis of this disease in chimpanzees to gain a better understanding of the infection process.

Malaria

Researchers are beginning to overcome some of the enormous obstacles in developing a vaccine against malaria, a disease that affects millions of people annually. New World monkeys and chimpanzees are the only species suitable for vaccine evaluation because they are susceptible to the same strains of the parasites that cause human malaria. A number of promising vaccines are being tested and have successfully stimulated protective responses in animals and may soon be ready for human trials.

Acute Respiratory Disease

Respiratory syncytial virus (RSV) can cause life-threatening respiratory infections in infants, young children, and the elderly. Since there is no effective therapy, a vaccine is a high medical priority in the U.S. Vaccines are being

tested for their ability to protect chimpanzees, the animal that is naturally infected by RSV and develops an illness with symptoms similar to those seen in humans.

Periodontal Disease

This infection of the tissue supporting the teeth is the most common cause of bone and tooth loss in humans and may be an important risk factor for cardiovascular disease. It is also a health problem for captive primates, making these species excellent models for studying the connection between chronic oral infections and systemic disease. Several groups of researchers have shown that immunizing

monkeys with a vaccine containing a killed oral bacterium can stop the progress of infection and suppress bone loss.

Aging and Nutrition

Scientists are currently studying the effects of long-term calorie restriction (CR) on the biology of aging in macaque monkeys. They have learned that a reduction in calories over a period of several years lowers body temperature, slows metabolism, lessens the risk of cardiovascular disease, and reduces predisposition toward diabetes. Long-term studies of CR have increased the life span of monkeys.

Brain Biology

Because nonhuman primates share many of the same features of brain biology and structure with humans, they are extremely valuable models for studying normal brain function and brain-related diseases, including mental, neurological, and addictive disorders.

Alzheimer's Disease

The decline of memory and other mental functions in patients with Alzheimer's Disease is associated with the loss of or damage to cholinergic nerve cells that use the chemical acetylcholine to transmit messages to other cells in the brain. Scientists have shown that grafting genetically modified cells to produce nerve growth factors directly into the brains of macaque monkeys is a safe procedure that enhances the survival and function of the cholinergic nerve sells. Such studies are now being extended to humans in an attempt to slow the loss of memory in patients with this disease.

Parkinson's Disease

Parkinson's Disease is a slow progressive disease generally found in the aged. Recently, scientists have found a new method to deliver the gene that produces GLNF (a factor that protects brain cells) directly in the brains of monkeys. The treatments successfully prevented the progression and reversed the symptoms

Yes, they have been very involved and monitor all USDA reports. In fact USDA and OLAW collaborate regularly and often site visit together (except government facilities which ironically don't fall under USDA law).

The care and use of animals comes into play many places, including in peer review of the original application and during the progress of the research, for example if there is an issue pointed out in the RPPR (progress report). Program officers generally do not do systematically monitoring although they are to have their ears to the rails, sort of speak, with many different type of programmatic issues that may raise compliance concerns (FCOI, HS, Animal). However the grantee institution **must** self report non compliance with the PHS policy, and this is where the vast majority of cases arise. This is required by PHS policy and USDA law and there are hundreds of self reports, most minor but some more serious. In addition, other cases are brought about from many sources, IACUCS, the public, advocacy groups, and by PIs and others at grantee institutions. OLAW has the primary responsibility and does site visits on a fairly regular basis but can only hit a few of the institutions each year for their proactive site visits because of the magnitude of organizations that have animal programs. Also they are responsible when there are findings by OLAW or the USDA to bring the programs back into compliance.

Also between IACUCs and ALAC (and there are many lab animal professional organizations) there is a very strong community that deals with these issues.

Sally J. Rockey, Ph.D.
NIH Deputy Director for Extramural Research
OD/NIH/DHHS
One Center Drive
Building 1, Room 144
Bethesda, MD 20892
301-496-1096
301-402-3469 Fax
rockeysa@od.nih.gov

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, June 30, 2014 4:32 PM
To: Rockey, Sally (NIH/OD) [E]
Cc: Anderson, James (NIH/OD) [E]
Subject: FW: Texas Biomedical Research Institute

I assume your OLAW folks monitor USDA inspections but wanted to share just in case.

Also, Sally, what obligations do our program folks have to be aware of and monitoring care and use for animals involved in nih supported research?

From: Tracie Letterman [mailto:tletterman@humanesociety.org]
Sent: Monday, June 30, 2014 3:26 PM
To: Hudson, Kathy (NIH/OD) [E]; Anderson, James (NIH/OD) [E]
Subject: Texas Biomedical Research Institute

Dear Kathy and Jim,

I hope your summer is going well. I wanted to follow up with you regarding the complaint we filed with USDA regarding Texas Biomedical Research Institute. The USDA posted an inspection report today, which I have attached. As you will see, the findings reinforce what we found at the facility-failure to properly monitor social groups, resulting in injuries,

and failure to provide medical treatment of wounds, which led to the death of a baboon. Additionally, the facility isn't properly reporting when animals are involved in research that causes unrelieved pain and distress. We were told by USDA today that there is also a case pending with Investigative and Enforcement Services.

The conditions at Texas Biomed raise serious concerns for us and getting the government-owned chimpanzees out of that facility is a top priority for us, as was reflected in the sanctuary plan. I know an assessment of those animals is underway, but I do hope these findings will reinforce the need to retire those animals as soon as possible into existing space at Chimp Haven.

Thank you so much, in advance, for considering this additional information.

Best,
Tracie

Tracie Letterman
Director of Regulatory Affairs, Federal Affairs
tletterman@humanesociety.org
t 202.676.2303 c 301.275.1901

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Report to Office of Extramural Research Acting Director on Office of Laboratory Animal Welfare (OLAW) Site Visits to Chimpanzee Facilities – July 2010

INTRODUCTION

This report summarizes the results of a series of site visits to institutions that receive funds from the National Institutes of Health (NIH) for research and maintenance of chimpanzees. The objectives of the visits were to determine whether these institutions' programs and facilities for the care and use of chimpanzees were consistent with their Animal Welfare Assurance (Assurance) with OLAW and to evaluate the current state of social housing, husbandry, enrichment, veterinary care, and training practices for chimpanzees.

BACKGROUND

As a condition of receipt of Public Health Service support for research involving laboratory animals, institutions must provide a written Assurance to OLAW describing the means they will employ to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). OLAW negotiates and approves these Assurances on behalf of the Director, NIH. Each Assurance is a detailed document tailored to the individual institution's needs, research practices, and procedures. It must be consistent with the PHS Policy. An Assurance approved by OLAW commits the institution and its personnel to full compliance with the PHS Policy, the applicable regulations (9 CFR, Subchapter A) issued by the United States Department of Agriculture under the Animal Welfare Act, and the *Guide for the Care and Use of Laboratory Animals (Guide)*. Through the partnership established by the Assurance, the shared responsibility for the welfare of laboratory animals is discharged in accordance with Section 495 of the Public Health Service Act.

In March 2009, OLAW received from the Office of the Secretary of the Department of Health and Human Services a list of allegations made by the Humane Society of the United States (HSUS) of potential noncompliance with the PHS Policy and the *Guide* at the University of Louisiana – Lafayette, New Iberia Research Center (NIRC). The allegations were accompanied by undercover video footage obtained by a HSUS informant who had worked at the facility for nine months. The same allegations were presented to the Secretary of Agriculture who directed Animal Care (AC) of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA) to conduct inspections of registered research facilities housing chimpanzees and assess current housing, husbandry, and handling practices. In order to investigate the allegations made against NIRC and to conduct a cross sectional evaluation of all Assured institutions housing chimpanzees, OLAW began a year long series of site visits, many of them conducted in conjunction with the USDA inspections.

The following institutions were visited:

University of Louisiana – Lafayette, NIRC (Louisiana)
Bioqual, Inc. (Maryland)

University of Texas, MD Anderson Cancer Center (Texas)
Southwest Foundation for Biomedical Research (Texas)
Emory University/Yerkes National Primate Research Center (Georgia)
Georgia State University (Georgia)
Chimp Haven (Louisiana)
Great Ape Trust of Iowa (Iowa)
NIH/Alamogordo Primate Facility (New Mexico)

FINDINGS

Overall, the institutions housing chimpanzees were found to be in compliance with PHS Policy.

Social Housing and Enrichment of Chimpanzees

The chimpanzees were, with rare exception, socially housed. They had complex and stimulating environments, were provided with environmental enrichment in the form of manipulanda and food treats, and had positive interactions with the staff. In cases where an animal was singly housed due to study requirements or incompatibility with other animals, efforts were made to provide enrichment and return the animal to a partner as soon as feasible.

Training of Chimpanzees

Many institutions had successfully trained the chimpanzees to cooperate with requests from handlers such as moving between enclosures and allowing ready access for procedures such as obtaining body temperatures, blood, or other biological samples. In cases where animals were not trained or cooperating, institutions utilized a variety of handling methods for the conduct of procedures or administered anesthetics or tranquilizers including use of dart guns.

Husbandry and Veterinary Care of Chimpanzees

Without exception, the quality of care being provided was uniformly high and supported by dedicated and knowledgeable animal care teams with integrated animal behavior and enrichment professionals. The veterinary care included state of the art resources rivaling major human medical centers.

Social Housing of Other Nonhuman Primates

Many of the facilities visited also housed other nonhuman primates such as macaques and squirrel monkeys. Regarding these species, the numbers of animals being socially housed varied among facilities. In some institutions the majority of primates were housed with conspecifics whereas in others most animals were singly housed. Reasons given for single housing included lack of appropriate caging or study requirements limiting pair or group housing.

CONCLUSIONS AND RECOMMENDATIONS

Overall the institutions were found to be in compliance with the PHS Policy and the quality of care and commitment to the psychological well-being of the chimpanzees and other nonhuman primates was high. The following issues were identified as requiring further enhancement:

- In situations where it is safe and feasible, chimpanzees and other nonhuman primates should be given positive reinforcement training to perform desired cooperative activities. This type of training may also aid in reducing stress from capture and restraint and the need for chemical darts.
- Housing of primates in social settings (pairs or groups) is the requirement of the USDA regulations and single housing is the exception. Greater effort must be made to co-house animals. Exemptions to the social housing requirement must be based on strong scientific justification approved by the Institutional Animal Care and Use Committee or for a specific veterinary or behavioral reason. Lack of appropriate caging does not constitute an acceptable justification for exemption.

In order to assist these facilities and the larger community in enhancing the care and well-being of nonhuman primates in the research setting, the following actions have been planned and are being implemented:

1. OLAW in consultation with USDA Animal Welfare Information Center (AWIC) will provide online resources addressing positive reinforcement training practices for nonhuman primates.

2. OLAW and USDA Animal Care have addressed or will address the social housing issue in various forums. These include:
   - a joint workshop at the Public Responsibility in Medicine and Research (PRIMR) meeting in March 2010;
   - a training presentation with the added assistance of USDA AWIC to the USDA Veterinary Medical Officers in April 2010;
   - a joint webinar by OLAW, USDA Animal Care and AWIC recorded and available on the OLAW website in summer 2010;
   - expanded guidance on the OLAW website as Frequently Asked Questions; and
   - presentation of the issue at other professional meetings.

Through the educational efforts outlined above and proactive engagement by research institutions, nonhuman primates should be afforded enhanced social housing opportunities and positive reinforcement training resulting in improved animal welfare.

Bordine, Roger (NIH/OD) [E]

From: Katherine Roe <katheriner@peta.org>
Sent: Tuesday, July 08, 2014 12:36 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: Follow-up from PETA

Great. Thanks again.

From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]
Sent: Tuesday, July 08, 2014 12:33 PM
To: Katherine Roe
Subject: RE: Follow-up from PETA

yes

From: Katherine Roe [mailto:katheriner@peta.org]
Sent: Tuesday, July 08, 2014 12:30 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: FW: Follow-up from PETA

Hi Dr. Hudson,

I hope you had a great fourth of July weekend. I just wanted to make sure you got our follow-up materials re our meeting last week.

Thanks again for your time,

Katherine

From: Katherine Roe
Sent: Thursday, July 03, 2014 12:00 PM
To: 'kathy.hudson@nih.gov'
Subject: Follow-up from PETA

July 3, 2014

Dr. Kathy Hudson
Deputy Director for Science, Outreach, and Policy
Building 1, Room 109
1 Center Drive
Bethesda, MD 20892

Dear Kathy,

Thank you for meeting with us to discuss concerns about NIH's maternal deprivation and depression experiments on monkeys.

As promised, I have attached a critical review of these studies prepared in consultation with subject matter experts. You'll see that the document elaborates on the points we spoke about on Tuesday, with extensive evidence of the inapplicability of these studies to human health, the availability of existing data and superior human-based research methodologies, and the problematic lack of oversight of these studies which cause suffering and harm to primates.

Having conducted research with human subjects at NIMH, I have always lauded the Intramural Research Program as one that dedicates itself to using the most innovative and humane methodology available in the interest of science and human health. So, as you might imagine, learning about the existence and details of these projects came as quite a surprise to me, as I hope it did for you, and I have no doubt it will to others inside and outside the research community.

As we brought up Tuesday, the NIH's own analysis of experiments on chimpanzees confirmed that it is possible for practices that are cruel and scientifically unnecessary to be reviewed, approved, funded and conducted within the NIH's intramural program for a long time without question. At the same time, the NIH's decision to suspend, review and ultimately end experiments on chimpanzees demonstrates how additional, objective scrutiny of a deeply-embedded practice can serve to benefit the agency, animals, researchers and taxpayers and acknowledge evolving public opinion. **We believe that the same process can and should be applied here, and we hope to hear from you soon about plans to end these experiments.**

Also, in light of the NIH's forthcoming review of intramural projects that you mentioned are to occur due to budget cuts, we urge that close attention be paid to all experiments on animals that involve pain and distress, particularly those in what NIH refers to as "USDA Column E," where suffering is unmitigated. I think you will find that the mother/infant deprivation experiments we discussed are wrongly categorized as Column C, and belong in Column E because of the intentional, prolonged and unrelieved distress caused during experimental trials and the studies overall. As you know, other countries have put in place more stringent regulations governing the use of animals in experiments that cause considerable, unrelieved suffering to animals (known here as "USDA Column E").

I hope we will hear from you regarding the status of your inquiry into the maternal deprivation and depression experiments on monkeys that we discussed before you leave for your bike trip next month.

Please contact me with any questions.

Sincerely,

Katherine Roe, Ph.D.
Research Associate
Laboratory Investigations Department
KatherineR@peta.org
240-355-6656

Bordine, Roger (NIH/OD) [E]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, July 21, 2014 10:08 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Jorgenson, Lyric (NIH/OD) [E]
Subject: talking with Jane
Attachments: PETA review of NIH primate experiments July 2014.pdf

This work?

