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November 20, 2014

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Burwell:

Public Citizen, a consumer advocacy group with more than 350,000 members and supporters nationwide, is writing to express grave concern regarding new revelations — disclosed in recent internal Department of Health and Human Services (HHS) emails we obtained — that one or more senior officials in the HHS Immediate Office of the Secretary (IOS) abruptly transferred responsibility from the Office for Human Research Protections (OHRP) to the National Institutes of Health (NIH) for rewriting key sections of a draft notice of proposed rulemaking (NPRM) that is expected to propose extensive revisions to the Federal Policy for the Protection of Human Subjects (known as the Common Rule). These circumstances are deeply troubling given that NIH — the largest federal funder and conductor of human subjects research — has an obvious direct conflict of interest as an entity regulated by OHRP under the HHS human subject protection regulations at 45 CFR Part 46, Subpart A (the HHS codification of the Common Rule).

This decision by the HHS IOS — which at a minimum appears to have involved HHS Chief of Staff Andrea Palm — to assign NIH a lead role in revising the draft NPRM reflects extraordinarily poor judgment and undermines public trust in the integrity of the process for revising the critically important federal regulations for the protection of human subjects. These actions undercut the authority of OHRP and echo unethical conduct by senior HHS officials under your predecessor, then-Secretary Kathleen Sebelius. Those officials in 2013 knowingly allowed the NIH director and other senior NIH officials to interfere with the independence of OHRP's ongoing compliance oversight investigation of the NIH-funded Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (the SUPPORT study). These two incidents together demonstrate a disturbing pattern of conduct in which senior HHS officials fundamentally compromised OHRP's regulatory authority and almost certainly caused long-lasting and possibly irreparable harm to the status of this critically important regulatory agency, whose primary mission is to protect human subjects.

We therefore urge you to immediately return full responsibility for the final drafting of the entire NPRM to OHRP, where it had initially resided, and take steps to ensure that agencies such as NIH are not allowed to play a lead role in regulatory matters in which they have significant, direct conflicts of interest. Moreover, the HHS official(s) in your immediate office who demonstrated such poor judgment in this matter should be removed from further involvement in overseeing OHRP activities and the drafting of the Common Rule NPRM.

Below we summarize (a) background information on efforts to revise the Common Rule and (b) recent emails documenting that the HHS IOS abruptly transferred responsibility for rewriting key sections of the Common Rule NPRM to NIH.

I. Background on efforts to revise the Common Rule

The current Common Rule was finalized in 1991 and has not previously been revised. On July 26, 2011, HHS published in the *Federal Register* an advance notice of proposed rulemaking (ANPRM) requesting public comment on how current federal regulations for protecting human research subjects might be modernized and revised to be more effective.¹ OHRP appropriately played the lead role in drafting and issuing the ANPRM, which identified Dr. Jerry Menikoff, Director of OHRP, as being the primary contact for obtaining further information about the ANPRM and for submitting comments by mail.

The ANPRM indicated that HHS was contemplating changes to the following aspects of the current Common Rule, with the stated goal being to “enhance the effectiveness of the research oversight system by improving the protections for human subjects while also reducing burdens, delays, and ambiguity for investigators and research subjects:”

- Refinement of the existing risk-based regulatory framework;
- Utilization of a single institutional review board (IRB) review of record for domestic sites of multisite studies;
- Improvement of consent forms and the consent process;
- Establishment of mandatory data security and information protection standards for all studies that involve identifiable or potentially identifiable data;
- Establishment of an improved, more systematic approach for the collection and analysis of data on unanticipated problems and adverse events;
- Extension of federal regulatory protections to all research, regardless of funding source, conducted at institutions in the U.S. that receive some federal funding from a Common Rule agency for research with human subjects; and
- Improvement in the harmonization of regulations and related agency guidance.

The ANPRM posed 74 questions spanning the above seven areas. The comment period for the ANPRM closed on October 26, 2011. Public Citizen was among the 1,142 organizations, individuals, and groups of individuals that submitted comments.²

On multiple occasions over the past few years since the revision process began, HHS officials have publicly signaled that OHRP— appropriately — was the lead agency within HHS responsible for reviewing the public comments and drafting an NPRM to amend the Common Rule. For example, OHRP presented a summary of the public comments on the ANPRM to the Secretary’s Advisory Committee on Human Research Protections (SACHRP) on February 28,

¹ 76 FR 44512-44531.

