
EVIDENCE OF MISCONDUCT IN DANISH-CDC COLLABORATION

MISMANAGEMENT & INTENTIONAL COLLUSION BY CDC STAFF WITH PRINCIPAL INVESTIGATOR POUL THORSEN

Poul Thorsen Report 2017

CDC-Danish Contract Autism Research Related to Vaccines

Beth Clay for the World Mercury Project

13 NOVEMBER 2001 – CDC DIANA SCHENDEL SEEKS SOLE SOURCE CONTRACT FOR DANISH COLLABORATION

WHO: NCBDD (Lisa Garbarino, Diane Schendel, Tom Horn, Larry Wilkenson)

NOTES: The meeting was held to discuss a sole source program announcement (02006) for Danish Medical Research Council (DMRC). The issues discussed were: OMB Clearance to not abide by the Paperwork Reduction Act, I.R.B., Project Period, Award Schedule, 1267, last FY's supplemental funds, Suspense/Award Procedures and a missing Payment.

1) OMB Clearance- Diane has been in contact with OMB regarding not abiding by the Paperwork Reduction Act. They have not responded back to her as of yet. When she hears from them she will forward me their response for the official file.

13 NOVEMBER 2001 – CDC DIANA SCHENDEL SEEKS SOLE SOURCE CONTRACT FOR DANISH COLLABORATION-CONTINUED

2)I.R.B.- The DMRC's I.R.B. process is different. Their I.R.B. is in effect for the entire length of the project. The question is how can we set make record of this and meet our federal requirements?

3)Project Period- It has been requested that this grantee be allowed a five year project period instead of the 3 year period stipulated in the HHS Policy Statement.

4)Award Schedule-A copy of the award schedule was supplied to me by Lisa, who stated that it had been determined by NCBDD and the previous Grants Specialist.

13 NOVEMBER 2001 – CDC DIANA SCHENDEL SEEKS SOLE SOURCE CONTRACT FOR DANISH COLLABORATION-CONTINUED

TO DO:

- 1)Talk with Virginia Talley regarding I.R.B. requirements
- 2)Check in to obtaining a waiver from HHS for a 5 year project period
- 3)Followup with program for the funding documents
- 4)During Budget Negotiations talk with grantee about Domestic Banking and Procedure to change the PI
- 5)Research Missing Payment

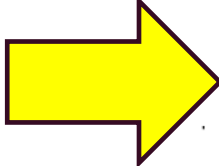
15 NOVEMBER 2001 – NOTE OF ANGELIA HILL, CDC GRANTS MANAGEMENT SPECIALIST

FOLLOWUP

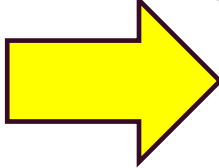
WHEN: November 15, 2001

WHO: Virginia Talley and Diane Schendel

NOTE:



Talked with Virginia Talley regarding the I.R.B. for Danish Medical Research Council(DMRC). Virginia stated that all grantees that accept Federal Funding must abide by Federal Laws. Thus DMRC must have their I.R.B. review human subject activities annually.



Talked with Diane and made her aware of my conversation with Virginia.

In addition on November 14, I talked with Dorimar Rosado regarding the Project Period. It was agreed that we would attempt to obtain a waiver and have a 5 year project period.

15 JANUARY 2009 – CDC STAFF NOTIFIED OF MISSING \$

Fra: Søren K. Kjærgaard

Sendt: 15. januar 2009 11:32

Til: Dorte Hejl

Emne: Resuming the projektactivities

Dear Diana, Nassi and Poul

The information that CDC considers the old project (Cooperative Agreement UR3/CCU018305) as closed financially (Anne Christiansen told us so after your telephone meeting with her the 6th January 2009) was a surprise. Poul has told us, and Aarhus University actually received a copy of a letter to Knud Gundersen and Poul Thorsen signed by Randolph B Williams in march 2008 that the 894.814\$ was still available in the project (see attached copy of letter). However, I understand that Anne Christiansen intends to follow up on this matter with Randolph B. Williams at PGO to get information on the whereabouts of these money.