1. Meeting with PETA
    a. Kathy Hudson and John Burklow met with this group as a non-experts in the field to listen to what they had to say.
    b. Representatives present: Dan Matthews (Senior VP), Alka Chandna (Lab Oversight Specialist), Katherine Roe(Research Associate in Lab Investigations Dept)
    c. Representatives expressed concerns about NIH's maternal deprivation and depression experiments on monkeys
    d. Provided research (attached) suggesting the inapplicability of these studies to human health, the availability of existing data and superior human-based research methodologies, and the problematic lack of oversight of these studies which cause suffering and harm to primates

2. NIH's position regarding research under question
    a. Nearly all of the footage in the PETA clip was from experiments undertaken by a research team that no longer exists. The investigator died and the research team disassociated.
    b. These studies conducted within the NIMH Non-Human Primate Core examined the effect of disrupting the mother-infant bond on the development of emotional and social competence
        i. The necessary controls needed to examine early stress requires the use of animal studies to carefully separate experience, genetic, and other environmental factors
        ii. Understanding the biological consequences of this disruption and factors gives scientists a more precise window for identifying risk factors for mental disorders and provides an avenue for the development of effective therapies to treat mental disorders in children
        iii. Testing procedures produced a range of animal responses, mirroring human traits and attributes, ranging from no response to momentary and transient anxiety
        iv. NIH team review of the video suggests that the most extreme responses were selected by PETA
        v. Each animal's well-being was closely monitored during and after testing by experienced and train animal care staff and veterinarians

3. Next Steps
    a. It would be inappropriate for me to take any personnel or other action against an investigator based solely on the fact that the research was questioned by PETA. That would be greeted with alarm by the research community and would invite further questioning by PETA.
    b. I do want to look further at the full range of non human primate research but in an objective way that is not perceived as a reaction to PETA. I am sure you appreciate the importance of that approach.
    c. I believe there is a whole set of invaluable NHP research but also perhaps some that has less value, particularly in light of budget constraints.

d. NIH will continue to value non-human primates in research and will continue to ensure that the research undertaken:
    i. Is held to the highest standards
    ii. Improves human health
    iii. Will continue to make efforts to minimize use and distress and are currently undertaking a review of intramural research projects and will evaluate the number and use of non-human primates

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: July 21, 2014 at 8:11:47 AM EDT
To: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>
Subject: talking with Jane

I have a phone call with Jane Goodall at noon today (I'll be in the car on the way downtown). This is the first interaction with her since the PETA pow-wow. Care to suggest the major points I should cover?

FC

Bordine, Roger (NIH/OD) [E]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, July 21, 2014 11:27 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Jorgenson, Lyric (NIH/OD) [E]
Subject: talking with Jane

The research done on monkeys separated from moms was done by NIMH researchers beginning in 2004 or 2005. The PI was Jim Winslow. The staff scientist was Dennis Charney. The PI (winslow) died 4 years ago and the lab was closed.

The startle test, the "novel cage" test and the human intruder were all winslows. The moving the head one and maybe one other are Suomi.

The novel cage video involves putting knocked out mom with baby in a novel cage (with tons of play things) to look at exploration and comfort of babies. Most babies ran and played and "checked" in that mom was still napping from time to time. Freaked out baby was rarity we are told.

I would not get into a big discussion about the science since it is just really hard to get exactly the right story.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, July 21, 2014 10:53 AM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: talking with Jane

Very helpful. What year was the research done that was captured in the PETA videos? The investigator was not Suomi, right?

FC

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, July 21, 2014 10:08 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Jorgenson, Lyric (NIH/OD) [E]
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        i. Is held to the highest standards
        ii. Improves human health
        iii. Will continue to make efforts to minimize use and distress and are currently undertaking a review of intramural research projects and will evaluate the number and use of non-human primates

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: July 21, 2014 at 8:11:47 AM EDT
To: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>
Subject: talking with Jane

I have a phone call with Jane Goodall at noon today (I'll be in the car on the way downtown). This is the first interaction with her since the PETA pow-wow. Care to suggest the major points I should cover?

FC

Bordine, Roger (NIH/OD) [E]

From: Nelson, Eric (NIH/NIMH) [E]
Sent: Monday, July 21, 2014 11:55 AM
To: Stratakis, Constantine (NIH/NICHD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Suomi, Stephen (NIH/NICHD) [E]; NICHDsd; Pine, Daniel (NIH/NIMH) [E]
Subject: Meeting with PETA

The studies that involved testing with the mother and with startle were conducted by the nonhuman primate core facility of NIMH. Dr. James Winslow (now deceased) was the PI. This core facility has now been terminated due to Dr. Winslow's death and budget restrictions. Other significant personnel included Dr. Eric Nelson and Dr. Daniel Pine (section on developmental affective neuroscience – NIMH), Dr. Steve Suomi (NICHD), Dr. Nathan Fox (University of Maryland) and the NHP core staff.

From: Stratakis, Constantine (NIH/NICHD) [E]
Sent: Monday, July 21, 2014 11:22 AM
To: Jorgenson, Lyric (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Nelson, Eric (NIH/NIMH) [E]; NICHDsd
Subject: RE: Meeting with PETA

Dr. Suomi should be able to answer this: PI/protocol per minutes of the video...

Constantine A. Stratakis, MD, DMSci
NICHD, NIH

From: Jorgenson, Lyric (NIH/OD) [E]
Sent: Monday, July 21, 2014 11:12 AM
To: Guttmacher, Alan (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Nelson, Eric (NIH/NIMH) [E]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: RE: Meeting with PETA

Dear All,

I have one more question about the video stream with NHPs that we discussed roughly a month ago – could you tell me the researcher team(s) involved and in what year it was conducted? I don't think I recorded this in my notes from our conversation.

Thanks.

From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 26, 2014 10:27 AM
To: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Raber, James (NIH/NEI) [E]; Quinn, Kevin (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA

Thank you all for joining me the other day to discuss the use of non-human primates in research. In line with our discussions, I have decided that it would be best if I meet with the folks from PETA on my own, especially to show that while I am willing to listen, NIH is not debating the scientific merits of this research with this organization.

What would be helpful is if you folks could work with Lyric to generate the 3-4 salient points that articulate why NHPs are so invaluable to research, especially the behavioral research depicted in the video stream we discussed. I would like to concisely and firmly emphasize (and repeat as needed) NIH's position about the value of these animal models and highlight some of the advances they have enabled that have had a critical impact on human and animal health.

Can we guys work with Lyric to pull something together by tomorrow, COB?

Thanks so much,

Kathy

Bordine, Roger (NIH/OD) [E]

From: Suomi, Stephen (NIH/NICHD) [E]
Sent: Monday, July 21, 2014 12:34 PM
To: Jorgenson, Lyric (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Nelson, Eric (NIH/NIMH) [V]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: Meeting with PETA

Lyric (et al.),

The first 90 seconds or so of the video stream focused on one infant (out of a total of 16) being run on one 3-minute segment of a battery of neonatal tests (adopted from a pediatric behavioral protocol routinely used for human infants) that was repeated a total of 7 times for each infant over the first month of life, i.e., 90 seconds, edited down from over 65 hours of available video.
The research was carried out in 2011 (and subsequently published), it was part of a PhD dissertation (Eliza Nelson, now a faculty member of Florida Atlantic University) that was an addendum to the ongoing long-term NICHD project, and it was only performed once; it was NOT included in the renewal of the currently active protocol.

Dr. Eric Nelson can provide the details of the remaining 7 1/2 minutes of the video stream, which were taken from a now-terminated NIMH protocol.

Hope this helps.

Steve

From: Jorgenson, Lyric (NIH/OD) [E]
Sent: Monday, July 21, 2014 11:12 AM
To: Guttmacher, Alan (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Nelson, Eric (NIH/NIMH) [E]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: RE: Meeting with PETA

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Sent: Thursday, June 26, 2014 10:27 AM
To: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Raber, James (NIH/NEI) [E]; Quinn, Kevin (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA

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Can we guys work with Lyric to pull something together by tomorrow, COB?

Thanks so much,

Kathy

Bordine, Roger (NIH/OD) [E]

From: Francis Collins (b) (6)
Sent: Monday, July 21, 2014 5:56 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: Follow-up after NIH meeting

Yep, please send a note, I will remain silent.

On Mon, Jul 21, 2014 at 5:43 PM, Hudson, Kathy (NIH/OD) [E] <Kathy.Hudson@nih.gov> wrote:
You don't respond.

If you want, I can send a note saying thanks for the meeting and materials. Then we go dark. There is no benefit to continued discussion unless u want to start ww3.

We don't negotiate. We listened. That is all

Kathy Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy
NIH
301 496 1455
kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>

On Jul 21, 2014, at 5:10 PM, "Francis Collins"
(b) (6) >> wrote:

My call with Jane Goodall didn't go through -- hard to make contact in (b) (6) We are trying for another date.

Meanwhile, here comes Dan again. How do you suggest I respond, if at all?

FC

---------- Forwarded message ----------
From: Dan Mathews <DANM@peta.org<mailto:DANM@peta.org>>
Date: Mon, Jul 21, 2014 at 5:09 PM
Subject: RE: Follow-up after NIH meeting
To: Francis Collin (b) (6) >>
Cc: Jane Goodall <

Hi Francis,
I wanted to follow-up on my email of 3 weeks ago to learn of any progress since our meeting at NIH about the maternal deprivation experiments on monkeys in Poolesville. We are anxious to move forward but haven't heard a peep. Please advise ASAP, and thanks.
Dan
From: Dan Mathews
Sent: Thursday, July 03, 2014 3:00 PM

To: 'Francis Collins'; 'Jane Goodall'

Subject: Follow-up after NIH meeting
Importance: High

Greetings Francis and Jane,
On Tuesday, a pair of PETA's scientific advisors and I met with NIH's Dr. Kathy Hudson about the decades-old maternal deprivation monkey experiments that continue in Poolesville. It was a very friendly exchange; thanks to both of you for setting it up.
We presented documents from experts and publications showing that the scientific objectives of these monkey experiments are better achieved using human-based research methods. Kathy asked good questions and seemed to recognize systemic problems in oversight and the general benefits of research modernization. NIH's Dr. Lyric Jorgensen, who we expected to attend, was a no-show. Dr. Hudson mentioned a general, forthcoming review of all intramural projects because of reduced funding, but made no suggestion that the project we are concerned about would get any special attention now or later. We were happy to be heard, but disappointed that it wasn't more of a 2-way conversation and that nothing was brought to the table.
Today, the neuroscientist who led the discussion (she worked at NIH for years before coming to PETA) sent the follow-up letter below with the attached overview that elaborates on the concerns we brought up in person. Francis, we'd very much appreciate you taking a look and making sure that it gets circulated and prompts more critical thought and discussion.
In a nutshell, our formal request to the NIH is twofold:
1) end the maternal deprivation and depression experiments in question
2) during upcoming budgetary reviews, seriously consider cutting those animal experiments classified as "column E" (those involving the most excruciating pain and distress); this would fall in line with policies enacted in Switzerland and the Netherlands, and would create an enormous amount of goodwill with the public
Thanks again! Please let me know your thoughts on this; we're keen to resolve the Poolesville monkey matter as soon as possible.
Dan Mathews
Senior VP, PETA

From: Katherine Roe
Sent: Thursday, July 03, 2014 12:00 PM
To: 'kathy.hudson@nih.gov<mailto:kathy.hudson@nih.gov>'
Subject: Follow-up from PETA

July 3, 2014

Dr. Kathy Hudson
Deputy Director for Science, Outreach, and Policy
Building 1, Room 109
1 Center Drive
Bethesda, MD 20892

Dear Kathy,

Thank you for meeting with us to discuss concerns about NIH's maternal deprivation and depression experiments on monkeys.

As promised, I have attached a critical review of these studies prepared in consultation with subject matter experts. You'll see that the document elaborates on the points we spoke about on Tuesday, with extensive evidence of the inapplicability of these studies to human health, the availability of existing data and superior

human-based research methodologies, and the problematic lack of oversight of these studies which cause suffering and harm to primates.

Having conducted research with human subjects at NIMH, I have always lauded the Intramural Research Program as one that dedicates itself to using the most innovative and humane methodology available in the interest of science and human health. So, as you might imagine, learning about the existence and details of these projects came as quite a surprise to me, as I hope it did for you, and I have no doubt it will to others inside and outside the research community.

As we brought up Tuesday, the NIH's own analysis of experiments on chimpanzees confirmed that it is possible for practices that are cruel and scientifically unnecessary to be reviewed, approved, funded and conducted within the NIH's intramural program for a long time without question. At the same time, the NIH's decision to suspend, review and ultimately end experiments on chimpanzees demonstrates how additional, objective scrutiny of a deeply-embedded practice can serve to benefit the agency, animals, researchers and taxpayers and acknowledge evolving public opinion. We believe that the same process can and should be applied here, and we hope to hear from you soon about plans to end these experiments.

Also, in light of the NIH's forthcoming review of intramural projects that you mentioned are to occur due to budget cuts, we urge that close attention be paid to all experiments on animals that involve pain and distress, particularly those in what NIH refers to as "USDA Column E," where suffering is unmitigated. I think you will find that the mother/infant deprivation experiments we discussed are wrongly categorized as Column C, and belong in Column E because of the intentional, prolonged and unrelieved distress caused during experimental trials and the studies overall. As you know, other countries have put in place more stringent regulations governing the use of animals in experiments that cause considerable, unrelieved suffering to animals (known here as "USDA Column E").

I hope we will hear from you regarding the status of your inquiry into the maternal deprivation and depression experiments on monkeys that we discussed before you leave for your bike trip next month.

Please contact me with any questions.

Sincerely,

Katherine Roe, Ph.D.
Research Associate
Laboratory Investigations Department
KatherineR@peta.org<mailto:KatherineR@peta.org>
240-355-6656<tel:240-355-6656>

Bordine, Roger (NIH/OD) [E]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Tuesday, July 22, 2014 3:48 PM
To: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Follow-up from PETA

Fyi.

I do not plan to respond at this time.

FC – Jane is getting "used" here in a tacky way.

From: Dan Mathews [mailto:DANM@peta.org]
Sent: Tuesday, July 22, 2014 3:45 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: FW: Follow-up from PETA

Hi Kathy,

Jane and I would like to know if NIH intends to act on any of the information.

Dan

From: Hudson, Kathy (NIH/OD) [E] [mailto:Kathy.Hudson@nih.gov]
Sent: Tuesday, July 22, 2014 8:27 AM
To: Katherine Roe
Cc: Dan Mathews
Subject: FW: Follow-up from PETA

Hi,

In your original overture to Drs. Collins and Goodall you asked for the opportunity to provide a briefing. That opportunity was provided. In addition, I wanted to make sure you are both aware that I received your email and attached information. We have reviewed this information and have a good understanding of your perspective and concerns. Thanks for taking the time to look into these issues and share your perspectives with us.

I understand that Dan has continued to send emails to Dr Collins on his personal email address. I would ask that you stop using his personal email address. He has asked me to handle these issues but if you feel compelled to communicate with him, his work address is francis.collins@nih.gov

Best,

Kathy

From: Katherine Roe [mailto:katheriner@peta.org]
Sent: Tuesday, July 08, 2014 12:30 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: FW: Follow-up from PETA

Hi Dr. Hudson,

I hope you had a great fourth of July weekend. I just wanted to make sure you got our follow-up materials re our meeting last week.

