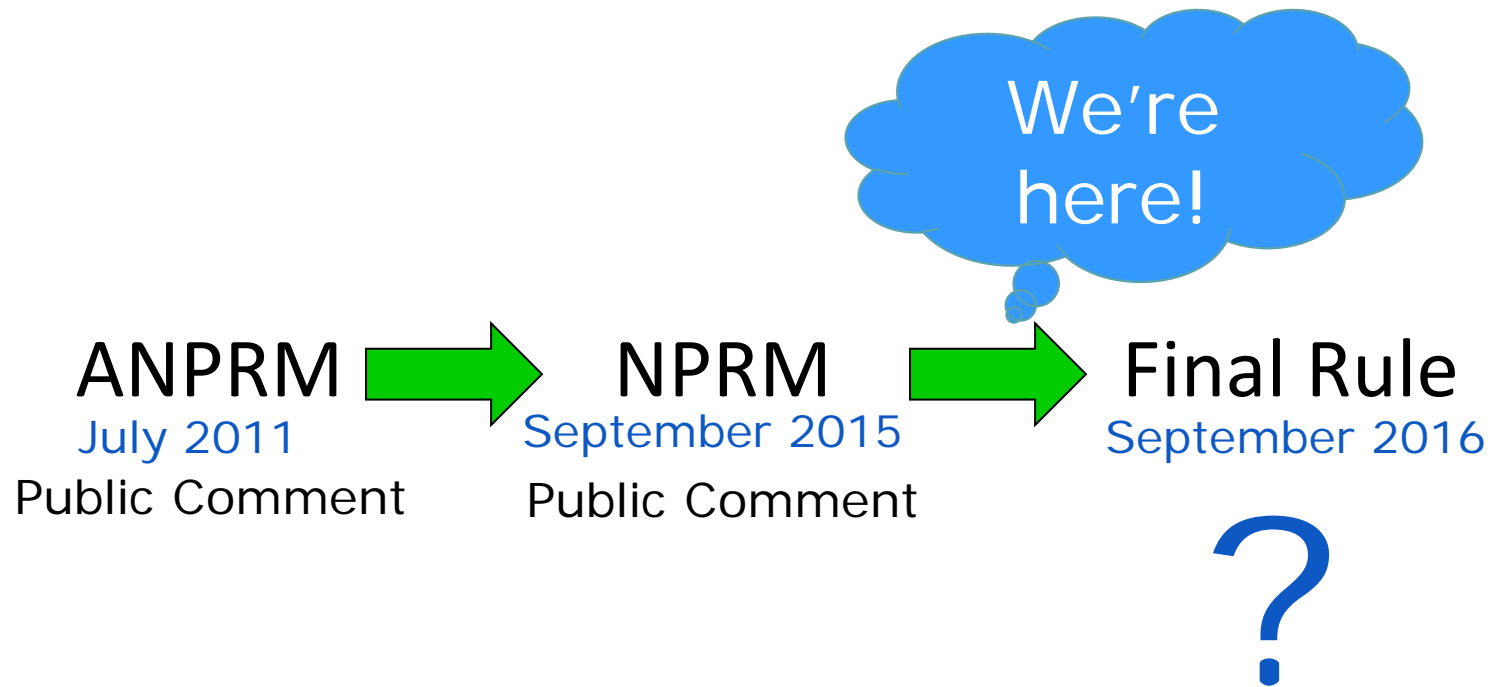


# Changes to the Common Rule

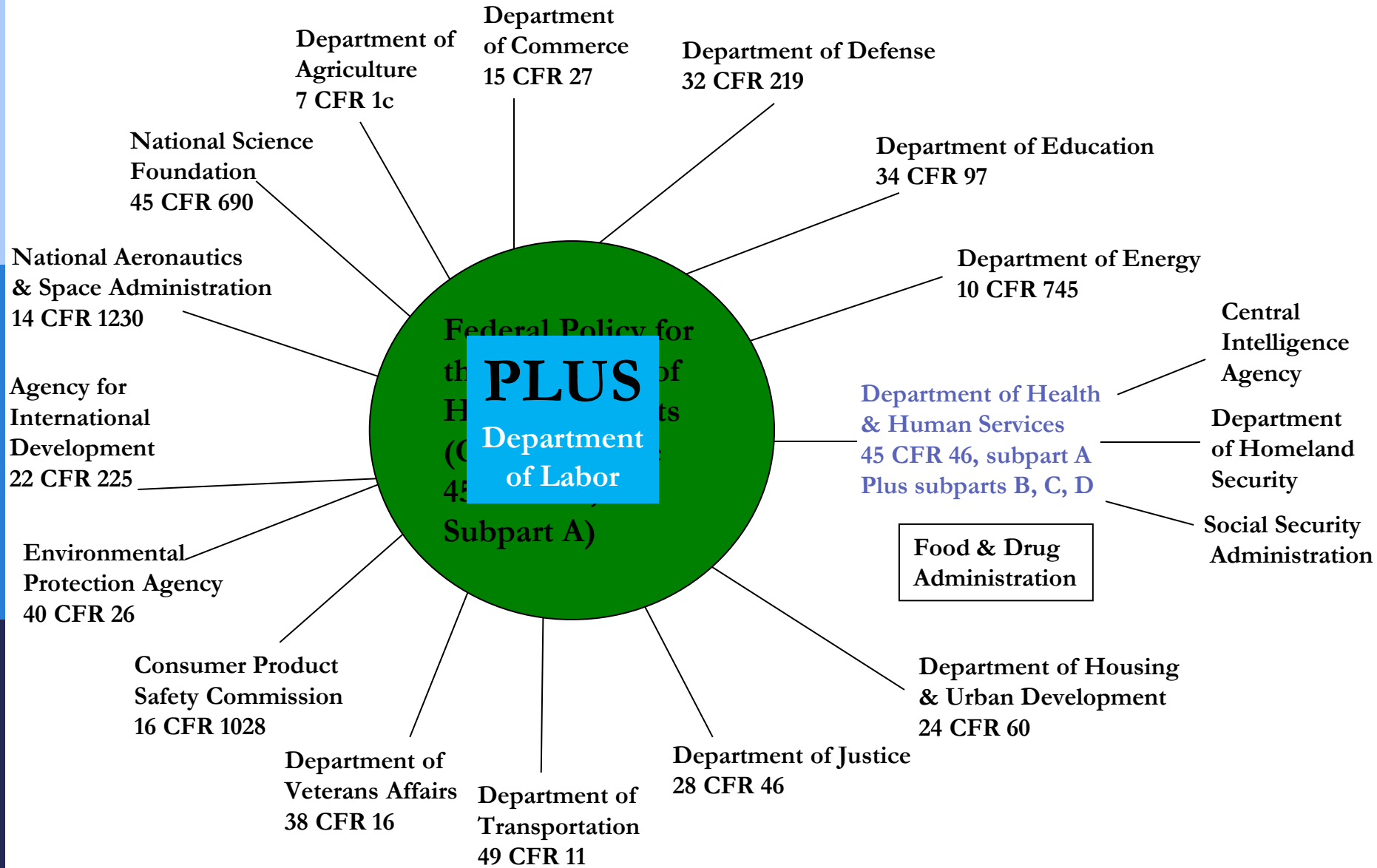
Ivor Pritchard

Senior Advisor to the Director (SAD)  
Office for Human Research Protections  
September 28, 2016

# Overview of Rulemaking Process



# 18 Common Rule Departments & Agencies



# The ABC's of the Common Rule

An **A**ssurance of the Institution's Human  
Research Protection Program

Prospective Review and Approval by an  
Institutional Review **B**oard (IRB)

Informed **C**onsent of the Human Subject

# Why Revise the Common Rule?

- Because changes in the research enterprise demand changes in protections
- To strengthen protections and promote respect
- To facilitate valuable research by reducing wasteful burden, delay, and ambiguity for investigators





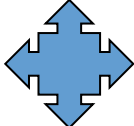
# Major Changes Proposed

1. Improve informed consent
2. Expand the definition of “human subject” to include all biospecimens – regardless of identifiability
3. Almost always require informed consent for secondary use of biospecimens
4. Mandate single IRB review of cooperative research conducted at U.S. institutions
5. Eliminate continuing review for certain minimal risk research

# Major Changes Proposed (2)

5. Extend the scope of the Common Rule to cover all clinical trials at U.S. research institutions – regardless of the source of funding
6. Require standardized privacy safeguards
8. Exclude 11 categories of activities from the Rule
9. Revise the categories of exempt research to establish 8 categories so as to better calibrate the level of review to the level of risk, create an exemption tool to facilitate exemption decisions, include a documentation requirement and certain conditions.