CDC LEAD SCIENTIST AND PRINCIPAL INVESTIGATOR INTIMATELY INVOLVED

Emails between Diana Schendel and Poul Thorsen on her government account confirm what many long suspected - Schendel and Thorsen maintained a personal, intimate relationship at least as early as 2002. Their email communications confirm that they traveled on romantic vacations and exchanged expensive gifts.

This violates ethics rules for US federal employees.

APRIL 21, 2009 – CDC MANAGERS NOTIFIED OF 330 EMAILS FOUND BETWEEN SCHENDEL AND THORSEN USING “LOVE” AS SEARCH TERM

From: Wojcik, Joanne (CDC/CCHP/NCBDDD)

Sent: Tuesday, April 21, 2009 5:27 PM

To: Carlton, Darlene (CDC/OCOO/OD)

Cc: Ghosh, Sudevi (CDC/OCOO/OD); Yeargin-Allsopp, Marshalyn (CDC/CCHP/NCBDDD); Wojcik, Joanne (CDC/CCHP/NCBDDD); Kipreos, Victoria (CDC/CCHP/NCBDDD)

CONTINUED: APRIL 21, 2009 – CDC MANAGERS NOTIFIED OF 330 EMAILS

Good Afternoon: This is a followup to this afternoon's discussion. I have provided as a PDF a select group of emails from Diana Schendel's email box. This info was previously requested as a part of a larger ITSO email box review related to a Denmark cooperative agreement.

ITSO provided me a DVD with a 'snapshot' of Dr. Schendel's email box. When I did a word search on 'love' I was able to retrieve approx 330 emails. Attached is a smaller grouping of emails related to this afternoon's discussion.

JULY 14, 2009 EMAIL TO COLEEN BOYLE & OTHERS NOTES SPECIFIC GIFTS EXCHANGED BETWEEN SCHENDEL AND THORSEN

You also asked that I provide add'l info re any potential gifts. Included in this email grouping are below discussions concerning potential gifts.

PDF Page 13, 11/12/2006, gift of 2 Rosendahl wine carafes from P Thorsen to D Schendel.

PDF Page 22, 2/1/04, gift of earrings from P Thorsen to D Schendel.

PDF Page 24, 11/19/03, gift of sword?? from D Schendel to P Thorsen.

PDF Page 27, 4/27/03, discussion of retreat in the North GA Mountain (D Schendel & P Thorsen).

10 JULY 2009: BOYLE TO SCHENDEL – DO NOT CONTACT THORSEN ON BEHALF OF CDC

-----Original Message-----

From: Boyle, Coleen (CDC/CCHP/NCBDDD)
Sent: Friday, July 10, 2009 3:24 PM
To: Schendel, Diana (CDC/CCHP/NCBDDD)
Cc: Yeargin-Allsopp, Marshalyn (CDC/CCHP/NCBDDD)
Subject: RE: Svar: RE: LETTER TO THE DANISH AGENCY & UNIVERSITY OF AARHUS

Diana:

I appreciate your clarifying the work that is underway at the lab and the case information that they have. Let's look at the bio panel that David sends and give some thought to its usefulness and the commitment of funds to complete the work.

Also, please do not contact Poul about additional activities. It is best that all future correspondence to Poul about the project from CDC come from me.

Thanks,

Coleen

FROM THE OUTSET THE CDC-DANISH PROJECT WAS TAINTED DECEMBER 2002 – EVIDENCE OF ESTABLISHED RELATIONSHIP

LOVE, HUGS and see you very soon!
Poul

-----Oprindelig meddelelse-----

Fra: Schendel, Diana [mailto:dcs6@cdc.gov]

Dato: 31. december 2002 03:55

Til: Poul Thorsen

Emne: Coffee mug flashbacks

Hello love,

You have been at the front of my thoughts all the long day, but even so you burst like a rocket through my mind when I unexpectedly saw your coffee mug in my kitchen cabinet this evening.

One of the dark blue ones from the summer house. I had taken it with me, filled with strog coffee, when I left the house for my drive to Billund a few weeks ago. I debated whether I should take the liberty of taking the mug without asking, but I really needed the caffeine to keep me alert on the drive. I was very tired and sleepy and all-night diners serving coffee to drowsy drivers don't seem to be part of the highway scene in Denmark. In the end, I decided you wouldn't mind.

What a blast to my imagination and memory. Scene after scene, of me, of you, of us both, in the summerhouse flying through my mind in an instant.