Thanks again for your time,

Katherine

From: Katherine Roe
Sent: Thursday, July 03, 2014 12:00 PM
To: 'kathy.hudson@nih.gov'
Subject: Follow-up from PETA

July 3, 2014

Dr. Kathy Hudson
Deputy Director for Science, Outreach, and Policy
Building 1, Room 109
1 Center Drive
Bethesda, MD 20892

Dear Kathy,

Thank you for meeting with us to discuss concerns about NIH's maternal deprivation and depression experiments on monkeys.

As promised, I have attached a critical review of these studies prepared in consultation with subject matter experts. You'll see that the document elaborates on the points we spoke about on Tuesday, with extensive evidence of the inapplicability of these studies to human health, the availability of existing data and superior human-based research methodologies, and the problematic lack of oversight of these studies which cause suffering and harm to primates.

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As we brought up Tuesday, the NIH's own analysis of experiments on chimpanzees confirmed that it is possible for practices that are cruel and scientifically unnecessary to be reviewed, approved, funded and conducted within the NIH's intramural program for a long time without question. At the same time, the NIH's decision to suspend, review and ultimately end experiments on chimpanzees demonstrates how additional, objective scrutiny of a deeply-embedded practice can serve to benefit the agency, animals, researchers and taxpayers and acknowledge evolving public opinion. **We believe that the same process can and should be applied here, and we hope to hear from you soon about plans to end these experiments.**

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Please contact me with any questions.

Sincerely,

Katherine Roe, Ph.D.
Research Associate
Laboratory Investigations Department
KatherineR@peta.org
240-355-6656

Gmail **Francis Collins** <(b) (6)

Phoning

10 messages

Jane Goodall <(b) (6) Sun, Jul 20, 2014 at 3:46 AM
To: Francis Collins(b) (6)

Dear Francis,
I am finally back on email. Am so sorry it is proving so difficult to connect on the phone. Today is Sunday, and they are doing a birthday party for me at an orphanage for HIV victims – they are not infected, but their mothers died.
We do Roots & Shoots there, and other groups are coming in for the occasion, and I have to have a supper there.
Tomorrow evening is free, though, before early start for Dar es Salaam.
I am assuming the call is about monkeys, but that is guess-work.
With love,
Jane

Francis Collins (b) (6) Sun, Jul 20, 2014 at 8:39 AM
To: Jane Goodall <(b) (6)
Cc: "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>

Hi Jane,

Wow, it sounds as if you are having a very special day! And my phone call is not super urgent -- I just wanted to talk with you about where we are with monkeys and the PETA concerns.

I have my two wonderful granddaughters visiting for the next week, but I could call you around noon EDT tomorrow (Monday), which I think would be 7 PM where you are. Would that work?

Love, Francis
[Quoted text hidden]

Jane Goodall <(b) (6) Mon, Jul 21, 2014 at 4:27 AM
To: Francis Collins(b) (6)

Dear Francis,
Yes - I have to give out prizes at a huge R&S football tournament, and then there is a large JGI and R&S dinner. But that does not start till 7.30. So from 7.00 I'll be in the house.
With love,
Jane
[Quoted text hidden]

Francis Collins <(b) (6)> Mon, Jul 21, 2014 at 4:37 AM
To: "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" <amcmanus@od.nih.gov>

Phone call at noon today!
[Quoted text hidden]

Jane Goodall <(b) (6)> Mon, Jul 21, 2014 at 9:43 AM
To: Francis Collins (b) (6)

Dear Francis,
This is Africa. Undoubtedly we shall run late tonight. So I gave you Dr. ANTHONY Collins (!!!) cell phone, in case (you have land line)
At least we can make contact.
(b) (6)
(b) (6)

Sending love from (b) (6)
Jane

On 20 July 2014 13:39, Francis Collins <(b) (6)> wrote:
[Quoted text hidden]

Francis Collins <(b) (6)> Mon, Jul 21, 2014 at 10:00 AM
To: "McManus, Ayanna (NIH/OD) [E]" <amcmanus@od.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>

---------- Forwarded message ----------
From: **Jane Goodall** (b) (6)
Date: Mon, Jul 21, 2014 at 9:43 AM
Subject: Re: Phoning
To: Francis Collins (b) (6)

[Quoted text hidden]

Francis Collins (b) (6)> Mon, Jul 21, 2014 at 12:04 PM
To: Jane Goodall (b) (6)
Cc: "McManus, Ayanna (NIH/OD) [E]" <amcmanus@od.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>

Hi Jane,

We tried that number but couldn't get through. This is not an emergency, and it sounds as you are having an incredibly busy day! Let's try again at a time that might work for you -- I should be fairly flexible for the next 10 days.

All the best, Francis
[Quoted text hidden]

McManus, Ayanna (NIH/OD) [E] <amcmanus@od.nih.gov> Mon, Jul 21, 2014 at 12:08 PM
To: Francis Collins <(b) (6)>

Just talked to Jane's assistant and she mentioned that trying to get through is comparable to a lottery. I will try a few more times and will connect you if successful.

From: Francis Collins [m(b) (6)
Sent: Monday, July 21, 2014 12:05 PM
To: Jane Goodall
Cc: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: Re: Phoning

[Quoted text hidden]

Jane Goodall <(b) (6) Tue, Jul 22, 2014 at 6:12 AM
To: Francis Collins(b) (6)

Dear Francis,
Yesterday was hopeless! Sorry - in (b) (6) which was bvery noisy. Giving you a different phone no. as the phone was old. The two together, noise and bad phone, not good!
Am free from now all after noon and evening.
(b) (6) a better phone!
If this is no good, tell me when is good time next days. More or less any time.
(b) (6) Jane
[Quoted text hidden]

Francis Collins <(b) (6) Tue, Jul 22, 2014 at 12:54 PM
To: "Wood, Gretchen (NIH/OD) [E]" <woodgs@od.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" <amcmanus@od.nih.gov>

Can you work some magic to find a time for this call? Keep in mind that Jane is 7 hours ahead of us. Today looks hopeless, but perhaps Wednesday or Thursday -- even if you have to use time right at the beginning of what is called "personal"?

FC

---------- Forwarded message ----------
From: **Jane Goodall** <(b) (6)
Date: Tue, Jul 22, 2014 at 6:12 AM
Subject: Re: Phoning
To: Francis Collins <(b) (6)

[Quoted text hidden]

Bordine, Roger (NIH/OD) [E]

From: Kathy Hudson <(b) (6)
Sent: Wednesday, July 13, 2016 4:08 PM
To: Abel, Kathy (NIH/OD) [E]
Subject: Fwd: follow-up: confidential meeting date

---------- Forwarded message ----------
From: **Dan Mathews** <DANM@peta.org>
Date: Mon, Jun 9, 2014 at 1:13 PM
Subject: follow-up: confidential meeting date
To: Kathy Hudson <(b) (6)

Hi Kathy,

I wanted to follow-up on my email from May 30 about the private meeting; what's your availability the week of June 23?

I know everyone is very busy but this case is extremely important. Please let me know ASAP and thanks!

Dan

From: Dan Mathews
Sent: Friday, May 30, 2014 12:15 PM
To: 'Kathy Hudson'
Subject: confidential meeting date
Importance: High

Hi Kathy,

Regarding the private meeting, what's your availability the week of June 23?

Thanks and have a great weekend,

Dan

From: Kathy Hudson (b) (6)
Sent: Wednesday, May 21, 2014 3:57 PM
To: Dan Mathews
Subject: Connecting

Bordine, Roger (NIH/OD) [E]

From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Wednesday, May 14, 2014 4:31 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: Poolesville Site
Attachments: 2011-06-15-NIHACpresentation full.pdf

Possible background re Poolesville.

Alan

From: Brown, Crystal (NIH/NICHD) [C]
Sent: Wednesday, May 14, 2014 4:25 PM
To: Guttmacher, Alan (NIH/NICHD) [E]
Cc: Jarman, John (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]
Subject: Poolesville Site

Here is more information for the Poolesville site.

Crystal Brown | Staff Assistant to the Director
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Office of the Director
31 Center Drive, Bldg. 31, Rm. 2A03, MSC 2425, Bethesda, MD 20892
Phone: 301.496.3455 | Mobile: 301.222.7270 | Fax: 301.402.1104 | Email: Crystal.brown@nih.gov

Eunice Kennedy Shriver National Institute
of Child Health and Human Development

"Be kinder than necessary, for everyone you meet is fighting some kind of battle."

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Bordine, Roger (NIH/OD) [E]

From:	Guttmacher, Alan (NIH/NICHD) [E]
Sent:	Wednesday, May 14, 2014 4:32 PM
To:	Hudson, Kathy (NIH/OD) [E]
Subject:	Poolesville Animal Center Information
Attachments:	Development Concepts for NIH Animal Center.pdf; NIHAC Master Plan.pdf; Poolesville Site Floor Plan.pdf

(Much) more...

Alan

From: Brown, Crystal (NIH/NICHD) [C]
Sent: Wednesday, May 14, 2014 12:46 PM
To: Guttmacher, Alan (NIH/NICHD) [E]
Cc: Jarman, John (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]
Subject: Poolesville Animal Center Information

Alan,

Dr. Stratakis asked that I give you the attached documents per your discussion in this morning's meeting. I'm also giving you the link to the Master Plan http://www.nems.nih.gov/Documents/NIH%20Animal%20Center%20Draft%20Master%20Plan.pdf.

Crystal Brown | Staff Assistant to the Director
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Office of the Director
31 Center Drive, Bldg. 31, Rm. 2A03, MSC 2425, Bethesda, MD 20892
Phone: 301.496.3455 | Mobile: 301.222.7270 | Fax: 301.402.1104| Email: Crystal.brown@nih.gov

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

"Be kinder than necessary, for everyone you meet is fighting some kind of battle."

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Bordine, Roger (NIH/OD) [E]

From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Friday, May 16, 2014 10:12 AM
To: Hudson, Kathy (NIH/OD) [E]
Subject: Need to reschedule
Attachments: lab outline.pdf

FYI...

Alan

-----Original Message-----
From: Suomi, Stephen (NIH/NICHD) [E]
Sent: Friday, May 16, 2014 10:11 AM
To: Guttmacher, Alan (NIH/NICHD) [E]
Cc: Stratakis, Constantine (NIH/NICHD) [E]
Subject: RE: Need to reschedule

Alan,
I usually go out to Poolesville via River Road (b) (6) but INSTEAD of turning right on Partnership, going through Poolesville on White's Ferry Road, and then left on Elmer School Road to the NIHAC, I keep going on River Road, then turn right on West Willard Road and then left on Westerly Road (bypassing Poolesville entirely, with its speed cameras, and stop signs) until it ends, turn right on Edwards Ferry Road, then immediately left on Club Hollow Road and stay on it until it ends at Elmer School road, which is on the edge of the NIHAC (b) (6) 35 from the Bethesda campus).
I started with that route this morning, but West Willard was flooded at the Seneca Creek Bridge so I turned around and took Partnership into Poolesville and got onto Whites Ferry Road, which was also flooded, turned around again, got onto West Willard in Poolesville, and then Club Hollow Rd, which was also flooded, but when I saw a 4x4 in front of me make it through OK I decided to try it myself -- and just barely made it through!

Attached is something you also might take a look at when you are ready to visit!
Hope to see you (and Kathy) out here soon.
Steve

Stephen J. Suomi, Ph.D.
Chief, Laboratory of Comparative Ethology Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health, DHHS Bethesda, MD 20892-7971
Phone: 301-496-9550
Fax: 301-496-0630
e-mail: ss148k@nih.gov

-----Original Message-----
From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Friday, May 16, 2014 9:43 AM
To: Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]
Subject: RE: Need to reschedule

Well, I suppose the good news is that it will give me chance to actually read the article that is the basis for the PNAS cover before visiting.

Out of curiosity, what routes did each of you use to get there this morning?

Alan

-----Original Message-----
From: Suomi, Stephen (NIH/NICHD) [E]
Sent: Friday, May 16, 2014 9:00 AM
To: Guttmacher, Alan (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]
Subject: RE: Need to reschedule

Alan,

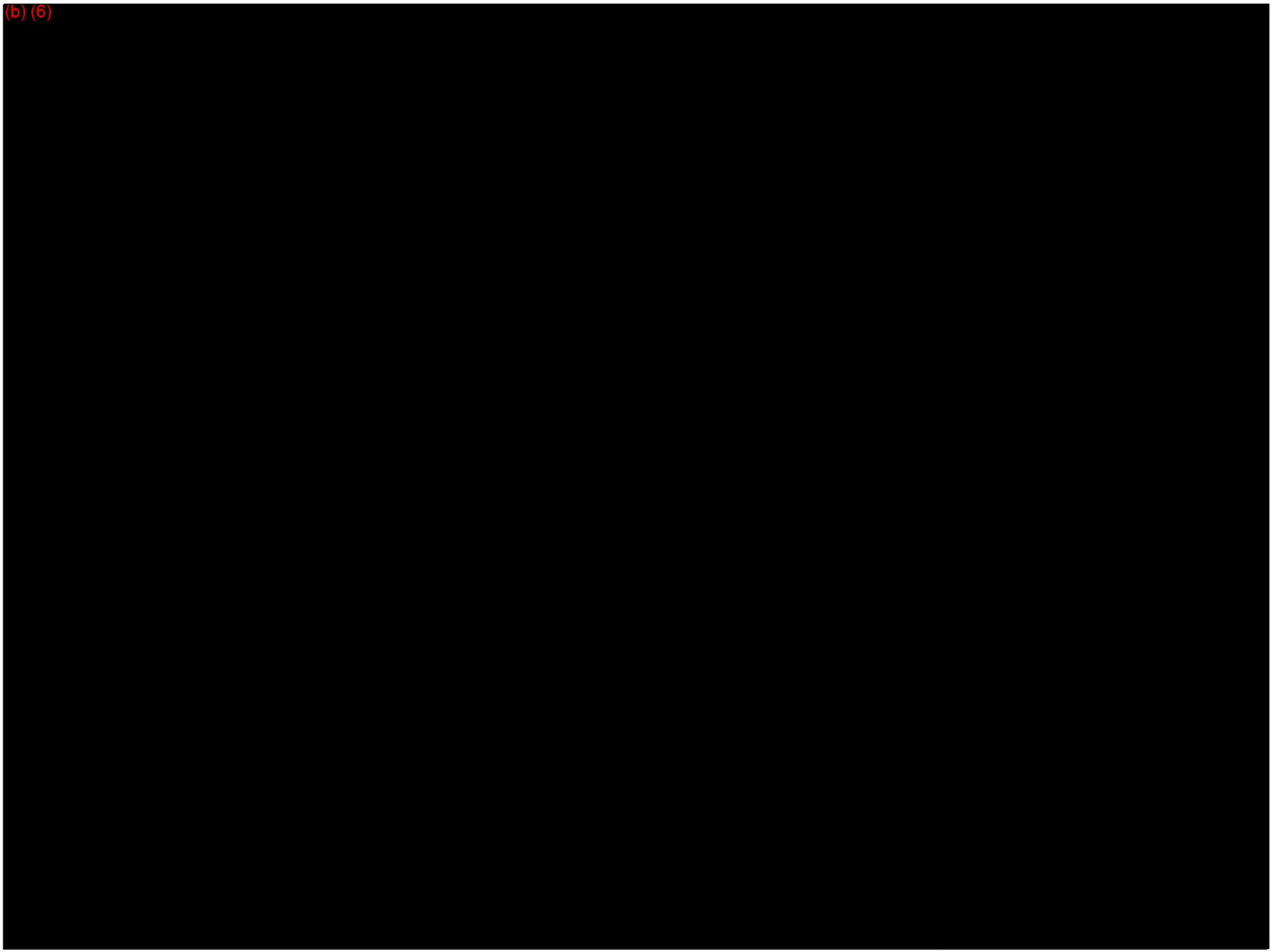
Thanks for trying, anyway.
For what it's worth, coming from (b) (6) I had to turn around twice and try a different route myself -- third time turned out to be a charm, although even that was a bit hairy...
We will be ready and eager to see you and Kathy out here whenever you can reschedule.