² Public Citizen. Letter to Secretary of Health and Human Services Kathleen Sebelius and Office of Science and Technology Policy Director John P. Holdren providing comments on the ANPRM proposing changes to the Common Rule. October 26, 2011. <http://www.citizen.org/documents/comments-on-anprm-human-subject-research-protections.pdf>. Accessed November 16, 2014.

2012.³ During SACHRP's discussion of the comments, Dr. Menikoff affirmed that OHRP would be the lead agency responsible for evaluating the comments.⁴ Likewise, on March 12, 2014, Dr. Howard Koh, then-HHS Assistant Secretary for Health, told SACHRP that OHRP was actively working on an NPRM to revise the Common Rule.⁵

Based on emails we obtained, discussed in Section II below, an initial draft NPRM prepared by OHRP underwent review over the past several months by the Office of Management and Budget (OMB) and an interagency workgroup convened by OMB that was composed of representatives from each of the federal departments and agencies that sponsor human subjects research and have adopted the Common Rule.

II. HHS emails regarding the rewriting of the Common Rule NPRM

Enclosed are copies of a series of very recent internal emails documenting that the HHS IOS abruptly transferred from OHRP to NIH responsibility for rewriting key sections of the draft Common Rule NPRM. At a minimum, the HHS Chief of Staff appears to have played a key role in this action.

In particular, NIH has been assigned responsibility for revising the preamble of the NPRM. The preamble will be the longest and most important part of the NPRM, as it will contain sections describing, among other things: (a) the summary and analysis of the public comments on the ANPRM; (b) the government's response to those comments; (c) the resolution of key policy disagreements that were during the earlier drafting of the NPRM; (d) the proposed changes to the Common Rule; and (e) the rationale for making those changes, all of which ultimately will have a major impact on the actual final content of the proposed revised Common Rule regulatory text.

The following are key excerpts from the internal emails obtained by Public Citizen (note that Public Citizen did not have access to any attachments referenced in these emails):

- (1) October 29, 6:30 p.m., email from Margo Schwab (Office of Information and Regulatory Affairs, Office of Management and Budget) to Andrea Palm (Chief of Staff and Senior Counselor, HHS), with Cc to Allison Orris, Brenda Aguilar, Julie Wise, and Tania Simoncelli:

Subject: Annotated draft [regulatory] text for Common Rule

Andrea: Attached please find the updated draft regulatory text for the NPRM designed to modernize the Common Rule. Below we describe the scope of the

³ Minutes of the February 28-29, 2012, meeting of the Secretary's Advisory Committee on Human Research Protections. <http://www.hhs.gov/ohrp/sachrp/mtgings/2012%20Feb%20Mtg/meetingminutes.pdf>. Accessed November 18, 2014. At pages 8-12.

⁴ *Ibid.* At page 10.

⁵ Minutes of the March 12-13, 2014, meeting of the Secretary's Advisory Committee on Human Research Protections. <http://www.hhs.gov/ohrp/sachrp/mtgings/mtg03-14/meetingminutessachrp12-13,2014.html>. Accessed November 18, 2014. At **Welcome and Remarks, Howard Koh, M.D., M.P.H., Assistant Secretary for Health (ASH)**.

recommendations. Please note that we did *not* provide conforming recommendations to HHS' original draft of the preamble.

The recommended changes to the regulatory text are designed to address many of the comments that were raised during the interagency working group. The solutions adopted are not always those recommended by an interagency commenter – either because conflicting comments were submitted or because the comments stemmed from internal inconsistencies in the draft NPRM and/or lack of clarity in the purpose of provisions in the draft. The changes adopted were designed to be consistent with the risk-based framework initially articulated in the ANPRM. ...

We have also flagged several **higher level policy issues** for HHS' resolution. These same provisions are likely to be the ones that draw the most public attention, including from the American Medical Association and major universities. These include:

- Issues tied directly to the precision medicine effort:
 - Whether to cover research use of biospecimens collected for non-research purposes (e.g., medical/clinical/surveillance).
 - Whether all biospecimens should be considered identifiable (given rapidly evolving technology and an abundance of caution).
- Whether to allow full or partial agency exemptions (regardless of risk).
- Conditions under which waiver of a single IRB requirement would be permissible.
- How to audit or otherwise assure that researchers make the right designations about their excluded and/or exempt research.