Transported. By a small blue cup.

Dear Diana,

Thank you so very much for the nice letter – I love you and I love to read these small notes and descriptions of life and weather in Atlanta. I just finished the exam-questions for the students and proper answers too, and tomorrow will be a new teaching day. However, on my trip this late afternoon, there was this glooming reddish light over the sea and at the same moment a full moon rising – that made me think of you and times with you! Keep the spirit high – someone is thinking of you and someone is waiting for you You know the person very well!!!

Hugs and kisses across a red sea,
Poul

-----Oprindelig meddelelse-----

Fra: Schendel, Diana [mailto:dcs6@cdc.gov]

Sendt: 16. februar 2003 23:04

Til: Poul Thorsen

Emne: wet Sunday afternoon

Hello love,

I am just about ready to leave the office for home and wanted to get in touch with you. I have been here this afternoon working on a backlog of promised-work-that-I-never-got-done related to the autism centers c-c study. The extra benefit will be that all this increased familiarity with autism that I am slowly acquiring can be applied to our DNBC autism application!

But I don't want to talk about work. It's a real February sunday - tons of rain, low low clouds, bone-chilling wet (not freezing, but temp about 3-5 degrees), wisps of fog, blurry lights, fragrance of wood smoke from chimneys in the air, empty streets. I brought a candle from home and lit it here - watching the flame now and thenfunny thing its relaxing, but also provides a focus for my thoughts.

Actually, I don't have much to say, but it was worth it to sit here for a bit and think about you. I have enjoyed these past minutes with you. Hugs can fly, you know, with proper encouragement and without regard for time or weather. Well, here's one from me.... a bit musty from damp wool and wood smoke, but with a faint scent of perfume - like a memory.

We need to hold onto those memories over weeks and months, hold tight tight.

I love you,
D.

Love Notes from the
CDC Senior Scientist
Overseeing a \$16 million
project!

IN NOVEMBER 2002, THE DANES ARE DEALING WITH THE REJECTION OF THEIR THIMEROSAL PAPER FROM JAMA AND SEEK CDC'S HELP WITH PEDIATRICS

From: Schendel, Diana
Sent: Tuesday, November 26, 2002 9:44 AM
To: Boyle, Coleen
Subject: FW: Autism thimerosal paper - cover letter

Diana doing Poul's bidding on promoting paper.

Hi Coleen,

I read through this quickly and it still needs a bit of work, but about Poul's request - what do you think? If you want to prepare the letter, I could take it with me - but ask that they not send it until all our comments are resolved. (or send it without the letter - whichever they prefer).

Let me know - thanks, Diana

NOVEMBER 26, 2002: BOYLE AGREES TO DRAFT LETTER FOR DR. CORDERO, CDC TO SEND WITH THIMEROSAL PAPER AS A MOTIVATOR TO PEDIATRICS EDITORS

From: Boyle, Coleen
Sent: Tuesday, November 26, 2002 2:10 PM
To: Schendel, Diana
Cc: Cordero, Jose
Subject: RE: Autism thimerosal paper - cover letter

I will prepare the letter for Jose's signature -- but won't get to it until next week. I would suggest that it accompany the submission as support of the importance of the work. I can fedex it so it arrives late next week.

Jose: We need to discuss. thx

Pediatrics upon receiving the paper with cover letter from the Division Director, Dr. Jose Cordero quickly accepted it and published it in the September 2003 issue.

DECEMBER 13, 2002: SCHENDEL ASKS POUL & DANISH TEAM HOW TO DISCUSS STUDY WITH CONGRESS RATHER THAN HER SUPERVISORS

Hi Kreesten and Poul,

We are having persistent questions from one of the congressional offices about data on the prevalence of autism in Denmark - in response to the NEJM article. I keep telling them that the information has been submitted for publication, I am not a co-author, and I can not give out any information that is under peer review (apart from the fact I don't have the actual data) - professional courtesy and ethics (and good science practice) just will not allow such mishandling. Coleen has been saying the same thing when they go to her (I didn't know that!).

