Human Subjects Research Protections:

Enhancing Protections for Research Subjects

Reducing Burden, Delay, and Ambiguity for Investigators

Notice of Proposed Rulemaking (NPRM)

Panel Representatives

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Objectives

- Brief introduction to NPRM
- Review proposed changes to one of the nine key topic areas
- Open for discussion

Submit Extension Request & Comments at www.regulations.gov/
Resources

- NPRM Home Page
  www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html
- PRIM&R Resources Page – Webinar recording, Comments, Blog posts
  www.primr.org/publicpolicy/nprmresources/
- PRIM&R Comparison Chart
  www.primr.org/publicpolicy/nprmchart.aspx
- Verrill Dana, LLP - Academic & Clinical Research Group Redline Version & Decision Charts

Major Proposals to Modernize Common Rule

A. Changes to Scope/Applicability of the Regulations
B. Changes to Obtaining, Waiving, & Documenting Informed Consent
C. Changes to Protect Information & Biospecimens
D. Harmonization of Agency Guidance
E. Cooperative Research
F. Changes to Promote Effectiveness & Efficiency in IRB Operations
G. Changes to IRB Operational Requirements
H. Other proposed changes
I. Effective & Compliance Dates

NPRM Goals of Proposed Consent

- To facilitate prospective subjects’ decision & enhance autonomy
- To be consistent with majority of public’s autonomy interests & increase trust, partnership, & participation rates
- Increase transparency, accountability, & impose strict requirements on information that must be given & the manner in which it is given

Changes to make consent more meaningful
109 (b)

1. Essential information & required elements presented first
2. Include all other information in appendices
3. Organize to provide sufficient detail but also facilitate understanding
4. Changes are intended to lead to substantially shorter consent forms
5. Secretary will publish “how to” guidance at a later time

New Basic Element:
Future use of non-identified data 116 (a)(9)

1. Applies to all research collecting identifiable private information
2. Include a statement indicating whether the subject’s de-identified data:
   • will or will not be used for future studies; and/or
   • will or will not be shared with other researchers for future research without additional informed consent
3. Does not require specification of the future uses

New Additional Elements: New required informed consent elements 116 (b)(7-9)

1. Statement that biospecimens may be used for commercial profit & whether the subject will or will not share in this profit
2. Statement whether clinically relevant results will be returned to the subject, & if so, under what conditions
3. Options for subject to consent or refuse to consent to be contacted for more information/biospecimens or to discuss participation in another research study
Broad consent for secondary research w/biospecimens or Identifiable Private Information (IPI) 116 (c)(d)

1. Obtain broad consent for future secondary uses of IPI & biospecimens collected for other research or non-research purposes
2. For biospecimens, consent must be written
3. For IPI, may be oral if obtained through excluded or exempt categories; otherwise consent must be written
4. Secretary of HHS will publish in the Federal Register, a broad consent template
5. If subject declines to consent to research use of biospecimens or IPI, must be documented

Waiver limitations & considerations 116 (e)(f)(g) 117 (c)

1. Very limited use of consent waiver in biospecimen research
2. If individual was asked & declines to consent to collection/storage or secondary research use of biospecimens or IPI, the IRB cannot waive consent
3. IRB may approve screening, recruiting, or eligibility determinations without consent with assurance that investigator will implement standards for data protection/security
4. A signed consent form may be waived under certain circumstances for research involving groups for whom signing documents is not the norm

Posting of Consent Forms 116 (h)(1-2)

1. Only applies to clinical trial conducted or supported by HHS
2. Investigators will post final IRB-approved consent form
3. Only one posting required for each multi-site study
4. Within 60 days after trial is closed to recruitment
5. Could make more proprietary information public than what is required for a clinicaltrials.gov registration

• Changes to make consent more meaningful 109 (b)
• New Basic Element: Future use of non-identified data 116 (a)(9)
• New Additional Elements: New required informed consent elements 116 (b)(7-9)
• Broad consent for secondary research w/ biospecimens or Identifiable Private Information (IPI) 116 (c)(d)
• Waiver limitations & considerations 116 (e)(f)(g) 117 (c)
• Posting of Consent Forms 116 (h)(1-2)