[Emphasis in original]

This email documents OMB transmitting to the HHS Chief of Staff an updated version of the regulatory text for the draft NPRM that included changes recommended by members of the interagency workgroup convened by OMB, along with a list of several key higher-level policy issues that required resolution by HHS. The preamble for the NPRM will address these policy issues and their resolution, which will significantly affect the content of the final proposed regulatory text.

- (2) November 3, 3:00 p.m., email from Julie Kaneshiro (Deputy Director, OHRP) to Julia Gorey (Executive Director, SACHRP), Sanjur Brooks (Oak Ridge Institute for Science and Education [ORISE] Fellow, Division of Policy and Assurances, OHRP), Kristina Borrer (Director, Division of Compliance Oversight, OHRP), Michelle Feige (Division of Education and Development, OHRP), Edward Bartlett (International Activities, OHRP), Yvonne Lau (Director, Division of Education and Development, OHRP), Lauren Hartsmith (ORISE Fellow, Division of Policy and Assurances, OHRP), Laura Odwazny (Office of the General Counsel, HHS), Kathi Hanna, and Andrew Zacher (Office of the General Counsel, HHS), with Cc to Jerry Menikoff (Director, OHRP), Ivor Pritchard (Senior Advisor to the Director, OHRP), and Irene Stith-Coleman (Director, Division of Policy and Assurances, OHRP):

Subject: Current draft NPRM regulatory text

Attachments: Draft Common Rule NPRM Regulatory Text 10-29-2014 with comments.docx.

Here is the current version of the regulatory text, **but several provisions are still in flux**. This is the draft that OMB shared with Andrea Palm (one of the Secretary's counselors) last week. I've included Margo's note to Andrea below so you can see what she communicated.

The expectation is that Andrea will coordinate HHS's review of this draft, as well as put in place a process to resolve the higher-level policy issues that have been flagged by OMB and OSTP. At the same time, NSF is being asked to review the draft to see if changes should be made to better address social and behavioral research.

We have not yet heard from Andrea about how she wants to proceed with seeking HHS input on the draft. We expect that several of the HHS agencies will not like some of the changes (e.g., the narrowing of the quality improvement and public health exclusions, and the narrowing of the exemption related to public benefit programs). In addition, the flagged issue about whether all biospecimens should be treated as identifiable has already undergone significant discussion within HHS, so we do not know how much additional discussion will take place about this.

In the meantime, Margo has asked that we draft responses to the Common Rule agencies' comments based on this draft of the regulatory text, so we are proceeding with this.

[Emphasis added]

This email from the OHRP Deputy Director to other OHRP staff transmitted the email message sent by OMB to the HHS Chief of Staff in (1) above, along with the current version of draft NPRM regulatory text (without the critically important preamble). It indicates that the HHS Chief of Staff was responsible for coordinating the HHS' review of the draft and resolution of higher-level policy issues identified by OMB. It also notes that several HHS agencies — with NIH likely among them — will not like some of the proposed changes in the regulatory text.

- (3) November 10, 6:39 p.m., email from Julie Kaneshiro (Deputy Director, OHRP) to all of the same recipients of the preceding email:

Subject: Call with NIH on NPRM ...

I just had a conversation with Sarah Car [sic; Acting Director, Office of Clinical Research and Bioethics Policy, NIH] and Stephanie Devaney [Health Policy Analyst, Office of the Director, NIH]. They confirmed that NIH has

been asked to draft the entire preamble. I told them our plan to send them our version of the draft preamble sometime tomorrow with sections highlighted that we think need to be revised. They have been working from the December 2013 version thus far.

We talked briefly about the policy question we discussed today about whether all data from a biospecimen should be considered to be covered by the rule, regardless of the identifiability of the data. They had not considered that issue, but now will.

I told Sarah and Stephanie that we will be [sic] planning to have the draft regulatory text ready to share on Thursday. **They understand that they will need our assistance to make the preamble consistent with the regulatory text.**

More to come on Wednesday, I'm sure. **We will need something more than cookies to make this palatable.**

[Emphasis added]

This email from the OHRP Deputy Director to other OHRP staff documents that OHRP received confirmation from NIH officials — not HHS IOS officials — that the HHS IOS assigned NIH the responsibility for rewriting the entire preamble to the Common Rule NPRM. Giving NIH the lead responsibility for rewriting the preamble allowed it, rather than OHRP, to resolve the higher-level policy issues, despite the fact that NIH has direct conflicts of interest regarding the outcome of those issues.