But, they have now asked if we can tell them the subject matter of the paper. So, what do you feel about this - telling them it's an ecologic study of thimerosal use and autism rates over time in Denmark - period. Don't feel like you have to say yes to this request - no pressure at all. Hopefully the paper will be published and they'll see it soon anyway. Let me know what you think - Monday if possible. I don't have Marlene's email anymore, so please forward to her. Again, absolutely no pressure to comply. And we wanted to get your permission before we say anything

19 APRIL 2009 -NOTICE OF THORSEN RESIGNATION

From: Anne Christiansen [mailto:anch@fi.dk]

Sent: Sunday, April 19, 2009 8:58 AM

To: Irannejad, Nosrat (Nassi) (CDC/CCHP/NCCDPHP); Williams, Randolph B. (CDC/OCOO/PGO)

Subject: Reg. 5 U10 DD000230 - DD07-001

Dear Nassi & Randolph,

With this email I wish to officially confirm that co- principal investigator Poul Thorsen has resigned from his position at University of Aarhus. Consequently, research activities and spending of funds related to project year 3 (budget period 01022009 - 31012010) has been put on hold until a solution has been found with regards to the principal investigator issue.

Kind regards

Anne Christiansen

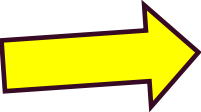
14 MAY 2009 – DIANA SCHENDEL OFFICIALLY REPRIMAND

Charge: Unethical or improper use of official authority or credentials

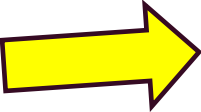
Specification 1: As part of an ongoing investigation related to funding irregularities with the Denmark Cooperative Agreement (-018305 and DD-0230), CDC staff members were authorized to search all e-mails of those in authority related to the Denmark Cooperative Agreement. In so doing, it was discovered that a long term relationship of a romantic nature has been ongoing between you and the Principal Investigator (PI) for the Denmark project, Dr. Poul Thorsen. During this review, it was also noted that information of a sensitive/budgetary/programmatic nature was shared by you with the grantee (Dr. Thorsen). In addition, intense advocacy to the point of impartiality and lack of objectivity on your part for the Denmark project has been witnessed and reported by others to your immediate supervisors. Because of this personal relationship, and your official activities as the scientific lead for the Denmark project, there is an appearance of impropriety and lack of appropriate judgment on your part related to the project. Information about the nature of the relationship was apparently known by many outside CDC and has subsequently come to the attention of leadership within the NCBDDD as well as at Emory University where Dr. Thorsen now has an academic appointment. Because of the perceived conflict of interest and lack of objectivity related to the project, you are being directed to suspend all activities as the lead Science Collaborator for this Cooperative Agreement. You will be able to complete analyses already begun, as to be determined by your immediate supervisor.

JUNE 8-12 SITE VISIT REPORT TO FILE – DR. BOYLE FUDGES

Dr. Boyle merges the Autism-CP ethical clearance in order to make it appear like the autism approvals are in place – they are not. (This is how she orchestrates the cover-up)



Autism/Cerebral Palsy Medical Records Abstraction Update: Coleen Boyle and Joanne Wojcik met with Aarhus University Hospital, Skejby. Lars Jorgen Østergaard and Inge V. Arbs provided an update concerning their activities related to this grant. Currently they are abstracting data on cerebral palsy children. All of their abstractors are 4th medical students. Twelve students were trained last year and they plan on training an additional group of new students this year. The Medical students take a 2 day introductory course where they then are given the opportunity to score high enough on test histories. Once they succeed in scoring, they are then given a license to work in “Q Docs”. They gain from this experience more indepth knowledge related to histories and medical, records. The Q Docs server is located at Skejby. They have approximately 24 laptops that transmit through a secure data network to the server at Skejby.



Lars mentioned that there is no hospital review board but they do have an ethics committee. He also mentioned that Poul Thorsen received all human subjects approval for this project.

Truth is that Dr. Boyle appears to never report up the chain of command is that the Danes concluded that Poul Thorsen never even requested ethical clearances for autism studies

10 NOVEMBER 2009 – CDC STAFF MEETING WITH DANES INCL THORSEN
BOYLE, SCHENDEL, YEARGIN-ALLSOPP, RICE, NAARDIN, WOJCIK PRESENT

Denmark Grantee Autism/CP Call
November 10, 2009
8 am Eastern/2pm Denmark

W/10/09
Exhibit 6

Action List/To Do Items (consolidated listing):

1. Søren and Carsten to provide an SSI update on our next call.
2. Poul is requested to provide Aarhus University a copy of all permissions in his files ASAP.