Steve

Stephen J. Suomi, Ph.D.
Chief, Laboratory of Comparative Ethology Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health, DHHS Bethesda, MD 20892-7971
Phone: 301-496-9550
Fax: 301-496-0630
e-mail: ss148k@nih.gov
-----Original Message-----
From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Friday, May 16, 2014 8:38 AM
To: Stratakis, Constantine (NIH/NICHD) [E]; Suomi, Stephen (NIH/NICHD) [E]
Subject: Need to reschedule

Sorry, but we are still hitting flooded out roads. It is getting so late that we had best figure out another date.

Alan E. Guttmacher, M.D.
Director
Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health


(b) (6)

Bordine, Roger (NIH/OD) [E]

From: Guttmacher, Alan (NIH/NICHD) [E]
Sent: Thursday, May 22, 2014 4:41 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: Suomi Lab / Letter from Catherine Driessen of 5/16/14
Attachments: Letter-Response from Ms. Driessen, regarding LCE Lab project and funding....pdf

FYI...

Alan

From: Hanning, Brenda (NIH/NICHD) [E]
Sent: Thursday, May 22, 2014 4:34 PM
To: Guttmacher, Alan (NIH/NICHD) [E]; NICHDsd; Stratakis, Constantine (NIH/NICHD) [E]
Cc: Kaeser, Lisa (NIH/NICHD) [E]
Subject: Suomi Lab / Letter from Catherine Driessen of 5/16/14

Dear Drs. Guttmacher and Stratakis,

The attached letter came to our office this afternoon, for Dr. Stratakis. Please note that it is copied to Dr. Collins, Dr. Suomi, Senators Baldwin and Johnson, as well as Representative Ribble.

Sincerely yours,

Brenda

Brenda R. Hanning
Deputy Director, Liaison & Training
Office of the Scientific Director
Division of Intramural Research
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bldg. 31, Room 2A46
31 Center Drive
Bethesda, MD 20892-2425
t 301-451-7753
http://irp.nih.gov/

May 16, 2014

Constantine A. Stratakis, MD, D(med)Sci
Scientific Director
Eunice Kennedy Shriver National Institute of
Child Health and Human Development (NICHD)
31 Center Drive
Building 31, Room 2A32
Bethesda, MD 20892-2425

cc: Francis S. Collins, MD, PhD
Stephen J. Suomi, PhD
Senator Ron Johnson
Senator Tammy Baldwin
Representative Reid Ribble

SUBJ: To determine whether taxpayer funding of the project "Developmental Continuity of Individual Differences in Reactivity in Monkeys" conducted by Stephen J. Suomi and associates over a span of 29 years at a cost of $16+ million has resulted in any real world applications to benefit children which would justify continued funding.

Dear Dr. Stratakis,

Thank you for your March 12, 2014 response to my November 7, 2013 inquiry into the aforementioned project. I have attached my initial letter and your response as reference.

In my November 7 letter, I asked four questions:

1) How was the scientific language of this research translated to lay terms, and who translated it?
2) What child treatments and/or programs resulted from this research, and who modeled them?
3) Which federal, state or local child care agencies are using these treatments and/or programs?
4) How have the results of these treatments and/or programs been measured for success or failure?

None of these questions were answered by your letter. You vaguely referenced "some therapists working with children" and "several scientists working with very young children".

So I ask again.

Dr. Stratakis, Dr. Collins, Mr. Suomi - can any one of you provide me with specific answers to the above referenced questions.

Or ..... might this project be an example of an NIH/NICHD "Bridge to Nowhere"?

Sincerely,

Catherine Driessen

Catherine Driessen
(b) (6) [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

March 12, 2014

Ms. Catherine Driessen
(b) (6)
[redacted]

Dear Ms. Driessen:

Thank you for writing to Dr. Francis Collins, Director of the National Institutes of Health (NIH), to express your concern about the work of one of our laboratories. Since I am the Scientific Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), which houses the lab, I was asked to respond to your letter.

While the majority of funding (approximately 80%) provided to NIH is distributed to academic institutions across the country, NIH also maintains a number of research laboratories on or near the NIH campus in Bethesda, Maryland. The scientific staff who work in these labs are leaders in their respective scientific fields, and the work they conduct here often is not performed anywhere else in the country.

The project you inquired about is one of many conducted by the Laboratory of Comparative Ethology (LCE), which is a basic research laboratory within NICHD that investigates behavioral, biological, and epigenetic development in nonhuman primates, primarily rhesus monkeys. Most of the investigations carried out in the LCE are aimed at helping us understand various aspects of human behavioral and biological development, as well as providing insights for developing new clinical approaches for improving child health. The research takes advantage of the many remarkable similarities between rhesus monkeys and humans with respect to their genetic make-up, basic physiological processes, patterns of brain growth and development, and increasing complexity of their social activities and relationships. Since some of this research supplements research with humans, the head of the laboratory actively collaborates with prominent researchers investigating parallel aspects of human development and participates in a number of research networks aimed at increasing our current understanding of human physical and mental health throughout the lifespan.

A major focus of current research in the LCE is measuring individual differences in rhesus monkeys' social and cognitive capabilities and understanding the interaction between genetic and environmental factors in shaping how an individual develops. One project demonstrated that monkeys are capable of perceiving whether others are mimicking their behaviors and found that they pay more attention to, and even prefer, interacting with the imitators than with other individuals. This finding has helped to increase the knowledge base about developmental disorders, leading to an increased emphasis by some therapists working with children with

autism spectrum disorders (ASD) on imitating the actions of those children as a means of increasing their involvement in social interactions. A second project identified individual differences among newborn monkeys in their own imitation capabilities, found and described specific patterns of brain activity associated with the imitative behavior, and documented the subsequent appearance of autistic-like behavior among those individuals who failed to imitate. These findings have contributed to new efforts by several scientists working with very young children deemed to be at high risk for developing ASD, with the goal of providing an early screening tool to detect these disorders. This foundational science also informs the work of other researchers who are trying to understand how to prevent neurodevelopmental disorders. Another major project of the LCE is investigating to what extent early social deficits are reversible if interventions are initiated later in life; the initial findings are promising, with implications in the future for helping children who have experienced abuse or other serious social challenges.

While it is difficult to document the actual number of individual therapists and practitioners who are directly applying these findings from the research conducted in the LCE, Dr. Suomi's work has attracted considerable interest in the media regarding the relevance of this work to human development and behavior. He is frequently asked to present the lab's findings at meetings of researchers, clinical practice, education, and public policy. Just this past spring, he was invited to present his work at an official White House Conference on Behavioral Economics.

Thank you again for taking the time to write to the NIH. I hope this information is helpful.

Sincerely,

Constantine A. Stratakis, M.D., D(med)Sci
Scientific Director, NICHD

November 7, 2013

Francis S. Collins, MD, PHD
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Mr. Collins,

I'm a 63 year old retired Wisconsin woman who is very concerned about our seemingly untethered federal spending. A web article about an NIH funded project caught my attention recently because I worked in a juvenile detention facility for ten years. Every year our budget application was a torturous process - we always came up short - and we basically got by on a wing and a prayer. Today child service agencies are under even more financial pressure. Considering the federally funded research mentioned below was again funded in 2013, I'm wondering how this NIH project has actually helped children.

These are the identifiers for the NIH project I'm inquiring about. (This information was obtained through web research and may not be complete.):

Research Project Title:	Developmental Continuity of Individual Differences in Reactivity in Monkeys
NIH Funding Institution:	National Institute of Child Health and Human Development
Principal Investigator:	Stephen J. Suomi
Fiscal Years:	1985-1988, 1990-2011, 2013

Budget amounts for years I've been able to determine are:

2007	$873,364
2008	$983,320
2009	$1,568,039
2010	$1,291,583
2011	$1,254,620

Not knowing how prior and later years trended against these amounts, let's assume around $16 million tax dollars were used for this research. What I would like to know is how the findings of this primate research have been applied in practical treatments/programs for the benefit of children, i.e.:

1) How was the scientific language translated to lay terms, and who translated it?
2) What child treatments and/or programs resulted from this research, and who modeled them?
3) Which federal, state or local child care agencies are using these treatments and/or programs?
4) How have the results of these treatments and/or programs been measured for success or failure?

Thank you for your attention to this inquiry.

Catherine Driessen
[redacted](b)(6)

Catherine Driessen

cc: Congressman Reid Ribble - 8th Congressional District of Wisconsin
1513 Longworth HOB, Washington, DC 20515

Bordine, Roger (NIH/OD) [E]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Wednesday, June 11, 2014 10:00 AM
To: Jorgenson, Lyric (NIH/OD) [E]
Subject: needs your input on monkeys

Tom suggested Jim Raber, Eric Nelson
Add lauren Higgins
Thanks for additional suggestion but I don't think we need them.

Schedule for week of june 23

From: Jorgenson, Lyric (NIH/OD) [E]
Sent: Wednesday, June 11, 2014 8:27 AM
To: Hudson, Kathy (NIH/OD) [E]
Subject: needs your input: monkeys

Kathy,

For the monkeys meeting, please respond with your thoughts on the list below so we can start trying to schedule:

1. Mike Gottesman
2. John Burklow
3. Lyric Jorgenson
4. Tom Insel
5. Alan Guttmacher
6. Stephen Suomi (Senior Investigator; Section on Comparative Behavioral Genetics)
7. Constantine Stratakis (NICHD, Head of section on genetics and endrocrinology)
8. Pat White

And then some possible others:

- Others in your email thread: Brenda Hanning (Deputy Director, Liaison and Training in the Office of the Scientific Director, Division of Intramural Research, NICHD)
- Who is the researcher that is actually in NIMH, NOT NICHD?
- Wildcard – my guess is no, but, before I found the emails - the search for "Constantine" - Steph suggested Franziska Grieder (Director, Office of Research Infrastructure Programs) and I found Charmaine Foltz (Director, Division of Veterinary Resources, ORS (professional and technical services to NIH intramural scientists))

From: Hudson, Kathy (NIH/OD) [E]
Sent: Tuesday, June 10, 2014 1:20 PM
To: Schulke, Hilda (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Abel, Kathy (NIH/OD) [E]

Bordine, Roger (NIH/OD) [E]

From: Rockey, Sally (NIH/OD) [E]
Sent: Monday, June 23, 2014 9:09 AM
To: Barros, Colleen (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Cc: Shaya, Cecile (NIH/OD) [E]
Subject: Animal Research center

And to add, does it trump other intramural programs.

Sally J. Rockey, Ph.D.
NIH Deputy Director for Extramural Research
OD/NIH/DHHS
One Center Drive
Building 1, Room 144
Bethesda, MD 20892
301-496-1096
301-402-3469 Fax
rockeysa@od.nih.gov

From: Barros, Colleen (NIH/OD) [E]
Sent: Monday, June 23, 2014 8:39 AM
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Barros, Colleen (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Rockey, Sally (NIH/OD) [E]
Cc: Shaya, Cecile (NIH/OD) [E]
Subject: Animal Research center

Francis-----re your question re the ARC, here is a short summary that was done this spring on that project. Designing and Constructing that facility would be a great help to our CI as we struggle to keep our old animal facilities up to accreditation standards. But does that trump money for RPGs? One of the eternal questions. The bottom line is if we want to do research here via the IRP, the infrastructure has to be supported----and the animal buildings are at the end of their usable life span.

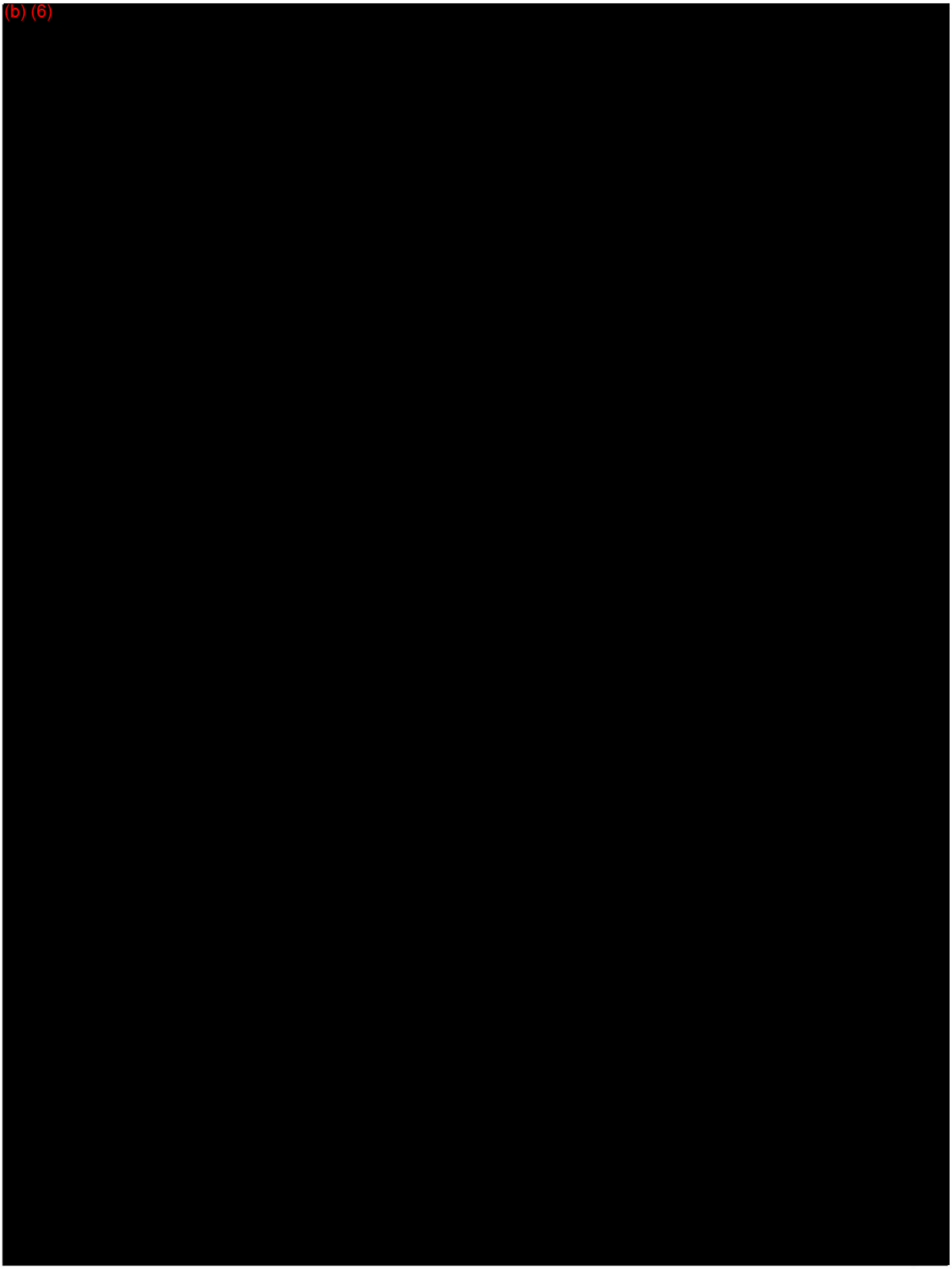
Bordine, Roger (NIH/OD) [E]