- (4) November 11, 8:05 a.m., email from Julie Kaneshiro (Deputy Director, OHRP) to Sarah Carr (Acting Director, Office of Clinical Research and Bioethics Policy, NIH), with Cc to Stephanie Devaney (Health Policy Analyst, Office of the Director, NIH):

Subject: RE: your call ...

I was thinking that one way to coordinate our drafting of the regulatory text and preamble would be for you to share draft sections of the preamble as you complete them. **Then we could provide comments along the way, which might also inform our drafting of the [regulatory] text. Working together in this way seems like the best way to proceed since the pieces we're working on will need to be knitted together.**

What do you think about this approach?

[Emphasis added]

This email from the OHRP Deputy Director to NIH officials involved in the rewriting of the preamble signals an attempt by OHRP to coordinate its rewriting of the actual regulatory text of the proposed revised Common Rule with NIH's rewriting of the

preamble section. This would have given OHRP at least some opportunity to have substantive input into the revision of the preamble.

- (5) November 11, 9:52 a.m., email from Sarah Carr (Acting Director, Office of Clinical Research and Bioethics Policy, NIH) to Julie Kaneshiro (Deputy Director, OHRP), with Cc to Stephanie Devaney (Health Policy Analyst, Office of the Director, NIH):

Subject: RE: your call ...

We appreciated your outreach yesterday **and agree that ideally coordinating our work would be the best approach. However, honestly, we aren't far enough along in the key section of what we're drafting to be of help with the regulatory text.**

Also, our time is so compressed that we don't really think there's time to go back and forth.

We'll look forward to getting your regulatory text as soon as possible so we can fully describe and explain the changes in the section by section chapter that we're developing.

Our understanding is that the stitching together of sections will be done at Andrea's level.

[Emphasis added]

This email shows one of the NIH officials involved in the rewriting of the entire preamble rebuffed the attempt by the OHRP Deputy Director to have OHRP and NIH coordinate on the rewriting of the NPRM. The NIH official also informed the OHRP Deputy Director that officials at the level of the HHS Chief of Staff will meld together OHRP's rewrite of regulatory text and NIH's rewrite of the preamble. It is uncertain whether OHRP will play a meaningful role in revising the preamble and in making the higher-level policy decisions assigned to NIH that will be discussed in the preamble. The process established by the HHS IOS appears to allow NIH to drive substantive changes to the content of the final regulatory text in the Common Rule NPRM.

- (6) November 11, 4:16 p.m., email from Julie Kaneshiro (Deputy Director, OHRP) to Sarah Carr (Acting Director, Office of Clinical Research and Bioethics Policy, NIH) and Stephanie Devaney (Health Policy Analyst, Office of the Director, NIH), with Cc to Jerry Menikoff (Director, OHRP), Ivor Pritchard (Senior Advisor to the Director, OHRP), Irene Stith-Coleman (Director, Division of Policy and Assurances, OHRP), Wanda Jones (Principal Deputy Assistant Secretary for Health, HHS), Andrea Palm (Chief of Staff and Senior Counselor, HHS), and Kathy Hudson (Deputy Director for Science Outreach and Policy, Office of the Director, NIH):

Subject: **Common Rule NPRM**

Sarah and Stephanie,

As we discussed yesterday, attached is a draft NPRM with tracked changes from the December 2013 draft. **We have highlighted sections of the preamble that need to be revised. In particular, the exclusions and exemptions sections will need significant revision** since these are the sections most heavily revised by OMB. Note that this version of the preamble includes technical edits and corrections made by the HHS agencies when the NPRM went through clearance last December. ...

We are still working on the regulatory text, but I am sharing our current draft that is annotated to identify the provisions of the regulations that stayed the same or changed. ... The key comments for the preamble are labeled "OHRP." The other comments relate to some pending policy issues. ...

[Emphasis added]

This email from the OHRP Deputy Director to OHRP staff, NIH officials, and senior HHS IOS officials transmits a copy of the draft NPRM with changes made since December 2013 and identifies key sections of the preamble that OHRP has decided need revision.

- (7) November 12, 4:09 p.m., email from Julie Kaneshiro (Deputy Director, OHRP) to all recipients in emails (2) and (3) above:

Subject: RE: NPRM [regulatory] text ...

Here is Laura's revised [regulatory] text based on our 2:30 meeting. If you have any additional changes, please let me know by 10:00 a.m. tomorrow.

We will send a clean version of the [regulatory] text to Andrea Palm by the end of the day tomorrow. What happens next is unknown.