10 NOVEMBER 2009 – CDC STAFF MEETING WITH DANES INCLUDING THORSEN -CONTINUED

Autism Update

Autism register data

Marshalyn asked if Aarhus University can work with Danish Psychiatric Data. Poul stated that this is the registry based data regarding vaccines. Permission should already be in place from the National Board of Health since this was initiated in 1999. Marshalyn verified that we can get all new permissions for anything related to autism. Eric and Carsten will be working hard to ensure we get all needed permissions.

10 NOVEMBER 2009 – CDC STAFF MEETING WITH DANES INCLUDING THORSEN -CONTINUED

Danish National Birth Cohort (DNBC) Based Studies

Marshalyn had questions regarding these studies. She verified that there was no medical abstraction of the autism perinatal records. She asked what is available from the DNBC?

Carsten verified that there was no abstraction of the perinatal data (on autism). Only the CP and some of the controls are finalized and only the registry data available. All of the data in the DNBC are available.

10 NOVEMBER 2009 – CDC STAFF MEETING WITH DANES INCLUDING THORSEN -CONTINUED

Laboratory biomarker panel development:

Permissions

Diana noted that no permission is required. She would appreciate an update from David Hougaard. Carsten mentioned that they would need a permission for access to a certain patient group.

Carsten has not found the original approval for completing this study. He is looking for Poul for original approvals for the Autism studies. Poul mentioned that there were multiple studies put together in one package. Poul cannot find the original permissions. It was noted that the data protection agency approval is in place.

Diana is incorrect, she was told at the outset of grant by CDC that ethical clearances would be needed annually, she failed and is attempting to shift midstream the facts on the Biomarker study – they end up 'borrowing' an ethical clearance just before publication.
(Unethical)

10 NOVEMBER 2009 – CDC STAFF MEETING WITH DANES INCLUDING THORSEN -CONTINUED

Carsten cannot find any permission on the biomarker study. It was noted that Kristine Svedgaard has send them a letter suggesting that this study received its permission in 2003. Poul stated that if folks are in doubt about the permissions then Aarhus University should secure new permissions.

Poul believes that there has been confusion on the permissions. Carsten believes we do not have permissions for the autism disorder case control study.

Poul suggested that Aarhus University may want to check with Kristine regarding the permissions; she may have tried to secure permission.

30 NOVEMBER 2009 – CDC CALL WITH DANES RE AUTISM
(BOYLE, YEARGIN-ALLSOPP, NAARDIN, WOJCIK FROM CDC)

Exhibit 7

Denmark Grantee Autism/CP Call

November 30, 2009

8 am Eastern/2pm Denmark

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30 NOVEMBER 2009 – CDC CALL WITH DANES RE AUTISM

2. Poul is requested to provide Aarhus University a copy of all permissions in his files ASAP.

Comments: Email note from Poul 11/30/09 – “The approvals for the studies, which I have on hand, have been revealed to Carsten and Erik previously and can be found on <http://www.datatilsynet.dk/english/>. As I have stated before to Carsten and Erik, I have not been able to locate the ethical approval for the autism pilot study. I recommend that new approvals are requested just as stated in the notes from the last conference call.”

30 NOVEMBER 2009 – CDC CALL WITH DANES RE AUTISM - CONTINUED

Bio- and genetic markers and autism

We have not been able to find a permission from ethical committee that covers both bio- and genetic markers and autism. As far as we understand only one paper has been published using these data¹ and Diana will soon be submitting another. Apart from the letter from the EC in our region (attached) we have not been able to locate the permission for abstraction of the psychiatric records, and it is likely that it does not exist. We are currently working on an application for bio- and genetic markers to the Ethical Committee (EC) and Data Protection Agency that will cover both CP and autism.

Dr. Boyle, Dr. Yeargin-Allsopp & Dr. Schendel are fully aware that the autism studies were conducted illegally, they continue to include Dr. Thorsen in discussions, and do not stop the Danish project.