From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, June 23, 2014 9:14 AM
To: Collins, Francis (NIH/OD) [E]
Subject: Animal Research center
Attachments: NEF Template Animal Research Center 05052014.docx

Might you ask for an inventory of all our animal facilities and, if you are feeling daring, the protocols using the most expensive animals? I was not aware of Dickerson and we know we have problems at Poolesville

From: Barros, Colleen (NIH/OD) [E]
Sent: Monday, June 23, 2014 8:39 AM
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Barros, Colleen (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Rockey, Sally (NIH/OD) [E]
Cc: Shaya, Cecile (NIH/OD) [E]
Subject: Animal Research center

Francis-----re your question re the ARC, here is a short summary that was done this spring on that project. Designing and Constructing that facility would be a great help to our CI as we struggle to keep our old animal facilities up to accreditation standards. But does that trump money for RPGs? One of the eternal questions. The bottom line is if we want to do research here via the IRP, the infrastructure has to be supported----and the animal buildings are at the end of their usable life span.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[redacted]

IV: Timeline of Acquisitions: NIH completed a Program of Requirements (POR) that defined the scope of the project in 2012 and the footprint and scale of the project is depicted on the approved 2014 NIH Master Plan. Should we receive NEF funding in FY 2014 to move forward with design we would anticipate an award of design by September FY 2015. The design documentation would take approximately 18 months to complete. This timeline would require us to submit to HHS a Facilities Project Approval Agreement (FPAA) for approval in January of 2015 so that the CIRB could approve the project in FY 2015. The FPAA will be submitted to the Director, Real Property and leasing, consistent with the HHS Facilities Program Manual. A Sources Sought Notice would be posted in FBO for the design contract in October 2014; however, a commitment of funding is necessary prior to any additional acquisition planning. If the Capital Asset Acquisition Costs for design are funded by NEF, there would be a requirement for out-year NEF funding for construction. There is no requirement for FTE support from NEF, since the

costs associated with the Project Officer and Contracting Officer overseeing the project is within NIH's base appropriation.

Timeline of Acquisitions

Contract	Amount	Month of Obligation
Design Contract	$20,000,000	September 2015
Total	$20,000,000	

V. Cost Table

Capital Asset Acquisition Cost

Cost Type	Multi-Year Cost (Yes/No)	Total Capital Cost	FTE# (Per Year)
Design	N	$20,000,000	0
Total			

(b) (6)

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(b) (6)

Bordine, Roger (NIH/OD) [E]

From: Barros, Colleen (NIH/OD) [E]
Sent: Monday, June 23, 2014 4:12 PM
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Rockey, Sally (NIH/OD) [E]
Cc: Shaya, Cecile (NIH/OD) [E]
Subject: Animal Research center

Will get on this.

Sent from my BlackBerry Wireless Handheld

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, June 23, 2014 04:05 PM Eastern Standard Time
To: Barros, Colleen (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Rockey, Sally (NIH/OD) [E]
Cc: Shaya, Cecile (NIH/OD) [E]
Subject: RE: Animal Research center

As per our conversation in the shuttle this morning, I'd like to have a briefing on the NIH animal facilities. That should include site, type of animals, capacity for each one, average occupancy, annual maintenance cost, and annual cost/animal (taking account of occupancy). Once I've seen this, I might also want to have a look at some sample protocols for the most expensive animals.

No huge rush on this, but sometime in the next month? I would think Michael's IRP review group would want to see these data also.

FC

From: Barros, Colleen (NIH/OD) [E]
Sent: Monday, June 23, 2014 8:39 AM
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Barros, Colleen (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Rockey, Sally (NIH/OD) [E]
Cc: Shaya, Cecile (NIH/OD) [E]
Subject: Animal Research center

Francis-----re your question re the ARC, here is a short summary that was done this spring on that project. Designing and Constructing that facility would be a great help to our CI as we struggle to keep our old animal facilities up to accreditation standards. But does that trump money for RPGs? One of the eternal questions. The bottom line is if we want to do research here via the IRP, the infrastructure has to be supported----and the animal buildings are at the end of their usable life span.

Excel Attachment on F: Drive (not printable)

Bordine, Roger (NIH/OD) [E]

From: Clark, Terri (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 3:34 PM
To: Gottesman, Michael (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]; Bordine, Donald (NIH/OD) [E]
Subject: Animal census
Attachments: NHP REPORT BETHESDA FOR MMG 6-24-14.xlsx

HI Michael – here is the requested summary. My hearty thanks to Don Bordine for pulling this together quickly today. Let us know if you need anything further. Cheers – Terri

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
301-496-5424/7236 // clarkte@od.nih.gov // http://oacu.od.nih.gov

From: Gottesman, Michael (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 1:31 PM
To: Clark, Terri (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]
Subject: Re: Animal census

Thanks, and if we could indicate where the various species of NHP are housed, that would be even better.
Michael

From: <Clark>, "Terri [E] (NIH/OD)" <ClarkTe@OD.NIH.GOV>
Date: Tuesday, June 24, 2014 12:46 PM
To: "Gottesman, Michael (NIH/OD) [E]" <GottesmM@mail.nih.gov>
Cc: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "\"Richard G Wyatt" <WyattRG@OD.NIH.GOV>, Joseph Kleinman <kleinmanj@od.nih.gov>
Subject: RE: Animal census

Hi – on the semiannual reports: yes. I'll ask Don to add this to the tally spreadsheet I provide you earlier. He should have it to you by the end of the day tomorrow. Cheers - Terri

From: Gottesman, Michael (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 11:24 AM
To: Clark, Terri (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]
Subject: Re: Animal census

Do we distinguish the various species of non-human primates?
Michael

From: <Clark>, "Terri [E] (NIH/OD)" <ClarkTe@OD.NIH.GOV>
Date: Tuesday, June 24, 2014 10:19 AM
To: "Gottesman, Michael (NIH/OD) [E]" <GottesmM@mail.nih.gov>

Cc: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "\"Richard G Wyatt" <WyattRG@OD.NIH.GOV>
Subject: RE: Animal census

Hi Michael - OACU tallies the IRP average daily census numbers with each semiannual report, so here are the numbers from April of this year that reflect both IC and facility location. Our populations remain pretty stable, so this should be a fairly accurate reflection of our current censuses. If you provide me with dates of your availability, I can work with the IC of interest and arrange tours for you. Terri

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
301-496-5424/7236 // clarkte@od.nih.gov // http://oacu.od.nih.gov

Excel Attachment in F:Drive (Not Printable)

-----Original Message-----
From: Gottesman, Michael (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 10:11 AM
To: Clark, Terri (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]
Subject: Animal census

Can you provide me and Kathy Hudson with our latest animal census (the one we report to OLAW) with numbers by species? Also, do we have information about where they are housed? Kathy would like to visit monkey facilities on campus and I would be interested in joining her.
Michael

Bordine, Roger (NIH/OD) [E]

From: Clark, Terri (NIH/OD) [E]
Sent: Thursday, June 26, 2014 9:41 AM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Subject: Animal census
Attachments: contract locations for IRP animals

Hi Kathy – I spoke to Richard yesterday and he gave me a little more background. Here's what we suggest for animal facilities to visit: sampling of 14 complex facilities (rodent and NHP), 10A (all rodent, good example of a re-purposed space), sampling of the ACRF facilities (rodents), 49 (NHP and rodents), 35 (rodents, newest facility), 6 (new zebrafish facility; largest in world). I've also attached a list of contract facilities for our local program. If you want to see all IRP contract facilities, I'll put out a request to the 5 outlying locations.

Would the weeks of July 7-11 or 14-19 be options for taking these tours? Please let me know who to coordinate with to set these up. Cheers - Terri

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
301-496-5424/7236 // clarkte@od.nih.gov // http://oacu.od.nih.gov

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From: Clark, Terri (NIH/OD) [E]
Sent: Wednesday, June 25, 2014 7:42 AM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]; Bordine, Donald (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Subject: RE: Animal census

HI Kathy – so for the animal facilities here on the main campus, are you interested in visiting a sample of NHP facilities or want to get to all of them? For NHP facilities you'll need a negative PPD within a year and evidence of a titer to measles-mumps-rubella. If you are enrolled in our Animal Exposure Program, OMS will have all this and/or can work with you for verification or needed components.

For the contract facilities, again are you just interested in contracts for NHPs for the Bethesda-based ICs? I can provide location and numbers held at the locations. I'll need to reach out to the ICs for that information, so hopefully will have it to you in a few days.

Thanks – Terri

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
301-496-5424/7236 // clarkte@od.nih.gov // http://oacu.od.nih.gov

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From: Hudson, Kathy (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 11:44 PM
To: Clark, Terri (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Cc: Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]; Bordine, Donald (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Animal census

Terri,
Thanks for this info. It would be useful to go ahead and add in the IRP contract facilities that take care of other NIH owned or IRP used animals.

Having been to Poolesville, it would be great to get a chance to see the other animal facilities. Can you help arrange a visit for me? I have had the requisite tests I think to visit all the animal facilities. Thanks.

From: Clark, Terri (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 3:34 PM
To: Gottesman, Michael (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]; Bordine, Donald (NIH/OD) [E]
Subject: RE: Animal census

HI Michael – here is the requested summary. My hearty thanks to Don Bordine for pulling this together quickly today. Let us know if you need anything further. Cheers – Terri

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
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From: Gottesman, Michael (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 1:31 PM
To: Clark, Terri (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]
Subject: Re: Animal census

Thanks, and if we could indicate where the various species of NHP are housed, that would be even better.
Michael

From: <Clark>, "Terri [E] (NIH/OD)" <ClarkTe@OD.NIH.GOV>
Date: Tuesday, June 24, 2014 12:46 PM
To: "Gottesman, Michael (NIH/OD) [E]" <GottesmM@mail.nih.gov>
Cc: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "\"Richard G Wyatt" <WyattRG@OD.NIH.GOV>, Joseph Kleinman <kleinmanj@od.nih.gov>
Subject: RE: Animal census

Hi – on the semiannual reports: yes. I'll ask Don to add this to the tally spreadsheet I provide you earlier. He should have it to you by the end of the day tomorrow. Cheers - Terri

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From: Gottesman, Michael (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 11:24 AM
To: Clark, Terri (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Kleinman, Joe (NIH/OD) [E]
Subject: Re: Animal census

Do we distinguish the various species of non-human primates?
Michael

From: <Clark>, "Terri [E] (NIH/OD)" <ClarkTe@OD.NIH.GOV>
Date: Tuesday, June 24, 2014 10:19 AM
To: "Gottesman, Michael (NIH/OD) [E]" <GottesmM@mail.nih.gov>
Cc: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "\"Richard G Wyatt" <WyattRG@OD.NIH.GOV>
Subject: RE: Animal census

Hi Michael - OACU tallies the IRP average daily census numbers with each semiannual report, so here are the numbers from April of this year that reflect both IC and facility location. Our populations remain pretty stable, so this should be a fairly accurate reflection of our current censuses. If you provide me with dates of your availability, I can work with the IC of interest and arrange tours for you. Terri

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
301-496-5424/7236 // clarkte@od.nih.gov // http://oacu.od.nih.gov

-----Original Message-----
From: Gottesman, Michael (NIH/OD) [E]
Sent: Tuesday, June 24, 2014 10:11 AM
To: Clark, Terri (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]
Subject: Animal census

Can you provide me and Kathy Hudson with our latest animal census (the one we report to OLAW) with numbers by species? Also, do we have information about where they are housed? Kathy would like to visit monkey facilities on campus and I would be interested in joining her.
Michael

Bordine, Roger (NIH/OD) [E]

From: Clark, Terri (NIH/OD) [E]
Sent: Wednesday, June 25, 2014 5:27 PM
To: Clark, Terri (NIH/OD) [E]
Subject: (b) (6) [redacted]

NHLBI
(b) (6) [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	(b) (6) [redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Dr. Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care & Use // Chief Veterinary Officer, CAPT, USPHS
301-496-5424/7236 // clarkte@od.nih.gov // http://oacu.od.nih.gov

More than 16 million Americans suffer from a disease caused by smoking.

Bordine, Roger (NIH/OD) [E]

From: Quinn, Kevin (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 5:06 PM
To: Nelson, Eric (NIH/NIMH) [V]; Hudson, Kathy (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA
Attachments: QA for animal research.docx

Here is a draft response from NIMH particularly addressing the NIMH related issues. Comments welcome. It is organized as a set of talking points around 4 basic questions that one could ask about NHP research.

Kevin

From: Nelson, Eric (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 4:46 PM
To: Hudson, Kathy (NIH/OD) [E]; Quinn, Kevin (NIH/NIMH) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

Do you still want us to work with Lyric to generate 3-4 talking points by tomorrow or should we just go with FBR?

Eric

From: Hudson, Kathy (NIH/OD) [E]
Sent: Thursday, June 26, 2014 4:15 PM
To: Quinn, Kevin (NIH/NIMH) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

Thanks. Burklow will work with nichd and nimh comms to reach out to FBR. I do not think video will change reception of peta so I would not make that investment for this purpose. In fact, most folks are unaware that NIH has a bunch of primates and we might just be raising awareness that does not need to be raised....

I think we do responsive, rather than proactive, communications on this but will defer to Burklow.

From: Quinn, Kevin (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 11:31 AM
To: Insel, Thomas (NIH/NIMH) [E]; Hudson, Kathy (NIH/OD) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

Q1. Explain the importance of research involving non-human primates.