# The Common Rule and the Notice of Proposed Rulemaking (NPRM)

- Complexity: 
- Scope of regulated biospecimen research: 
- Scope of regulated social behavioral research: 
- Informed consent 
- Administrative burden: 

Continuing Review, Exclusions, Exemptions,  
Exemption Documentation, Exemption Tool,  
Broad Consent Tracking,



# Who Submitted Comments?

- 2,100+ public comments on the NPRM
  - For comparison: 200 on the NPRM in 1974,
  - 1,100+ on the ANPRM in 2011
- A majority of the comments (80%) from people writing in their individual capacity
- Official institutional comments: Majority from medical institutions (including medical schools) and academic institutions

# General Comment Themes

## Concern about:

- Overall complexity and length of the NPRM
- Absence of key elements (e.g., exemption tool, broad consent template, Secretary's list of privacy safeguards)
- Proposals giving investigators too much leeway to determine if their research falls under the rule

# General Comments

Sample quotation:

*“The urgency to approve a final revised Common Rule prior to the end of the 2016 is deeply concerning and has resulted in a premature, rushed document that is replete with deficiencies, contradictions, areas of conflict or overlap with other federal requirements, undefined processes, categories or lists and yet to be developed forms and templates. The lack of availability of these items at this late stage in the rule making process makes commentary particularly challenging.”*

# NPRM Public Comments: 2,100+

1. Biospecimen Proposal: Include non-identified biospecimens, biospecimen exclusion, broad consent, storage & use exemptions, template, and stringent waiver criteria: 2,400+
2. Exclusions and Exemptions: 1,000+
3. Single IRB Review Mandate: 300+
4. Improving Informed Consent: 200+

# Opposition to the Biospecimen Expansion

- A strong majority of commenters oppose the constellation of biospecimen research proposals
- Opposition across all subgroups:
  - Patients
  - General public
  - Research-affiliated organizations and individuals

# Objections to the Biospecimen Expansion

- **Patients:** Concern about restricting access to biospecimens and slowing research
- **General public:** More supportive than any other group, but still opposed to broad consent and any waiver of consent
- **Research affiliation:** Overwhelmingly opposed because of administrative burden

# A Representative Biospecimen Comment

“The idea that biomedical researchers, who do good every day with de-identified clinical specimens, would now be prohibited from conducting ABSOLUTELY HARMLESS AND EXTRAORDINARILY SCIENTIFICALLY VALUABLE RESEARCH on human specimens gathered during routine clinical care unless informed consent is gathered first is NOTHING SHORT OF AN OUTRAGEOUS OBSTRUCTION OF EFFORTS TO BENEFIT THE CITIZENS OF THE UNITED STATES.....What are you people thinking?”

# Another Representative Biospecimen Comment

“I would like to give consent first if my blood/tissue samples were to be used for any purpose.”

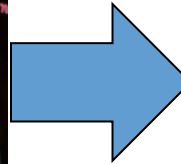
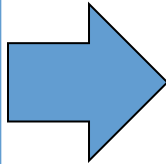


# Public Comments about Broad Consent

- The broad consent form would likely be so broad and vague as to not be informative to prospective research participants.
- Broad consent forms should be adaptable.
- IRBs should review and approve broad consent forms.

# The Two Stage Broad Consent Exemptions

**Broad  
Consent  
was  
obtained**



**Exemption to Label &  
Track §104(f)(1)  
Conditions:**

- §105 Privacy Safeguards
- Limited IRB Review of Consent Procedures and Adequacy of Privacy Safeguards

