



“This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.”

# The Common Rule

A SUMMARY OF THE PROPOSED RULE MAKING AND HOW THE REVISIONS WILL  
IMPACT IRB REVIEW

# Outline of Discussion

- ▶ History of Common Rule Revision Process
- ▶ Goals of the Proposed Rule Making
- ▶ Changes that Impact Convened IRB Review
  - ▶ New Consent Form Regulations
- ▶ Changes that Impact Other IRB Reviews
  - ▶ Updated Definitions of Human Subjects and Research
  - ▶ New Exemption Categories
  - ▶ New Ongoing Review Requirements
- ▶ Broad Consent Provisions
- ▶ Reliance Agreement Provisions
- ▶ What previously considered changes were not made?
- ▶ What happens next?

# History of Common Rule Revision Process

- ▶ 1974: The National Research Act was signed and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established to develop ethical standards for the conduct of research
- ▶ 1979: The Belmont Report was developed as a summary of these ethical considerations
- ▶ 1980s: The Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) revised their human subject regulations
- ▶ 1991: The Federal Policy for the Protection of Human Subjects was published
  - ▶ “The purpose of this effort was to promote uniformity, understanding, and compliance with human subject protections as well as to create a uniform body of regulations across Federal departments and agencies (subpart A of 45 CFR part 46), often referred to as the ‘Common Rule’ for the Protection of Human Subjects”

# History of Common Rule Revision Process

- ▶ 2011: HHS announced the Advance Notice of Proposed Rulemaking in an effort to obtain feedback about the human subject protection regulations and how they could be improved
- ▶ 2015: HHS and 15 federal agencies released the Notice of Proposed Rulemaking (NPRM) and outlined suggested revisions to the regulations
  - ▶ “The participating departments and agencies propose these revisions to the human subjects regulations because they believe these changes would strengthen protections for research subjects while facilitating important research”
  - ▶ 2,100+ comments were received in response to the proposal
- ▶ 2017: The Final Rule was published on 1/19/2017
- ▶ 2018: The policy will be effective 1/19/2018

# Goals of the Proposed Rule Making

- ▶ Focus resources on the review of greater than minimal risk research
  - ▶ More studies will qualify for exemption from IRB review
  - ▶ Continuing reviews will no longer be required for studies eligible for expedited review, or greater than minimal research that has completed study activities
- ▶ Enhance subject comprehension during the consent process
  - ▶ A summary of key information must be highlighted for subjects
  - ▶ The consent must be organized in a clear, concise way
- ▶ Allow broad consent to be obtained for the use of identifiable private information and identifiable biospecimens
- ▶ Require single IRB review for cooperative research

# Changes that Impact Convened IRB Review: New Consent Form Regulations

- ▶ New requirements were developed for the information that must be given to potential research subjects during the consent process
- ▶ Informed consent must begin with a concise, focused presentation of key information
  - ▶ Summaries will be protocol-specific
  - ▶ Regulations were drafted to allow for flexibility
- ▶ Key information includes the following elements:
  - ▶ Consent is being obtained for research and participation is voluntary
  - ▶ Purpose, duration of participation and procedures
  - ▶ Potential risks and benefits for subjects
    - ▶ Might include only the most relevant or significant risks of the research
  - ▶ Appropriate alternatives to participation
- ▶ The consent document must be organized in a way that facilitates comprehension and presents information in a way that does not merely provide lists of isolated facts, but rather facilitates understanding of the reasons why one might or might not want to participate

# New Elements of Consent

- ▶ Additional Basic Elements of Informed Consent
  - ▶ One of the following statements will be required for any research that involves the collection of identifiable private information or identifiable biospecimens:
    - ▶ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after removal, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent; or
    - ▶ A statement that subject's information or biospecimens collected as part of the research (even if identifiers are removed) will not be used or distributed for future research studies
- ▶ Additional, Additional Elements of Informed Consent
  - ▶ A statement that subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
  - ▶ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
  - ▶ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

# Changes that Impact Other IRB Reviews

- ▶ Human Subject Research Definitions
  - ▶ Examples of what is NOT research were added and include journalism activities, public health surveillance and criminal justice or intelligence activities
  - ▶ The definition of human subjects incorporates “information or biospecimens”
  - ▶ A federal definition of clinical trial has been provided
- ▶ New Exemptions for Low-Risk Studies
  - ▶ Examples:
    - ▶ Secondary research of identifiable private information and biospecimens
    - ▶ Behavioral interventions that collect sensitive and identifiable information
  - ▶ Projects will require IRB review to determine if they meet exemption and may require limited IRB review
- ▶ Ongoing Review Requirements
  - ▶ Continuing review is no longer required for studies eligible for expedited review, or greater than minimal research where remaining activities are limited to data analysis or standard of care follow-up procedures

# Broad Consent Provisions

- ▶ Regulations now define a mechanism for obtaining broad consent from subjects for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens
- ▶ This can be accomplished through a separate consent form and process, or as a part of the consent process for another trial
- ▶ Future research involving specimens and data where broad consent was obtained would be eligible for exemption and would not require a waiver of consent

# Reliance Agreement Provisions

- ▶ Multi-site research will be required to undergo review by a single IRB of Record if it is federally funded or (potentially) FDA-regulated
- ▶ Requirement does not apply to multi-site research that is not federally funded and not FDA-regulated
  - ▶ Single IRB review is encouraged for those studies
- ▶ Effective date of this requirement is 1/19/2020

# What changes were not made from the NPRM?

- ▶ Research with non-identifiable biospecimens will not require documented consent or be subject to the Common Rule;
- ▶ There will be no groups of “excluded” activities;
  - ▶ Instead, exclusions will likely be determined to either meet the criteria for exemption or not qualify as research
- ▶ Some of the proposed requirements, including use of consent templates and a national, online exempt decision tool, will not be implemented;
- ▶ Clinical trials that are not federally funded will not be subject to the Common Rule;
- ▶ Standardized privacy safeguards for identifiable private information and biospecimens will not be established;
- ▶ More strict criteria for a waiver of documentation of consent for research with identifiable biospecimens will not be implemented

# What happens next?

- ▶ Waiting...
  - ▶ Regulations promulgated near the end of a Presidential Term are subject to a streamlined repeal process that involves Congress and the new President, and which, under current law, can be undertaken through the first several months of a new Presidential Administration
  - ▶ We are waiting until late May or June 2017 to ensure that the new regulations are not repealed
- ▶ Informed Consent Changes...
  - ▶ It is possible that the Office of Human Research Protections (OHRP) might provide guidance about the new regulations
  - ▶ The Penn IRB is considering new templates/guidance and may seek input from IRB members/research community on changes
- ▶ Penn IRB Policy Overhaul...
  - ▶ The IRB is currently working on updating our Standard Operating Procedures
  - ▶ Policies and procedures related to expedited review and continuing review will be updated
  - ▶ New guidance will be drafted and additional presentations will be provided
  - ▶ Reliance Agreement Guidance/New Forms will be finalized Spring/Summer 2017