A. The use of animals in research has enabled scientists to identify new ways to treat illness, extend life, and improve health and well-being. Non-human primates (NHPs) are our closest relatives in the animal kingdom, providing exceptional insights into human biology and the need for special consideration and respect. While used very selectively and in limited numbers for medical research, NHPs have served an important role in advancing human health in the past. Although the 2010 Institute of Medicine report on the use of chimpanzees in research found that much research involving NHPs is no longer necessary, nevertheless it also recognized the continued importance of some ongoing NHP research on social and behavioral factors that affect the development, prevention, or treatment of disease.

Q2. Explain the importance of behavioral non-human primate research.

A. The studies conducted within the NIMH Non-Human Primate Core have examined the effect of disrupting the mother-infant bond on the subsequent development of emotional and social competence. Substantial evidence suggests that this type of experience has persistent and sometimes adverse consequences on the development of children. The necessary controlled examination of early stress cannot be carried out in humans and requires the use of animal studies to carefully separate experience, genetic, and other environmental factors.

Although much has been learned about how the brain regulates social attachment from rodents, comparative studies of rodents and monkeys provided an opportunity to extend these findings to studies of higher order social and cognitive behaviors. NHPs, like humans, are largely visual, rather than olfactory. Although they lack human language, monkeys produce categorical vocalizations, they form clear social preferences with reciprocal interaction, and they are capable of performing complex cognitive tasks similar to those used in clinical assessments of human patients. The monkey brain has a well-developed temporal lobe and an extensive prefrontal cortex, regions that are largely undeveloped in the rodent. These areas may be important for social and communicative functions.

Rhesus macaques live in large social groups, and there is much documentation regarding the need for maternal contact and group interactions for normal development in this species. The rhesus brain has also been extensively mapped, making it possible to monitor changes in target areas associated with social development and stress. The number of monkeys incorporated for the NIMH Non-Human Primate Core studies was the minimum number necessary for statistical analysis.

Q3. Explain the significance of the behavioral inhibition study.

A. Behavioral inhibition is a temperament that can be identified early in childhood and which is a known risk factor for development of psychopathology later in life when children transition into adolescence and young adulthood. It is well studied in children. However, not all children with this temperament develop psychopathology. Therefore, understanding the biology of this temperament and the factors associated in some children with the heightened risk for mental disorders gives scientists a more precise window for identifying risk factors for mental disorders and provides an avenue for the development of effective therapies to treat mental disorders in children. As well, by characterizing those behaviorally inhibited children who go on to develop psychopathology we hope to delay or prevent the onset of mental disorders, a major priority for NIMH research.

B. If behavioral inhibition is studied in human children why would one wish to study this phenomenon in non-human primates? The answer is that studies in a closely related animal species allows scientists to conduct more precise experiments (we have more control over the monkeys' environment) and it allows us to study not only the behavioral correlates of this temperament but to look at the neural correlates, understand the interaction with the environment, and to begin to test possible treatments, including pharmacological ones, before we try such treatments in human children. Non-human primate research has another advantage – that of time – the developmental time course for monkeys is 4xs as fast as humans, allowing researchers to conduct these studies in a much shorter time frame than would be possible in humans. So, developing a set of behavioral paradigms in non-human primates that parallel those used to assess behavioral inhibition in human children is important to achieving the broader aim of NIMH – not just treatment of mental disorders but their prevention.

Q4. Provide examples of health advances made using non-human primates.

A. Perhaps the most notable example of a biomedical medical advance made possible through the use of NHP is the polio vaccine, which has removed a once-feared scourge of childhood from the very consciousness of most Americans today. Less well-known, but highly significant research involving NHPs has contributed vitally to the development of prosthetic limbs, illustrating how brain-machine interfaces could be utilized to restore motor control after debilitating injuries. More immediately relevant to NIMH, NHP research has been indispensable in the realm of mental disorders. NHP research has enlightened us about the mechanisms underlying post-traumatic stress disorder: animal studies showed that reducing norepinephrine levels (heightened in response to stress) enabled appropriate activity in the prefrontal cortex and reduced inappropriate over-activity in the amygdala. Today, some norepinephrine-based drugs are used to help treat patients with PTSD. NHP research of brain structures involved in reward prediction has provided insights into a range of mental illnesses and addiction disorders. These studies have informed clinical trials of deep brain stimulation to help patients with chronic, treatment-resistant depression; elucidated the brain mechanisms of attention, which have been vital to the understanding and treatment of attention-deficit hyperactivity disorder; and, provided insights into the long-term effects of antipsychotic medication on the brain.

Bordine, Roger (NIH/OD) [E]

From: Stratakis, Constantine (NIH/NICHD) [E]
Sent: Thursday, June 26, 2014 5:17 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]; Quinn, Kevin (NIH/NIMH) [E]; Nelson, Eric (NIH/NIMH) [V]; NICHDsd; Stratakis, Constantine (NIH/NICHD) [E]
Subject: Meeting with PETA
Attachments: Four proposed talking pointsd for Dr. Kathy Hudson.docx

Dear Dr. Hudson,

NICHD has prepared the attached in terms of talking points. Dr. Suomi can provide the supportive documentation (in terms of scientific literature) if this is required at this point. Please let us know if anything else is needed.

Yours

Constantine A. Stratakis, MD, D(med)Sci
Scientific Director, NICHD, NIH

From: Quinn, Kevin (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 5:06 PM
To: Nelson, Eric (NIH/NIMH) [E]; Hudson, Kathy (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

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Kevin

From: Nelson, Eric (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 4:46 PM
To: Hudson, Kathy (NIH/OD) [E]; Quinn, Kevin (NIH/NIMH) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Meeting with PETA

Do you still want us to work with Lyric to generate 3-4 talking points by tomorrow or should we just go with FBR?

Eric

Talking points:

Recent research with rhesus monkeys has clearly demonstrated that:

1. Infants are born with remarkable perceptual, cognitive, and social capabilities, but social interactions beginning in the initial days and weeks of life are crucial for developing these capabilities to their full potential throughout development.
2. Early social experiences have profoundly significant influences not only on social, emotional, and cognitive development but also on neuroendocrine functioning, neurotransmitter metabolism, brain structure and function, and epigenetic patterns of gene expression that are genome-wide; in other words, early social experiences clearly can get "under the skin."
3. There are profound health consequences of early social adversity that can be life-long and, in some cases, transmitted to subsequent generations.
4. The extensive behavioral, biological, and epigenetic consequences of early social adversity are largely reversible through specially targeted behavioral and biological interventions later in life.

Bordine, Roger (NIH/OD) [E]

From: Nelson, Eric (NIH/NIMH) [E]
Sent: Friday, June 27, 2014 10:52 AM
To: Quinn, Kevin (NIH/NIMH) [E]; Hudson, Kathy (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Meeting with PETA
Attachments: Additional PETA points.docx

I think these are excellent points and extremely well-articulated.

I add two more here for what it is worth.

From: Quinn, Kevin (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 5:06 PM
To: Nelson, Eric (NIH/NIMH) [E]; Hudson, Kathy (NIH/OD) [E]; Insel, Thomas (NIH/NIMH) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Jorgenson, Lyric (NIH/OD) [E]
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Do you still want us to work with Lyric to generate 3-4 talking points by tomorrow or should we just go with FBR?

Eric

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Subject: RE: Meeting with PETA

Thanks. Burklow will work with nichd and nimh comms to reach out to FBR. I do not think video will change reception of peta so I would not make that investment for this purpose. In fact, most folks are unaware that NIH has a bunch of primates and we might just be raising awareness that does not need to be raised....

I think we do responsive, rather than proactive, communications on this but will defer to Burklow.

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Subject: RE: Meeting with PETA

I concur with Tom's suggestion – FBR is really effective in messaging about the value of animals in biomedical research. Frankie Trull, the FBR CEO is very adept at this. Within NIH, I recommend that we engage Maggie Snyder from OER who is our lead on dealing with animal activists and has a lot of experience dealing with these organizations and defending the use of animals in research. I also suspect Pat Brown from OLAW would have a lot to say in developing good talking points on the value of animals in research and NHPs in particular.

I will coordinate development of talking points from my shop with John Burklow (we have plans to follow up) but I'd also suggest that we preemptively shoot some video ourselves that more accurately portrays the daily lives of NHPs in Poolesville. We could send someone from my Communications Branch to do a shoot tomorrow if people thought that might be useful to have in our back pocket.

Kevin

From: Insel, Thomas (NIH/NIMH) [E]
Sent: Thursday, June 26, 2014 11:18 AM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Guttmacher, Alan (NIH/NICHD) [E]; White, Pat (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Suomi, Stephen (NIH/NICHD) [E]; Stratakis, Constantine (NIH/NICHD) [E]; Raber, James (NIH/NEI) [E]; Nelson, Eric (NIH/NIMH) [E]; Quinn, Kevin (NIH/NIMH) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: Re: Meeting with PETA

Thanks for follow up note - sorry to miss this meeting. Concur re plans for July 2nd. Since this is likely a communications battle that is brewing, do you want to reach out to FBR? They are real pros on these issues.
Tom

On Jun 26, 2014, at 3:27 PM, "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov> wrote:

> Thank you all for joining me the other day to discuss the use of non-human primates in research. In line with our discussions, I have decided that it would be best if I meet with the folks from PETA on my own, especially to show that while I am willing to listen, NIH is not debating the scientific merits of this research with this organization.
>
> What would be helpful is if you folks could work with Lyric to generate the 3-4 salient points that articulate why NHPs are so invaluable to research, especially the behavioral research depicted in the video stream we discussed. I would like to concisely and firmly emphasize (and repeat as needed) NIH's position about the value of these animal models and highlight some of the advances they have enabled that have had a critical impact on human and animal health.
>
> Can we guys work with Lyric to pull something together by tomorrow, COB?

Thanks so much,

Kathy

Some of the outcomes of psychological research on NHP go beyond specific disorders and profoundly influence our understanding of the nature of development and social relationships. Two examples of this:

1.) A dramatic shift occurred in the 20th century in the role that different parenting styles were thought to have on development. In the first half of the century parents were instructed to be sparing with the love and affection they provided to their children in order to harden them up and prepare them for life. This began to shift in the middle of the century when psychologists started to understand the impact that positive parental love and the negative effects of neglect on child development. The NHP research of Harry Harlow (which is now continuing under Dr. Suomi) is thought to have played an important role in that transformation.

2.) NHP research on development played a key role in our understanding of the principle of critical periods in development. Much of this work was performed on the development of the visual system in the 1960s. There are now thought to be many different critical periods for the maturation of different brain networks. Many of the brain networks that are shared by NHPs do not exist in rodents.

Bordine, Roger (NIH/OD) [E]

From:	Burklow, John (NIH/OD) [E]
Sent:	Saturday, June 28, 2014 8:23 AM
To:	Hudson, Kathy (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject:	1-s2.0-S0896627314004930-main.pdf
Attachments:	1-s2.0-S0896627314004930-main.pdf; ATT00001.htm

FYI. From NIMH. Timely article about value of nhp research.

CellPress

Neuron
NeuroView

Basic Neuroscience Research with Nonhuman Primates: A Small but Indispensable Component of Biomedical Research

Pieter R. Roelfsema[1,2,3,*] and Stefan Treue[4,5,6,*]
[1]Department of Vision and Cognition, Netherlands Institute for Neuroscience, an institute of the Royal Netherlands Academy of Arts and Sciences, Meibergdreef 47, 1105 BA Amsterdam, The Netherlands
[2]Department of Integrative Neurophysiology, Centre for Neurogenomics and Cognitive Research, VU University, 1081 HV Amsterdam, The Netherlands
[3]Psychiatry Department, Academic Medical Center, 1105 AZ Amsterdam, The Netherlands
[4]Cognitive Neuroscience Laboratory, German Primate Centre, 37077 Goettingen, Germany
[5]Bernstein Center for Computational Neuroscience Goettingen, 37077 Goettingen, Germany
[6]Faculty of Biology and Psychology, Goettingen University, 37073 Goettingen, Germany
*Correspondence: p.roelfsema@nin.knaw.nl (P.R.R.), treue@gwdg.de (S.T.)
http://dx.doi.org/10.1016/j.neuron.2014.06.003

Research with nonhuman primates represents a small component of neuroscience with far-reaching relevance that is irreplaceable for essential insights into cognitive functions, brain disease, and therapy. Transparency and widespread information about this research and its importance is central to ensure the support of politicians and the general public.

Two main fields of human endeavor that have propelled mankind forward over the last centuries are engineering and, more recently, biomedical research. Neither our standards of living nor the quality and length of our lives would have been possible without these efforts. Biomedical research has provided us with deep insights into the physiology and anatomy of organisms. But despite the progress, we are far from a complete understanding of humans and other animals in health and in disease. While the likelihood to survive cancer has increased tremendously and patients with AIDS now have a chance for many years of survival after their diagnosis, we still lack a complete understanding of these and many other diseases that would allow for their prevention or a cure. This is even more true for the complex illnesses of the human brain.

A multitude of techniques developed in the last decades underpin the progress that has been made, allowing new insights into the most challenging biomedical questions. Among this tool chest of methods are studies in animals. Here the ethical challenges of weighing the intrusion into the lives and wellbeing of animals against the benefits derived for human patients are complex. Our knowledge-based societies have addressed this conflict by implementing legal and regulatory frameworks, such as the recent Directive of the European Union on the protection of animals used for scientific purposes (http://eur-lex.europa.eu/procedure/EN/197584) and the resulting national animal protection laws, which are built on the broad consensus across science, politics, and society that a certain amount of research on animals is necessary and justifiable. This consensus includes the 3R principles (Russel and Burch, 1959) of Replace, Refine, and Reduce as the shorthand for the three core requirements for animal research, namely to replace animal experiments with alternatives whenever possible, to continuously refine the methodology to make experiments as efficient and of the least possible impact on the animals, and to reduce research using animals as far as possible. Accordingly, animal research represents a minute fraction of the animals used and killed, voluntarily and involuntarily, by human societies. For example, in European countries for every single research animal, about 200–300 animals are killed for human consumption. Of the research animals used, more than 80% are rodents and less than 0.1% are nonhuman primates. Thus, we consume about 500,000 animals for every nonhuman primate in research.

Because of the broad public agreement that some animal research is necessary to ensure human health and medical progress, groups opposed to any animal research have refocused their broad assault onto just "basic" (as opposed to "applied") research and on nonhuman primates (as opposed to the vast majority of other species used). We will therefore focus here on basic neuroscience research with monkeys (nonhuman primates [NHPs]) as a relatively small but essential part of biomedical research. It has provided the basis for groundbreaking discoveries and progress but has also been the focus of very vocal and sometimes violent opposition from well-funded groups waging a campaign against animal-based biomedical research.