[Emphasis added]

This email from the OHRP Deputy Director to other OHRP staff transmits a revised version of the regulatory text from the NPRM and signals uncertainty regarding what, if any, input OHRP will have in subsequent steps regarding reconciling this regulatory text with the text of the preamble being written by NIH.

- (8) November 13, 4:40 p.m., email from Julie Kaneshiro (Deputy Director, OHRP) to all recipients in emails (2), (3), and (7) above:

Subject: NPRM draft regulatory text to OS
Attachments: Common Rule NPRM Regulatory Text 11 13 2014v3.docx;
Preamble language related to Subpart C and vulnerable [populations] 11-13-2014.docx ...

Here's the regulatory text that we sent to Andrea. Andrea said she would be sharing this with NIH and ASPE [the Assistant Secretary for Planning and Evaluation].

Also attached is the suggested language for the preamble that I sent to NIH this afternoon regarding subpart C [of 45 CFR Part 46, Additional Protections for Research Involving Prisoners] and vulnerable populations.

[Emphasis added]

This email from the OHRP Deputy Director informs other OHRP staff that OHRP's final draft of the regulatory text for the NPRM has been transmitted to the HHS Chief of Staff. It also signals that changes will be proposed to HHS regulations that provide special protections for prisoners and other vulnerable subjects, and that NIH appears to have the lead role in drafting sections of the preamble related to these proposed changes as well.

III. Conclusions and requested actions

The forthcoming NPRM being drafted by HHS undoubtedly will propose many substantive changes to the Common Rule that will have significant impact on the human subjects research conducted by NIH under its intramural research program and funded under its extramural research program. While NIH — like any other regulated entity — certainly should have an opportunity to comment on the completed NPRM, it should not be permitted to be a lead drafter of any part of the NPRM, including the important preamble. Allowing NIH to play such a role corrupts the rulemaking process and is akin to asking the pharmaceutical and medical device industry to write the Food and Drug Administration's regulations regarding the approval process for drugs and medical devices or asking the pesticide industry to write the Environmental Protection Agency's regulations regarding pesticide exposure limits for workers and consumers. The public no doubt would find such circumstances to be grossly unacceptable.

As was the case with the OHRP's compliance oversight investigation of the SUPPORT study, one or more senior officials in the HHS IOS have facilitated inappropriate involvement by NIH in the drafting of the Common Rule NPRM despite the fact that NIH has an obvious direct conflict of interest as an entity regulated by OHRP under HHS human subject protection regulations. We suspect that NIH orchestrated such involvement in a deliberate attempt to undermine OHRP's regulatory authority and to achieve changes to the Common Rule that it desires. This shift of authority from the regulator to the regulated is unacceptable.

In closing, we urge you to immediately return full responsibility for the final drafting of the entire NPRM, including the preamble, to OHRP — where it originally resided — and take steps to ensure that agencies, like NIH, are not allowed to play a lead role in matters in which they have significant direct conflicts of interest. Moreover, you should take action to ensure that the HHS official(s) in your immediate office who demonstrated such poor judgment in this matter are removed from further involvement in overseeing OHRP activities and the drafting of the Common Rule NPRM. Please also provide answers to the following questions:

- (1) Were other HHS IOS officials, in addition to Andrea Palm, involved in the decision to give NIH responsibility for rewriting the important preamble to the draft NPRM proposing revisions to the Common Rule? If yes, please identify those individuals.
- (2) Did any NIH official play a role in orchestrating this action by the HHS IOS? If yes , please identify the NIH officials involved.

Thank you for your prompt attention to this important matter.

Sincerely,

Michael Carome, M.D.
Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen's Health Research Group

cc: Karen B. DeSalvo, M.D., M.P.H., M.Sc., Acting Assistant Secretary for Health, HHS
Shaun Donovan, Director, OMB
Howard Shelanski, Administrator, Office of Information and Regulatory Affairs, OMB
John P. Holdren, Director, Office of Science and Technology Policy
The Honorable Bernie Sanders, U.S. Senate
The Honorable Chuck Grassley, U.S. Senate
The Honorable Rosa DeLauro, U.S. House of Representatives
The Honorable Diana DeGette, U.S. House of Representatives