30 NOVEMBER 2009 – CDC CALL WITH DANES RE AUTISM - CONTINUED

Comments: Carsten believes one paper has been published using this dataset. Appears there is no permission to conduct this activity. They will apply for a new permission and mention that something was completed without permission. Diana mentioned that there was more than one paper completed. Carsten asked Diana to provide any additional papers published under this activity. Diana does not believe there were any papers published. Diana is not sure if the below paper was a part of this dataset.

Project has been so poorly managed that the CDC Senior Scientist on the project (Dr. Diana Schendel) does not even know what autism papers were published (illegally). This many months into the transition of principal investigators, the CDC team should have gotten everything organized since they initially failed to do so in managing the project, and yet they do not appear to have done so.

DANES SUGGEST 'BORROWING' (EXTENDING) ETHICAL CLEARANCE TO SCHENDEL BIOMARKER POST-RESEARCH/PRE-PUBLICATION (UNETHICAL)

Autism database

One paper has been published describing these data² and another describing the use of patient files³. At the time the psychiatric records were abstracted permission from the Danish National Board of Health (DNBH) should have been applied for. However, there was at that time confusion among scientists if the permission should come from the EC or DNBH or if it was really necessary. In fact EC gave permissions in this period. Although it probably is possible to get such a permission from DNBH that covers future projects, it seem like it will be difficult - probably impossible - to get a permission that covers ongoing or finalized project (back in time). We believe, however, that we have found a possible solution to this problem by extending a related permission from Ethical Committee that was given to a colleague at our institute (Rikke Maimburg). This project was approved in 2000 (title ' Obstetric factors and autism', the permission that covers one of the papers Diana is in charge of) and used mother's obstetric files. It is hoped that it is possible to extend this project to include psychiatric patient files for validating the Psychiatric Register diagnosis.

Dr. Boyle should have shut this down at the suggestion of 'borrowing an ethical clearance.

NEW DANISH PI LEARNS NO PERMISSIONS WERE SOUGHT!
MARSHALYN TRYING TO SUGGEST AFTER THE FACT THAT NO IRB NEEDED
(CANNOT BE APPLIED RETROSPECTIVELY)

Diana mentioned individual permission was received for the CP biobank data. For the autism dataset Diana remembers individual permission was not required of each participant. Individual permissions were received in the case control study. The Danish Agency has permission reviews four times a year. They are attempting to keep these activities on track to get permissions as soon as possible. Per Søren there should be no challenge to get it cleared. Coleen asked if we could continue the analyses? Coleen asked if there is a record of permission sought in the past? Eric asked the ethical committee if there were any previous permissions; none were found. Per Diana at the time the Danish Data Protection Agency was only required. No additional permission had been needed. Per Carsten he believes permission should have been sought previously by the ethical committee. Per Eric he has seen a similar application since the 1990's.

Carsten and Eric are attempting to gather all of the various permissions into one application package. Per Marshalyn it appears the rules are in the U.S. where you can access some data without individual consent. Carsten and Eric will be preparing the permissions application to the committee. Autism, CP and ADHD will be combined into one permission.

DIANA – THE CHIEF CDC SCIENTIST – RESPONSIBLE FOR OVERSEEING ALL THE DETAILS CANNOT CONFIRM SHE HAD ETHICAL CLEARANCE TO DO RESEARCH IN DENMARK – (AT THE LEAST THIS INDICATES GROSS MISMANAGEMENT)

Comments: Carsten stated there should have been an application to the National Board of Health; not from the Ethical Committee. It is difficult to get the permission back in time. Data have been used for a couple of studies. The medical records mentioned in the paper were referring to the validation study. According to the law the National Board of

Health should have been asked. Per Diana she believes the permissions were in place for the below paper. They had to get permission from each hospital and doctor to review the records. Diana does not recall the specifics for the administrative permissions for the below paper. Diana mentioned that at the time the thought was to establish an autism registry similar to the CP registry.

Lauritsen MB, Jorgensen M, Madsen KM et al. Validity of Childhood Autism in the Danish Psychiatric Central Register: Findings from a Cohort Sample Born 1990-1999. J Autism Dev Disord 2009.

Madsen KM, Hviid A, Vestergaard M et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med 2002;347(19):1477-1482.