Research in Nonhuman Primates Has Elucidated Many Basic Mechanisms Underlying Cognitive Functions

Within neuroscience, the consensus is that research using NHPs has led to a greater understanding of the mechanisms of brain function and many of the processes that underlie brain diseases. One of the fields of neuroscience that has benefitted from NHP research is cognitive neuroscience. Its goal is to understand the causal relationship between neuronal activity and cognitive functions. An important advantage of NHPs as a model for

Table 1. Example Domains in Cognitive Neuroscience where Research with NHP Provided Decisive Insights

Perception and perceptual organization
Recognition of objects and faces
Attentional modulation of sensory information processing
Storage of information in working memory
Decision making
Sensorimotor transformations
Coding of categories and numerical information
Neuronal representations of reward, punishments, and reinforcement
Motor control (including readout for neuroprosthetic devices)
Mirror neurons
Fate of information that reaches consciousness and that does not

such research is that they can be trained to carry out relatively complex sensory discriminations and motor tasks and can learn to make new associations. Researchers have developed sophisticated techniques that allow recording of the activity of single neurons or small groups of them in various brain structures so that the brain mechanisms for these cognitive functions can be understood. Research with NHPs has identified the functional role of individual nerve cells and brain areas and then taught us that many cognitive functions rely on networks of such areas in the cerebral cortex and subcortical structures (Moore and Armstrong, 2003; Roelfsema, 2006). These networks have evolved differently in animal species. Of all animal models used in neuroscience, the monkey brain is most similar to the human brain (Mantini et al., 2013). Let us consider, for example, the well-studied visual system with its intricate hierarchical structure. Much progress has been made since the groundbreaking work of Hubel and Wiesel, who started the systematic study of neural information coding in visual cortex, leading to their Nobel Prize in 1981. Since their work, we have learned many aspects of the function and connectivity between the many cortical and subcortical areas of the primate brain (Felleman and Van Essen, 1991). This information has been an important guide for our understanding of how sensory brain regions interact with higher brain regions in the parietal, temporal, and frontal cortices and with the thalamus, basal ganglia, and cerebellum.

Researchers take advantage of the rich anatomical information amassed about the macaque brain to reveal the mechanisms underlying many cognitive functions. One such function that has been studied extensively in NHPs is visual attention, our ability to focus onto those aspects of the visual world that are relevant for a task, so that we can ignore distracting aspects. An early breakthrough in attention research was the demonstration that it is possible to measure the effects of allocating spatial attention by recording from single neurons in the visual cortex of rhesus monkeys (Moran and Desimone, 1985). This and many following studies showed that the activity of neurons that code attended visual stimuli increases, whereas the activity of neurons that code unattended information is suppressed. This finding was important because it was among the first to demonstrate that it is possible to study internal mental states at the single-cell level, in a controlled manner. Later studies revealed how the selection by attention comes in many forms and how it influences neuronal activity across many brain structures (Reynolds and Chelazzi, 2004), in accordance with the correspondence between cognitive functions and brain networks mentioned above.

Attention is but one example. There are many domains of cognitive neuroscience where the study of the NHP brain provided decisive insights into the underlying mechanisms. These domains include, but are not limited to, the neuronal mechanisms for object recognition, working memory, decision making, the guidance of motor behavior by sensory information, the neural coding of categories and numerical quantities, the processing of reward and reward expectations for reinforcement and learning, and the difference between information that does and does not reach consciousness (Table 1). A recent, particularly exciting contribution has been the discovery of mirror neurons (Rizzolatti and Craighero, 2004). These neurons code for the intentions of other individuals, and their discovery had a strong impact on theories for social cognition and theory of mind, i.e., theories about how the nervous system of one individual can code for thought processes and emotions of others.

NHP Research Has Provided Insight into Many Brain Diseases

Although the main aim of many of these studies is to gain fundamental insight into the neuronal underpinnings of our mental world, they have also impacted on our understanding of brain disease. It is therefore a flawed approach to define a divide between studies that address the fundamental neuronal processes for cognition and those that apply this knowledge to understand brain disease and to develop new treatments. Let us give a few examples to illustrate this point (see Capitanio and Emborg, 2008 for a more complete review of contributions of NHP research to so-called translational neuroscience).

First, an early and important example has been the development of deep brain stimulation (DBS), a medical technique that has provided relief to more than a hundred thousand people with Parkinson's disease. The development of DBS was inspired by the observation that a number of users of a drug produced in a clandestine home lab developed Parkinson's disease (Capitanio and Emborg, 2008). Research in NHPs ultimately led to the discovery that electrical stimulation of subcortical structures, such as the subthalamic nucleus, alleviate many of the symptoms of Parkinson's disease when they can no longer be controlled with drugs (Kringelbach et al., 2007). Studies of the functional properties of neurons in the monkey brain led to more accurate targeting of deep brain structures in humans and have been decisive in the development of this new treatment.

Second, the study of brain structures involved in reward prediction has

provided crucial insights into various psychiatric diseases, including depression, obsessive-compulsive disorder, and addiction (Howell and Murnane, 2008). These studies paved the way for clinical trials that target brain structures with DBS to improve the condition of patients with treatment-resistant psychiatric diseases (Mayberg et al., 2005). Third, insights into the brain mechanisms for attention have proven to be important for our understanding and treatment of the attentional functions compromised in attention-deficit/hyperactivity disorder (ADHD; Volkow, 2012) and the effects of brain lesions in patients with the neglect syndrome (Corbetta and Shulman, 2011). Fourth, the study of mirror neurons inspired new approaches to autism and schizophrenia (McCormick et al., 2012; Vivanti and Rogers, 2014). A final example is provided by several promising approaches for prosthetic devices, which capitalize on our understanding of the NHP's nervous system. One of the aims is to develop prostheses so that paralyzed patients can control an artificial limb with their thoughts. Proof of principle has been demonstrated in monkeys that learned to control a prosthetic arm based on neuronal activity in cortical areas involved in motor control (Velliste et al., 2008). Other aims include the development of vestibular implants to improve the balance of patients suffering from peripheral vestibular disorders and of visual prosthesis for the blind. Thus, basic research in NHPs contributes to our understanding and to the treatment of brain diseases, and the fundamental knowledge that has been acquired will enable future advances.

Research in Humans and Nonhuman Primates Is Complementary

NHP research helps with the interpretation of findings obtained with neuroimaging techniques in humans, and, vice versa, findings in humans aid in the interpretation of the results obtained in NHPs. fMRI is an important technique that helps identify the neuronal structures underlying cognitive functions in healthy human volunteers and patients. Yet, the relationship between the fMRI signals and spiking and synaptic activity is remarkably complex, the spatial resolution of the fMRI signal does not allow to monitor neural activity at a finer scale than across thousands of nerve cells, and the temporal resolution is in the range of seconds, whereas many cognitive functions unfold on a much shorter timescale. Imaging and recording studies in NHPs are therefore necessary to aid in the interpretation of these signals, because they allow the direct comparison between fMRI signals and spiking activity as well as other electrophysiological markers of neuronal activity (Logothetis et al., 2001). Other imaging methods such as EEG and MEG have a better temporal resolution but also a limited spatial resolution because they rely on the synchronized activity of vast numbers of neurons. These methods provide an important, yet indirect way to study the mechanisms by which brain cells encode and decode information and control behavior. Advances in the field require complementary studies with high temporal and spatial resolution during cognitive functioning. In exceptional cases, it is possible to record the activity of single neurons in the human brain, such as during neurosurgical interventions in patients with epilepsy. These studies are restricted to those brain regions that are implicated in the generation of the individual patient's epileptic seizures so that studies in experimental animals remain necessary for systematic explorations of brain functions. This is particularly true if we want to understand how processes in the healthy brain are disrupted by disease, so that we can interpret data from human patients.

An important advantage of NHP research is the possibility of causal approaches. If studies demonstrate that nerve cells in a particular brain region change their activity during perception, action planning, or other types of mental activity, they do not necessarily address the question of whether this activity plays a causal role or is an indirect consequence of activity changes in another brain region. Causal studies directly test the involvement of brain regions in cognitive functions. Take, for example, area V5/MT, an area of visual cortex where neurons code for the direction of moving visual stimuli. Do the V5/MT neurons really cause motion perception? This is precisely the question that Salzman et al. (1990) asked in a groundbreaking study. They showed that activating cells that code for motion to the right with weak electrical pulses biases the monkey toward perceiving rightward motion, thus providing direct evidence for the involvement of these nerve cells in motion perception. Other causal methods include the introduction of well-defined inactivations of brain areas and neuropharmacological interventions (Herrero et al., 2008). Such local or systemic application of drugs allows researchers to investigate the effects of specific neurotransmitters or their receptors on neurons in different brain areas and their influence on the animals' behavioral performance. With some exceptions, these methods cannot be used in humans and they complement noninvasive techniques that interfere with activity in the human brain, such as transcranial magnetic stimulation and transcranial direct current stimulation. The specificity of these noninvasive techniques is more limited than intracortical stimulation, and the mechanisms by which they influence neuronal activity are not yet well understood. As a consequence, NHP research will remain important for causal approaches to understanding brain function.

The set of techniques to influence neuronal activity has recently been expanded by the introduction of optogenetics into NHP research (Diester et al., 2011), allowing researchers to achieve even more control over the activity of specific neurons. Yet, the available methods for optogenetics in NHPs are still more limited than those for rodents, in particular for mice, where the methods for the cell-specific expression of light-sensitive proteins are much more advanced due to the availability of a large diversity of transgenic animals.

Complementary Approaches in Rodents and Nonhuman Primates

The impact of neuroscience studies with rodents has increased in recent years, mostly due to the availability of transgenic rodent models for neurological or neurodegenerative disease but also because of the many new methods for manipulating and monitoring neuronal activity such as optogenetics and genetically encoded markers for neuronal activity (e.g., Chen et al., 2013; Fenno et al., 2011).

Mouse studies are providing insights into brain structures by, for example, elucidating the different role of the various types of interneurons. It is an exciting prospect that researchers will increasingly use these techniques to elucidate cognitive functions.

However, some important aspects of human brain function are difficult to address in rodents. Take, for example, the forward-looking eyes of NHPs, which allows for the binocular processing that gives rise to the perception of depth and the similarity of color perception between humans and NHPs, which is different in rodents. The motor system in NHPs is also radically different from that in rodents, especially in terms of advanced hand function and control of many different types of grip (Courtine et al., 2007). Moreover, some higher cognitive functions are too complex and evolutionarily recent to be meaningfully studied in rodents.

Thus, the many important insights that are generated in rodents permit insight into mechanisms that are difficult to address with NHPs and, vice versa, results in the NHP will complement them for processes and cognitive functions that are hard to study in rodents. An interesting development in the study of cognitive functions is the search for NHPs other than the macaque monkey, such as the marmoset (Mitchell et al., 2014), which breed faster and thereby more readily permit the introduction of genetic manipulations.

Informing the Public about the Necessity of Research Involving NHPs and the Efforts to Minimize Harm

As documented above, basic neuroscience research with nonhuman primates has been and continues to be of paramount importance for past and future medical progress. This does not release researchers studying nonhuman primates (or other species) from the great responsibility they have in ensuring the best possible science with the least possible harm to their animals. The awareness of this responsibility is visible in initiatives such as the international Basel Declaration (http://www.basel-declaration.org) and the recent UK Concordat on Openness on Animal Research (http://www.understandinganimalresearch.org.uk/policy/concordat-on-openness-on-animal-research/). In addition, scientific associations are increasingly recognizing their responsibility in informing the public about the importance of animal research and the efforts made to ensure that animal experiments are of the highest quality and of the least possible impact on the animals. Impressive examples of such information platforms are the UK's Understanding Animal Research (http://www.understandinganimalresearch.org.uk), France's Gircor (http://www.recherche-animale.org), and the BrainFacts website of the U.S. Society for Neuroscience (http://www.brainfacts.org). Noticeably absent from this list is a corresponding centralized source of high-quality information in Germany where the large research organizations have not yet been able to agree on the best approach. Similarly patchy has been the support in some of the larger research nations for ensuring the personal safety of researchers and providing the support for the best possible circumstances for the research animals. Most recently, this has been apparent in the silence of most European and American governments in the face of current tactics of antiresearch organizations to prevent responsible animal research by pressuring airline companies to stop transporting research animals. A notable exception was the statement by David Willetts, the UK Minister of State for Universities and Science, who spoke out to support the airlines transporting NHPs. Air transportation is in many cases beneficial for the monkeys, preventing longer and more stressful journeys by truck.

In summary, human societies have managed to develop a set of laws and regulations ensuring medical and scientific progress with the least possible harm to animals, resulting in a standard of human health and wellbeing that would have been unimaginable just a few generations ago. To ensure the public acceptance of this consensus, animal researchers need to embrace their responsibilities and communicate about the importance of animal research and the care taken in research with animals. Similarly society, through its policies and politicians, needs to protect and support responsible animal research that secures the scientific progress ensuring our standards of living as well as the quality and lengths of our lives.

ACKNOWLEDGMENTS

We thank Roger Lemon and Michael Goldberg for helpful comments. P.R.R. received funding from the European Research Council under the European Union's Seventh Framework Program (FP/2007-2013) / ERC Grant Agreement n. 339490. S.T. was supported by the Deutsche Forschungsgemeinschaft through Research Unit 1847 and by the EU-funded network EUPRIM-NET (http://www.euprim-net.eu).

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Bordine, Roger (NIH/OD) [E]

From: Rockey, Sally (NIH/OD) [E]
Sent: Tuesday, July 01, 2014 4:57 PM
To: Hudson, Kathy (NIH/OD) [E]
Subject: TBRI review
Attachments: Report_on_OLAW_Visits_to_Chimpanzee_Facilities.pdf; Pages from A3082-01 _Corresp.pdf; 157140935450164.pdf

OLAW did not participate in the routine inspection conducted by USDA on June 2, 2014. OLAW has site visited TBRI twice in the last five years. In May, 2009, the TBRI facilities were site visited as part of the OLAW review of all chimpanzee holding facilities. The summary report from those visits is attached. In September 2011, in response to allegations about the health of chimpanzees transferred to TBRI from the Alamogordo Primate Facility, OLAW and USDA conducted a joint site visit and inspection. The findings from that visit are attached.

As TBRI is one of the few remaining active chimpanzee holding facilities, it may be site visited when OLAW assesses ethologically appropriate housing options available to NIH. The site visit plans are not definitive at this time.

OLAW has reviewed the USDA report and is following up with TBRI about the citations and corrective actions TBRI is taking. A copy of the USDA inspection report is attached. OLAW would be happy to answer any additional questions about OLAW's oversight. It would be useful for you, Francis and Larry to hear from OLAW on how they function and their responsibilities. I'll set something up.

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From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, June 30, 2014 10:17 PM
To: Rockey, Sally (NIH/OD) [E]
Cc: Anderson, James (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: Texas Biomedical Research Institute

Thanks Sally. So it looks like there are ~33 M dollars of NIH money at Texas Biomed. Did OLAW go with USDA on this site visit? Did they generate a report? When was the last time OLAW visited Texas Biomed? Might they be planning a visit now?