Enclosure

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Monday, November 03, 2014 3:00 PM
To: Gorey, Julia G (HHS/OPHS); Brooks, Sanjur (HHS/OASH); Borrer, Kristina C (HHS/OASH); Feige, Michelle (HHS/OASH); Bartlett, Edward E (HHS/OASH); Lau, Yvonne (OS/OASH); Hartsmith, Lauren (OS/OASH) (CTR); Odwazny, Laura (HHS/OGC); Kathi Hanna; Zacher, Andrew W. (HHS/OGC)
Cc: Menikoff, Jerry (HHS/OASH); Pritchard, Ivor A (HHS/OASH); StithColeman, Irene E (HHS/OASH)
Subject: Current draft NPRM regulatory text
Attachments: Draft Common Rule NPRM Regulatory Text 10-29-2014 with comments.docx

All,

Here is the current version of the regulatory text, but several provisions are still in flux. This is the draft that OMB shared with Andrea Palm (one of the Secretary's counselors) last week. I've included Margo's note to Andrea below so you can see what she communicated.

The expectation is that Andrea will coordinate HHS's review of this draft, as well as put in place a process to resolve the higher-level policy issues that have been flagged by OMB and OSTP. At the same time, NSF is being asked to review the draft to see if changes should be made to better address social and behavioral research.

We have not yet heard from Andrea about how she wants to proceed with seeking HHS input on the draft. We expect that several of the HHS agencies will not like some of the changes (e.g., the narrowing of the quality improvement and public health exclusions, and the narrowing of the exemption related to public benefit programs). In addition, the flagged issue about whether all biospecimens should be treated as identifiable has already undergone significant discussion within HHS, so we do not know how much additional discussion will take place about this.

In the meantime, Margo has asked that we draft responses to the Common Rule agencies' comments based on this draft of the regulatory text, so we are proceeding with this.

I'll let you know when we learn more.

Julie

From: Schwab, Margo
Sent: Wednesday, October 29, 2014 6:30 PM
To: Palm, Andrea (HHS/IOS) (Andrea.Palm@hhs.gov)
Cc: Orris, Allison; Aguilar, Brenda; Wise, Julie; Simoncelli, Tania
Subject: Annotated draft reg text for Common Rule

Andrea: Attached please find the updated draft regulatory text for the NPRM designed to modernize the Common Rule. Below we describe the scope of the recommendations. Please note that we did not provide conforming recommendations to HHS' original draft of the preamble.

The recommended changes to the regulatory text are designed to address many of the comments that were raised during the interagency working group. The solutions adopted are not always those recommended by an interagency commenter – either because conflicting comments were submitted or because the comments stemmed from the

internal inconsistencies in the draft NPRM and/or lack of clarity in the purpose of provisions in the draft. The changes adopted were designed to be consistent with the risk-based framework initially articulated in the ANPRM.

Recommended changes in the attached version of the draft ANPRM include:

- An organization that more clearly articulates the reasons that activities are grouped as “excluded” versus “exempt;”
- Removes outdated provisions;
- Indicates where additional specificity would be better dealt with in supplemental guidance (rather than codifying).

We have also flagged several **higher level policy issues** for HHS’ resolution. These same provisions are likely to be the ones that draw the most public attention, including from the American Medical Association and major universities. These include:

- Issues tied directly to the precision medicine effort:
 - Whether to cover research use of biospecimens collected for non-research purposes (e.g., medical/clinical/surveillance).
 - Whether all biospecimens should be considered identifiable (given rapidly evolving technology and an abundance of caution).
- Whether to allow full or partial agency exemptions (regardless of risk).
- Conditions under which waiver of a single IRB requirement would be permissible.
- How to audit or otherwise assure that researchers make the right designations about their excluded and/or exempt research.

While HHS is resolving these policy issues, NSF will annotate the current version of the draft NPRM to ensure that the “non-biomedical science perspective” is covered. In particular, they will identify places in the current regulatory text and preamble where edits are necessary to make the NPRM consistent with the January 2014 National Academy of Sciences’ report that evaluated the applicability of the ideas presented in the 2011 ANPRM to the social and behavioral sciences.

We are available to answer any questions that you might have.

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Monday, November 10, 2014 6:39 PM
To: StithColeman, Irene E (HHS/OASH); Pritchard, Ivor A (HHS/OASH); Menikoff, Jerry (HHS/OASH); Odwazny, Laura (HHS/OGC); Kathi Hanna; Hartsmith, Lauren (OS/OASH) (CTR); Brooks, Sanjur (HHS/OASH); Gorey, Julia G (HHS/OPHS); Zacher, Andrew W. (HHS/OGC); Borrer, Kristina C (HHS/OASH); Feige, Michelle (HHS/OASH); Bartlett, Edward E (HHS/OASH); Lau, Yvonne (OS/OASH); 'stithcoleman@aol.com'
Subject: Call with NIH on NPRM

All,

I just had a conversation with Sarah Car and Stephanie Devaney. They confirmed that NIH has been asked to draft the entire preamble. I told them our plan to send them our version of the draft preamble sometime tomorrow with sections highlighted that we think need to be revised. They have been working from the December 2013 thus far.