30 NOVEMBER 2009

NO EVIDENCE C BOYLE NOTIFIED CDC IRB

Coleen believes CDC has to inform the CDC IRB office to alert them of the issue of permissions not available. Coleen asked for additional clarification regarding the Denmark Permission process.

ACTION ITEM: Carsten will provide the workgroup a description of the Denmark Permission process in English.

Diana mentioned that the Ethical Committee is similar to the U.S. IRB Board. Per Marshalyn an approach needs to be decided before a timeline can be finalized. Marshalyn believes this permission may be more complicated.

22 JANUARY 2010 – AARHUS UNIVERSITY ISSUES THORSEN STATEMENT

In March 2009, Dr. Thorsen resigned his faculty position at Aarhus University. In the mean time, it has come to the attention of Aarhus University that Dr. Thorsen has continued to act in such a manner as to create the impression that he still retains a connection to Aarhus University after the termination

Conclusion: Aarhus University wishes to confirm that Dr Poul Thorsen no longer has any connection to Aarhus University, and that Aarhus University will not be able to collaborate with Poul Thorsen in the future. To the extent that other parties collaborating with Aarhus University wish to draw on Poul Thorsen's expertise, Aarhus University will only accept such collaboration if it has the purpose of securing data or protecting the interests of participating researchers and funding agencies.

13 APRIL 2011: DR. POUL THORSEN, AGE 49, WAS INDICTED IN THE UNITED STATES ON 22 FEDERAL CRIMINAL COUNTS - 13 COUNTS OF WIRE FRAUD AND 9 COUNTS OF MONEY LAUNDERING.

THE UNITED STATES ATTORNEY'S OFFICE
NORTHERN DISTRICT *of* GEORGIA

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AUTISM RESEARCHER INDICTED FOR STEALING GRANT MONEY

FOR IMMEDIATE RELEASE

April 13, 2011

<http://www.justice.gov/usao/gan/>

CONTACT: Patrick Crosby

(404)581-6016

FAX (404)581-6160

Thorsen Allegedly Absconded With Over \$1 Million

PUBLIC LAW (PL) 93-348

US LAW REQUIRES IRB FOR FEDERALLY FUNDED RESEARCH

“INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

42 USC 289l-3.

“SEC. 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its

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PUBLIC LAW 93-348—JULY 12, 1974

[88 STAT.

Public Law 93-348

July 12, 1974
[H. R. 7724]

AN ACT

To amend the Public Health Service Act to establish a program of National Research Service Awards to assure the continued excellence of biomedical and behavioral research and to provide for the protection of human subjects involved in biomedical and behavioral research and for other purposes.

PL-93-348-CONTINUED

88 STAT.] PUBLIC LAW 93-348--JULY 12, 1974

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application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

“(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.”

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

Regulations.
42 USC 289l-3
note.

Ante, p. 352.

42 USC 289

42 USC 289: Institutional review boards; ethics guidance program Text contains those laws in effect on September 9, 2017
From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICES
SUBCHAPTER III-NATIONAL RESEARCH INSTITUTES
Part H-General Provisions

42 USC 289-CONTINUED

- **§289. Institutional review boards; ethics guidance program**
- (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.
- (b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.
- (2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.
- (July 1, 1944, ch. 373, title IV, §491, as added [Pub. L. 99-158, §2, Nov. 20, 1985, 99 Stat. 873](#).)

42 USC 289-CONTINUED

- **STUDY CONCERNING RESEARCH INVOLVING CHILDREN**

- Pub. L. 107-109, §12, Jan. 4, 2002, 115 Stat. 1416, provided that:

- "(a) Contract With Institute of Medicine.-The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for-
- "(1) the conduct, in accordance with subsection (b), of a review of-
- "(A) Federal regulations in effect on the date of the enactment of this Act [Jan. 4, 2002] relating to research involving children;
- "(B) federally prepared or supported reports relating to research involving children; and
- "(C) federally supported evidence-based research involving children; and
- "(2) the submission to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, not later than two years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

42 USC 289-CONTINUED

- "(b) Areas of Review.-In conducting the review under subsection (a)(1), the Institute of Medicine shall consider the following:
- "(1) The written and oral process of obtaining and defining 'assent', 'permission' and 'informed consent' with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).
- "(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.
- "(3) The definition of 'minimal risk' with respect to a healthy child or a child with an illness.
- "(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.
- "(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.
- "(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.
- "(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.
- "(c) Requirements of Expertise.-The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children."