**Exemption for  
Specific Secondary  
Research Use  
§104(f)(2) Conditions:**

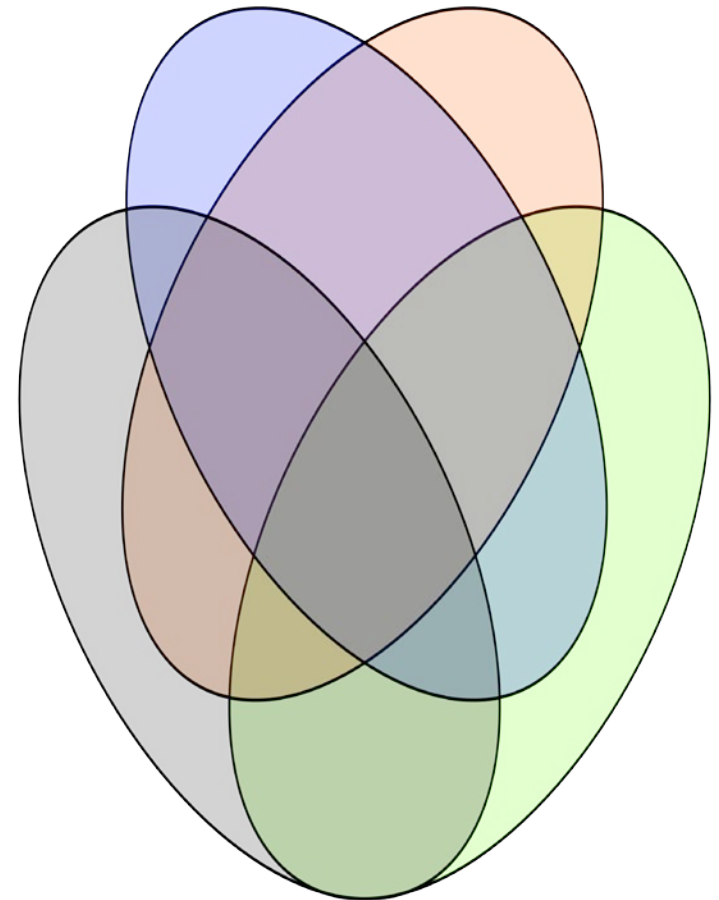
- §105 Privacy Safeguards
- No plan to return individual results

# 11 Exclusions and 8 Exemptions: 5 Types

1. Five involve governmental functions or government-generated information
2. Seven involve the secondary use of biospecimens or identifiable private information
3. Four involve interventions
4. Two involve testing, talking, or watching
5. One involves oral history, journalism, biography or historical scholarship

# General Objections to the Exclusions and Exemptions

- Too complex
- Exclusions add a new step to decision-making, with different categories and no documentation requirement
- Investigators have more license



# Comments on investigator use of the Exemption Decision Tool

- It is inappropriate and a conflict of interest
- Proposed exemptions categories are so nuanced that substantial guidance would be needed for investigators to input accurate information

# Comments on the Single IRB Review Mandate

- Some supported the concept, but opposed the mandate
- Individuals not commenting in their official institutional capacity tended to support the proposal
- Institutions tended to oppose the proposal
- Supporters and Opponents cited administrative burden and delay as reasons for their opinions
- Opponents cited the value of local review and of accountability

# Improving Informed Consent

## Revision to the introduction of §116 does the following:

- Emphasizes need to provide *essential* information a reasonable person would want to know, before providing other supplemental information to the subject



# Improving Informed Consent(2)

Revision to the introduction of §116 also stipulates:

- Information must be presented in sufficient detail, and must be *organized and presented* in a way that facilitates prospective subject's understanding of the reasons why one might or might not want to participate





# Comments on the Informed Consent Proposal

- Support for the spirit of the proposal
- A “core” consent form and appendices will not improve subject understanding
- The required elements of consent will not always be sufficient to enable an informed decision
- Guidance, not regulatory requirements, would be more appropriate
- The length and complexity of forms will not be reduced

# Comments on the proposal to Post Informed Consent Forms

- Some of the favorable comments viewed posting as a means of education and improving forms, while others saw little or no value
- Some commenters expressed concern about the timing of the posting

# Controversial Themes

- Should You have a Say?
- The Price of Increasing Cooperation
- Achieving Informed Consent
- Investigator Oversight

# Available OHRP Webinars

- 6 Topics Covered:
- Overview of the NPRM
- Exclusions and Exemptions
- Informed Consent
- IRB Review and Operations
- Research with Biospecimens
- Secondary Research Use of Data
- To watch, go to:

<http://www.hhs.gov/ohrp/education/training/nprmwebinars.html>

View the Comments at  
[https://www.regulations.gov/#!docket  
Detail;D=HHS-OPHS-2015-0008](https://www.regulations.gov/#!docketDetail;D=HHS-OPHS-2015-0008)



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