We talked briefly about the policy question we discussed today about whether all data derived from a biospecimen should be considered to be covered by the rule, regardless of the identifiability of the data. They had not considered that issue, but now will.

I told Sarah and Stephanie that we will be planning to have the draft regulatory text ready to share on Thursday. They understand that they will need our assistance to make the preamble consistent with the regulatory text.

More to come on Wednesday, I'm sure. We will need something more than cookies to make this palatable.

Julie

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Tuesday, November 11, 2014 4:25 PM
To: Menikoff, Jerry (HHS/OASH); Pritchard, Ivor A (HHS/OASH); StithColeman, Irene E (HHS/OASH); Jones, Wanda K. (DHHS/OS/OASH); Odwazny, Laura (HHS/OGC); Kathi Hanna; Hartsmith, Lauren (OS/OASH) (CTR); Brooks, Sanjur (HHS/OASH); Gorey, Julia G (HHS/OPHS); Borrer, Kristina C (HHS/OASH); Lau, Yvonne (OS/OASH); Zacher, Andrew W. (HHS/OGC); Feige, Michelle (HHS/OASH); Bartlett, Edward E (HHS/OASH)
Subject: FW: your call

FYI. In particular, note that it appears OS is planning to take on the task of making the regulatory text and preamble consistent.

Julie

From: Carr, Sarah (NIH/OD) [E] [CarrS@OD.NIH.GOV]
Sent: Tuesday, November 11, 2014 9:52 AM
To: Kaneshiro, Julie A (HHS/OASH)
Cc: Devaney, Stephanie (NIH/OD) [E]
Subject: RE: your call

Hi Julie:

We appreciated your outreach yesterday and agree that ideally coordinating our work would be the best approach. However, honestly, we aren't far enough along in the key section of what we're drafting to be of help with the regulatory text.

Also, our time is so compressed that we don't really think there's time to go back and forth.

We'll look forward to getting your regulatory text as soon as possible so we can fully describe and explain the changes in the section by section chapter that we're developing.

Our understanding is that the stitching together of sections will be done at Andrea's level.

Many thanks,

Sarah and Stephanie

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Tuesday, November 11, 2014 8:05 AM
To: Carr, Sarah (NIH/OD) [E]
Cc: Devaney, Stephanie (NIH/OD) [E]
Subject: RE: your call

Hi Sarah and Stephanie,

Thanks for making the time to talk last night. I'm glad we connected.

I was thinking that one way to coordinate our drafting of the regulatory text and preamble would be for you to share draft sections of the preamble as you complete them. Then we could provide comments along the way, which might also inform our drafting of the reg text. Working together in this way seems like the best way to proceed since the pieces we're working on will need to be knitted together.

What do you think about this approach?

Julie

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Tuesday, November 11, 2014 4:19 PM
To: Kathi Hanna; Hartsmith, Lauren (OS/OASH) (CTR); Brooks, Sanjur (HHS/OASH); Gorey, Julia G (HHS/OPHS); Odwazny, Laura (HHS/OGC); Bartlett, Edward E (HHS/OASH); Zacher, Andrew W. (HHS/OGC); Borrer, Kristina C (HHS/OASH); Feige, Michelle (HHS/OASH); Lau, Yvonne (OS/OASH)
Cc: Menikoff, Jerry (HHS/OASH); Pritchard, Ivor A (HHS/OASH); StithColeman, Irene E (HHS/OASH)
Subject: FW: Common Rule NPRM
Attachments: December 2013 NRPM merged with recent.docx; [Annotated for ASPE] Common Rule NPRM Regulatory Text 11 7 14_111014a.docx

FYI

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Tuesday, November 11, 2014 4:16 PM
To: Carr, Sarah (NIH/OD) [E]; Devaney, Stephanie (NIH/OD) [E]
Cc: Menikoff, Jerry (HHS/OASH); Pritchard, Ivor A (HHS/OASH); StithColeman, Irene E (HHS/OASH); Jones, Wanda K. (DHHS/OS/OASH); Palm, Andrea (HHS/IOS); Hudson, Kathy (NIH/OD) [E]
Subject: Common Rule NPRM

Sarah and Stephanie,

As we discussed yesterday, attached is a draft NPRM with tracked changes from the December 2013 draft. We have highlighted sections of the preamble that need to be revised. In particular, the exclusions and exemptions sections will need significant revision since these are the sections that were most heavily revised by OMB. Note that this version of the preamble includes technical edits and corrections made by the HHS agencies when the NPRM went through clearance last December. There are numerous places where OGC, OCR, or FDA corrected language regarding their regulations or statutes.