42 USC 289-CONTINUED

- **REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH**
- Pub. L. 106–310, div.A, title XXVII, §2701, Oct. 17, 2000, 114 Stat. 1167 , as amended by Pub. L. 106–505, title X, §1001(a), Nov. 13, 2000, 114 Stat. 2350 , provided that: "Notwithstanding any other provision of law, not later than 6 months after the date of the enactment of this Act [Oct. 17, 2000], the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 46 of title 45, Code of Federal Regulations."
- [Pub. L. 106–505, title X, §1001(b), Nov. 13, 2000, 114 Stat. 2350 , provided that: "The amendment made by subsection (a) [amending section 2701 of Pub. L. 106–310, set out above] takes effect on the date of the enactment of the Children's Health Act of 2000 [Oct. 17, 2000]."]

42 USC 289-CONTINUED

- **INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH**

- Pub. L. 113-240, §12, Dec. 18, 2014, 128 Stat. 2857 , provided that:

- "(a) In General.-Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act [42 U.S.C. 201 et seq.] until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.
- "(b) Effective Date.-Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act [Dec. 18, 2014].
- "(c) Regulations.-Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations."

42 USC 289A-I

- **§289a–I. Certain provisions regarding review and approval of proposals for research**
- **(a) Review as precondition to research**
- **(1) Protection of human research subjects**
- (A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 289(a) of this title by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.
- (B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.
- **(2) Peer review**
- In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 289a of this title unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review, and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval.

42 USC 289A-I-CONTINUED

- **(b) Ethical review of research**
- **(1) Procedures regarding withholding of funds**
- If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funds for the research because of ethical considerations unless-
 - (A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and
 - (B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or
 - (ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.
- **(2) Rules of construction**
- Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of-
 - (A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or
 - (B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

...

UCSF WEBPAGE EXPLAINS IRB REQUIREMENTS

- The human subject definition extends to a subject's identifiable private information. As such, the IRB must review most research proposing to use data from medical records — obtained directly or indirectly. IRB review is required even if the records are a physician's own patients.
- The guidelines apply to all medical records — both paper and electronic — that contain Protected Health Information (PHI), such as charts, office records including shadow charts and study reports, as well as various media like radiographic images and films. The UCSF HUB has detailed information on accessing electronic medical data at UCSF.

<http://irb.ucsf.edu/medical-record-review>

*While unaffiliated with the Danisih project, this is a worthwhile explanation.

WHEN IRB IS NOT REQUIRED

- Under some circumstances, research involving only unidentifiable/de-identified or coded private information or biological specimens is not human subjects research because investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong.
- In such cases, IRB review is not required. The PI makes and certifies this determination.
- In order for your use of data and/or biological specimens to not meet the definition of a human subject, all of the following conditions must apply:

<http://irb.ucsf.edu/not-human-subjects-research>

CDC cannot retrospectively apply this policy. In fact, the CDC specifically told Dr. Schendel annual IRB certification from the Danes would be required at the outset of funding. Furthermore when the money went missing, and Poul resigned, he confirmed via emails he had applied for and obtained ethical clearances (which turned out to be a lie) the new principal investigators were sure they needed ethical clearance (IRB approval).

FAILURE OF US PERSONNEL TO DISAVOW THORSEN

- Federal public health officials failed to distance themselves from Thorsen in any manner. This failure to disavow includes the following:
- At least two HHS employees continued to collaborate with this fugitive and co-author papers with him. (Diana Schendel of the CDC and Rosemary D. Higgins of the NICHD/NIH). Dr. Schendel eventually left her CDC job and moved to Denmark to lead autism research at Aarhus University. Dr. Higgins refused to discuss the matter when called on July 5, 2017. Recently received FOIA information is being reviewed.
- Dr. Thorsen continues to collaborate with the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network.
- Federal dollars continued to flow to studies in which he was or is involved.
- Both the HHS and DOJ continue to use his research as grounds to reject vaccine injury claims in the National Vaccine Injury Compensation.
- No retraction of the articles he was associated with during and subsequent to his 2004 to 2010 alleged criminal activities has occurred. The entire US public health machine acts as if the indictment never occurred.