From: Rockey, Sally (NIH/OD) [E]
Sent: Monday, June 30, 2014 5:05 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Anderson, James (NIH/OD) [E]
Subject: RE: Texas Biomedical Research Institute

Yes, they have been very involved and monitor all USDA reports. In fact USDA and OLAW collaborate regularly and often site visit together (except government facilities which ironically don't fall under USDA law).

The care and use of animals comes into play many places, including in peer review of the original application and during the progress of the research, for example if there is an issue pointed out in the RPPR (progress report). Program officers generally do not do systematically monitoring although they are to have their ears to the rails, sort of speak, with many different type of programmatic issues that may raise compliance concerns (FCOI, HS, Animal). However the grantee institution **must** self report non compliance with the PHS policy, and this is where the vast majority of cases arise. This is required by PHS policy and USDA law and there are hundreds of self reports, most minor but some more serious. In addition, other cases are brought about from many sources, IACUCS, the public, advocacy groups, and by PIs and others at grantee institutions. OLAW has the primary responsibility and does site visits on a fairly regular basis but can only hit a few of the institutions each year for their proactive site visits because of the magnitude of organizations that have animal programs. Also they are responsible when there are findings by OLAW or the USDA to bring the programs back into compliance.

Also between IACUCs and ALAC (and there are many lab animal professional organizations) there is a very strong community that deals with these issues.

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From: Hudson, Kathy (NIH/OD) [E]
Sent: Monday, June 30, 2014 4:32 PM
To: Rockey, Sally (NIH/OD) [E]
Cc: Anderson, James (NIH/OD) [E]
Subject: FW: Texas Biomedical Research Institute

I assume your OLAW folks monitor USDA inspections but wanted to share just in case.

Also, Sally, what obligations do our program folks have to be aware of and monitoring care and use for animals involved in nih supported research?

From: Tracie Letterman [mailto:tletterman@humanesociety.org]
Sent: Monday, June 30, 2014 3:26 PM
To: Hudson, Kathy (NIH/OD) [E]; Anderson, James (NIH/OD) [E]
Subject: Texas Biomedical Research Institute

Dear Kathy and Jim,

I hope your summer is going well. I wanted to follow up with you regarding the complaint we filed with USDA regarding Texas Biomedical Research Institute. The USDA posted an inspection report today, which I have attached. As you will see, the findings reinforce what we found at the facility-failure to properly monitor social groups, resulting in injuries,

and failure to provide medical treatment of wounds, which led to the death of a baboon. Additionally, the facility isn't properly reporting when animals are involved in research that causes unrelieved pain and distress. We were told by USDA today that there is also a case pending with Investigative and Enforcement Services.

The conditions at Texas Biomed raise serious concerns for us and getting the government-owned chimpanzees out of that facility is a top priority for us, as was reflected in the sanctuary plan. I know an assessment of those animals is underway, but I do hope these findings will reinforce the need to retire those animals as soon as possible into existing space at Chimp Haven.

Thank you so much, in advance, for considering this additional information.

Best,
Tracie

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Report to Office of Extramural Research Acting Director on Office of Laboratory Animal Welfare (OLAW) Site Visits to Chimpanzee Facilities – July 2010

INTRODUCTION

This report summarizes the results of a series of site visits to institutions that receive funds from the National Institutes of Health (NIH) for research and maintenance of chimpanzees. The objectives of the visits were to determine whether these institutions' programs and facilities for the care and use of chimpanzees were consistent with their Animal Welfare Assurance (Assurance) with OLAW and to evaluate the current state of social housing, husbandry, enrichment, veterinary care, and training practices for chimpanzees.

BACKGROUND

As a condition of receipt of Public Health Service support for research involving laboratory animals, institutions must provide a written Assurance to OLAW describing the means they will employ to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). OLAW negotiates and approves these Assurances on behalf of the Director, NIH. Each Assurance is a detailed document tailored to the individual institution's needs, research practices, and procedures. It must be consistent with the PHS Policy. An Assurance approved by OLAW commits the institution and its personnel to full compliance with the PHS Policy, the applicable regulations (9 CFR, Subchapter A) issued by the United States Department of Agriculture under the Animal Welfare Act, and the *Guide for the Care and Use of Laboratory Animals (Guide)*. Through the partnership established by the Assurance, the shared responsibility for the welfare of laboratory animals is discharged in accordance with Section 495 of the Public Health Service Act.

In March 2009, OLAW received from the Office of the Secretary of the Department of Health and Human Services a list of allegations made by the Humane Society of the United States (HSUS) of potential noncompliance with the PHS Policy and the *Guide* at the University of Louisiana – Lafayette, New Iberia Research Center (NIRC). The allegations were accompanied by undercover video footage obtained by a HSUS informant who had worked at the facility for nine months. The same allegations were presented to the Secretary of Agriculture who directed Animal Care (AC) of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA) to conduct inspections of registered research facilities housing chimpanzees and assess current housing, husbandry, and handling practices. In order to investigate the allegations made against NIRC and to conduct a cross sectional evaluation of all Assured institutions housing chimpanzees, OLAW began a year long series of site visits, many of them conducted in conjunction with the USDA inspections.

The following institutions were visited:

University of Louisiana – Lafayette, NIRC (Louisiana)
Bioqual, Inc. (Maryland)

University of Texas, MD Anderson Cancer Center (Texas)
Southwest Foundation for Biomedical Research (Texas)
Emory University/Yerkes National Primate Research Center (Georgia)
Georgia State University (Georgia)
Chimp Haven (Louisiana)
Great Ape Trust of Iowa (Iowa)
NIH/Alamogordo Primate Facility (New Mexico)

FINDINGS

Overall, the institutions housing chimpanzees were found to be in compliance with PHS Policy.

Social Housing and Enrichment of Chimpanzees

The chimpanzees were, with rare exception, socially housed. They had complex and stimulating environments, were provided with environmental enrichment in the form of manipulanda and food treats, and had positive interactions with the staff. In cases where an animal was singly housed due to study requirements or incompatibility with other animals, efforts were made to provide enrichment and return the animal to a partner as soon as feasible.

Training of Chimpanzees

Many institutions had successfully trained the chimpanzees to cooperate with requests from handlers such as moving between enclosures and allowing ready access for procedures such as obtaining body temperatures, blood, or other biological samples. In cases where animals were not trained or cooperating, institutions utilized a variety of handling methods for the conduct of procedures or administered anesthetics or tranquilizers including use of dart guns.

Husbandry and Veterinary Care of Chimpanzees

Without exception, the quality of care being provided was uniformly high and supported by dedicated and knowledgeable animal care teams with integrated animal behavior and enrichment professionals. The veterinary care included state of the art resources rivaling major human medical centers.

Social Housing of Other Nonhuman Primates

Many of the facilities visited also housed other nonhuman primates such as macaques and squirrel monkeys. Regarding these species, the numbers of animals being socially housed varied among facilities. In some institutions the majority of primates were housed with conspecifics whereas in others most animals were singly housed. Reasons given for single housing included lack of appropriate caging or study requirements limiting pair or group housing.

CONCLUSIONS AND RECOMMENDATIONS

Overall the institutions were found to be in compliance with the PHS Policy and the quality of care and commitment to the psychological well-being of the chimpanzees and other nonhuman primates was high. The following issues were identified as requiring further enhancement:

- In situations where it is safe and feasible, chimpanzees and other nonhuman primates should be given positive reinforcement training to perform desired cooperative activities. This type of training may also aid in reducing stress from capture and restraint and the need for chemical darts.
- Housing of primates in social settings (pairs or groups) is the requirement of the USDA regulations and single housing is the exception. Greater effort must be made to co-house animals. Exemptions to the social housing requirement must be based on strong scientific justification approved by the Institutional Animal Care and Use Committee or for a specific veterinary or behavioral reason. Lack of appropriate caging does not constitute an acceptable justification for exemption.

In order to assist these facilities and the larger community in enhancing the care and well-being of nonhuman primates in the research setting, the following actions have been planned and are being implemented:

1. OLAW in consultation with USDA Animal Welfare Information Center (AWIC) will provide online resources addressing positive reinforcement training practices for nonhuman primates.

2. OLAW and USDA Animal Care have addressed or will address the social housing issue in various forums. These include:
   - a joint workshop at the Public Responsibility in Medicine and Research (PRIMR) meeting in March 2010;
   - a training presentation with the added assistance of USDA AWIC to the USDA Veterinary Medical Officers in April 2010;
   - a joint webinar by OLAW, USDA Animal Care and AWIC recorded and available on the OLAW website in summer 2010;
   - expanded guidance on the OLAW website as Frequently Asked Questions; and
   - presentation of the issue at other professional meetings.

Through the educational efforts outlined above and proactive engagement by research institutions, nonhuman primates should be afforded enhanced social housing opportunities and positive reinforcement training resulting in improved animal welfare.

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

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Rockledge One, Suite 360
6705 Rockledge Drive
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Telephone: (301) 496-7163
Facsimile: (301) 402-7065

DATE: September 13, 2011

TO: Assurance Folder A3082-01

FROM: Director, Division of Compliance Oversight, OLAW

SUBJECT: Site Visit Findings to Texas Biomedical Research Institute

On September 7, 2011 a joint site visit was conducted by veterinary representatives from the Office of Laboratory Animal Welfare (OLAW) and the U.S. Department of Agriculture (USDA) to assess the status of fourteen chimpanzees which had been transferred from the Alamogordo Primate Facility (APF) to the Texas Biomedical Research Institute (TBRI) in 2010. The site visit team examined the husbandry, housing, health status, psychological well being, veterinary care, environmental enrichment, and research status of these specific animals. The findings are as follows:

- The fourteen chimps were housed in their original (same composition as at APF) compatible social groups subdivided into four females, four males, and six males. All chimpanzees appeared to be calm, well adjusted, and compatible upon observation.

- All fourteen chimpanzees were closely observed by the site visit team and appeared to be in excellent health. One animal (4X0539 Elijah) had evidence of some treated and healing skin abrasions sustained in an unprovoked competition for food with a pen mate that was quickly resolved and has not recurred. This animal also has a minor umbilical hernia which will be scheduled for surgical repair. One individual (4X0215 Rosie) was reported within the last year to have sustained a cut to her sex skin which was treated with antibiotics and has healed. All chimpanzees have good hair coats and are in appropriate body condition. None of these animals are currently in need of or receiving any form of medication except for one animal receiving vitamins.

- All chimpanzees are housed with compatible conspecifics and receive some form of ongoing environmental enrichment consisting of provision of manipulanda, climbing opportunities, tire swings, and daily varied food treats. A staff of six behaviorists provide the enrichment for the TBRI animal population. The staff also provides ongoing training of animals to voluntarily perform tasks such as moving between pens and into transfer crates as well as having animals present for injections or sample taking. All fourteen chimpanzees have been successfully trained to present for injection and to willingly enter transfer boxes.

- The housing consists of a primadome, a "condominium", and a "hotel." All housing is compliant with the provisions of the *Guide for the Care and Use of Laboratory Animals*. New space is currently being renovated and the animals in the condos and hotels will be moved to this area by the end of November, 2011.

- An active pest control system is in place. The food storage cooler and behavioral treat preparation kitchen were clean and orderly.

- The medical, behavioral, and Institutional Animal Care and Use Committee records are thorough and well organized.

- All fourteen chimpanzees are currently on a holding protocol which covers routine husbandry and veterinary care including diagnostic tests. No research studies are currently underway with this group of animals.

- The husbandry, behavior, and veterinary teams are extremely well trained and experienced to handle chimpanzees of all ages and are extremely attentive to the needs of the animals. The upper administrative staff is committed to providing adequate resources to maintain a compliant program of animal care and use.

OLAW found the chimpanzees to be in excellent condition and receiving appropriate husbandry and veterinary medical care as well as having their psychological well being adequately addressed. OLAW found no evidence of noncompliance with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for the housing or care of the fourteen animals in question.

Axel Wolff, MS, DVM

Axel Wolff, M.S., D.V.M.

USDA

United States Department of Agriculture
Animal and Plant Health Inspection Service

EPANNILL
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Inspection Report

Texas Biomedical Research Institute
P. O. Box 760549
San Antonio, TX 78245

Customer ID: **1512**
Certificate: **74-R-0003**
Site: 001
SOUTHWEST FOUNDATION FOR BIOMEDICAL RESEARCH

Type: ROUTINE INSPECTION
Date: Jun-02-2014

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Records were reviewed for one young male baboon,30938. They state he died as a result of septicemia from trauma wounds. Clinical records indicate that this animal had a clean health check and was in good body condition approximately 3 weeks before his death. At time of the health check on 10/28/13, the animal was relocated to a new enclosure which housed a large number of male baboons. Daily observational logs during this time period do not document an animal with wounds. They do not indicate any behavioral observation of the newly introduced animal for acceptance into the group. The necropsy report states the animal was emaciated at time of death and had multiple scabs from bite wounds on the body and a large abscess on the leg and ankle. The description of the wounds and body condition indicate that the animal had injuries for many days before its death. The animal received no care for his injuries as it was not identified or reported to the veterinary staff.

Records were reviewed for an adult female rhesus, 29458. This animal was placed in a newly formed group of conspecifics in building 134 in March 2013. Sometime prior to September 2013 this animal suffered a tail de gloving injury. On October 30, 2013 the animal was involved in a second traumatic episode and sustained injuries that included multiple lacerations to the face and body. A portion of the tail was also amputated during the altercation. A staff veterinarian stated during this inspection that the injuries were severe enough to warrant assessment of the group by the facility behavior team. There is no documentation that any behavior assessment of the individual or group was performed post injury.

An adequate program of veterinary care includes daily observation of all animals to assess their health and well-being. Daily observation may be accomplished by someone other than the attending veterinarian, but there must be direct and frequent communication so timely and accurate information on problems with animal health, behavior and well - being is conveyed to the attending veterinarian.
Newly introduced animals must be observed for adjustment issues and animals with trauma wounds must be promptly identified and the behavior and vet staff promptly notified for intervention to provide adequate veterinary care to the animals.
CORRECT BY : 6-10-14

Prepared By: ELIZABETH PANNILL, D.V.M.
ELIZABETH PANNILL, D.V.M. USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER Inspector 4018
Date: Jun-06-2014

Received By: (b)(6),(b)(7)(c)
Title:
Date: Jun-06-2014

Inspection Report

2.36 (b) (7) **REPEAT**

ANNUAL REPORT.

The annual report submitted for 2013 does not accurately report the number of animals involved in studies that had accompanying pain or distress that did not receive anesthetic, analgesics or tranquilizing drugs as the administration of such would have adversely affected the results of the project. One non human primate on protocol,1327 CJ ,was improperly reported. The annual report must be amended and resubmitted to include an accurate count of the number of animals affected.

The inspection and exit briefing was conduced on June 2-4 2014 with the attending veterinarian and facility employees.

Prepared By:	ELIZABETH PANNILL, D.V.M.	
	ELIZABETH PANNILL, D.V.M. USDA, APHIS, Animal Care	**Date:**
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