We are still working on the regulatory text, but I am sharing our current draft that is annotated to identify the provisions of the regulations that stayed the same or changed. We sent this draft to ASPE as well so that they can begin work on the RIA. The key comments for the preamble are labeled "OHRP." The other comments relate to some pending policy issues. We plan to send you a more finalized version of the regulatory text on Thursday.

If you have any questions, please let us know.

Thanks,

Julie

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Wednesday, November 12, 2014 4:09 PM
To: StithColeman, Irene E (HHS/OASH); Pritchard, Ivor A (HHS/OASH); Menikoff, Jerry (HHS/OASH); Odwazny, Laura (HHS/OGC); 'Kathi Hanna'; Hartsmith, Lauren (OS/OASH) (CTR); Brooks, Sanjur (HHS/OASH); Gorey, Julia G (HHS/OPHS); Zacher, Andrew W. (HHS/OGC); Borrer, Kristina C (HHS/OASH); Feige, Michelle (HHS/OASH); Bartlett, Edward E (HHS/OASH); Lau, Yvonne (OS/OASH)
Subject: RE: NPRM reg text

All,

Here is Laura's revised reg text based on our 2:30 meeting. If you have any additional changes, please let me know by 10:00 a.m. tomorrow.

We will send a clean version of the reg text to Andrea Palm by the end of the day tomorrow. What happens next is unknown.

Thanks for all the work throughout this crazy process.

Julie



Common Rule
NPRM Regulator...

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Wednesday, November 12, 2014 12:47 PM
To: StithColeman, Irene E (HHS/OASH); Pritchard, Ivor A (HHS/OASH); Menikoff, Jerry (HHS/OASH); Odwazny, Laura (HHS/OGC); Kathi Hanna; Hartsmith, Lauren (OS/OASH) (CTR); Brooks, Sanjur (HHS/OASH); Gorey, Julia G (HHS/OPHS); Zacher, Andrew W. (HHS/OGC); Borrer, Kristina C (HHS/OASH); Feige, Michelle (HHS/OASH); Bartlett, Edward E (HHS/OASH); Lau, Yvonne (OS/OASH)
Subject: RE: NPRM reg text

All,

Here is the reg text we will be discussing this afternoon. The changes related to the comments/text highlighted in green will be the focus of the meeting, since these are the changes that came out of our meeting on Monday.

(Laura, I made a few minor editorial changes and added a few of additional comments which are labeled "JK").

Talk to you shortly.

Julie

<< File: Common Rule NPRM Regulatory Text annotated 11 12 14 v2.docx >>

From: Kaneshiro, Julie A (HHS/OASH)
Sent: Thursday, November 13, 2014 4:40 PM
To: Odwazny, Laura (HHS/OGC); 'Kathi Hanna'; Hartsmith, Lauren (OS/OASH) (CTR); Brooks, Sanjur (HHS/OASH); Gorey, Julia G (HHS/OPHS); Zacher, Andrew W. (HHS/OGC); Borrer, Kristina C (HHS/OASH); Feige, Michelle (HHS/OASH); Bartlett, Edward E (HHS/OASH); Lau, Yvonne (OS/OASH)
Cc: Menikoff, Jerry (HHS/OASH); Pritchard, Ivor A (HHS/OASH); StithColeman, Irene E (HHS/OASH)
Subject: NPRM draft regulatory text to OS
Attachments: Common Rule NPRM Regulatory Text 11 13 2014v3.docx; Preamble language related to Subpart C and vulnerable pops 11-13-2014.docx

All,

Here's the regulatory text that we sent to Andrea. Andrea said she would be sharing this with NIH and ASPE.

Also attached is the suggested language for the preamble that I sent to NIH this afternoon regarding subpart C and vulnerable populations.

Thank you very much for all the work that went into this. As we learn more about next steps I will let you know.

Julie