

Update on the Common Rule NPRM

A Bit of History

Date	Event
1947	Nuremberg Code
1964	WMA Declaration of Helsinki
1966	PHS guidelines on informed consent and independent review
1972	New York Times article on the Tuskegee syphilis study
1974	HEW Regulations on the Protection of Human Subjects
1974	National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
1979	National Commission's Belmont Report
1981	Revised HHS Regulations
1991	Common Rule

Two Simple Overarching Goals of the Modernization Effort

- Enhance safeguards and respect for research participants
- Increase the efficiency of the oversight process



Major Reforms

- Calibrate oversight to level of risk
- Enhance respect for research participants
- Facilitate broad participation in research
- Increase privacy and security safeguards
- Simplify consent documents
- Streamline IRB review

Expansion of Scope

- Will cover clinical trials that are not currently subject to Federal regulation:
 - Conducted at an institution that receives federal funding for non-exempt human subjects research; and,
 - Conducted at an institution in the U.S.
- Estimated to be 1,399 trials in 2016

Exclusions – Not Research

- Oral history, journalism, biography, and historical scholarship focusing on specific individuals
- Collection of data and biospecimens for authorized intelligence or national security activities
- Collection of data and biospecimens for criminal justice activities
- Collection of data and biospecimens for institutional program improvement
- Quality assurance and quality improvement for the delivery or quality of an accepted practice or service
- Public health surveillance

Exclusions – Low-Risk Research

- Research involving information originally collected for purposes other than the proposed study when these sources are either:
 - publicly available; or
 - the information is de-identified, the investigator does not contact the subjects and will not re-identify subjects
- Research gathering non-identifiable or non-sensitive information through educational tests, survey or interview procedures, or observation of public behavior

Exclusions – Low-Risk Research that has Independent Controls

- Research gathering identifiable, sensitive information through educational tests, survey or interview procedures, or observation of public behavior if subject to [Paperwork Reduction Act, E-Government Act, Privacy Act](#)
- Research conducted by a federal agency using information generated or collected by the government for non-research purposes, including criminal history data, that is subject to [Paperwork Reduction Act, E-Government Act, Privacy Act](#)
- Research involving data collection and analysis of identifiable health information for the purposes of health care operations, research, or public health activities if subject to [HIPAA](#)

Exclusions – Low-Risk Biospecimen Research that does Not Diminish Autonomy

- Research involving de-identified biospecimens that will not reveal new information about an individual, e.g.:
 - test and assay development and validation
 - quality assurance and control activities, and
 - proficiency testing

Exemptions – **Safeguards** May Apply

- Standard tool or expert with knowledge must determine exemption status; records must be kept**
- Safeguards apply to protect information and biospecimens**
- Limited IRB Review of consent process and safeguards**
- Broad consent using an approved template**

Exemption – Low Risk Research

- Research in educational settings/practices unlikely to adversely impact students' opportunity to learn
- Research and demonstration projects supported by the federal government to evaluate public benefit or service programs
- Research involving benign interventions or video recording if the info is de-identified or not sensitive
- Taste and food quality evaluation



Exempt determination made and recorded

Exemption – Research with Sensitive Information

- Research gathering identifiable, sensitive information through educational tests, survey or interview procedures, or observation of public behavior
- Secondary research using identifiable, sensitive information collected for non-research purposes if:
 - Prior notice was given to the individuals that the information might be used in research
 - The secondary investigator uses the information only for the research for which they received it



Exempt determination made and recorded

Safeguards to protect information and biospecimens

Exemption – Research with Biospecimens and Identifiable Data

- Collection of biospecimens and identifiable information for the establishment of databases and biobanks

- Exempt determination made and recorded
- Safeguards to protect information and biospecimens
- Broad Consent
- Limited IRB Review

- Secondary research with biospecimens or identifiable information when there are no plans to return individual research results

- Exempt determination made and recorded
- Safeguards to protect information and biospecimens

Require Consent for Research with Biospecimens

- Requiring consent for the use of biospecimens, whether identifiable or de-identified, is respectful of persons
- Growing literature suggests participants expect control over their involvement in research
- Increasing ability to re-identify individuals from biospecimens and reveal potentially sensitive information

Higher Bar for Waiving Consent

- Additional criteria have been added for waiving consent for research involving biospecimens
 - There must be compelling scientific reasons
 - Research cannot be conducted with consented biospecimens
- Waiver not allowed for research with biospecimens or identifiable information if individual was asked to consent and declined

Allow Broad Consent

- Allows broad consent for collection and use of biospecimens and identifiable data
 - Return of individual results not allowed
 - Must use approved template (to be developed by the Secretary with public comment)

Broad Consent Elements

- General description of types of research that may be conducted
- Description of the scope of the consent, i.e., what will be collected and for how long (may be up to 10 years or date of legal age of consent)
- Time period of availability for secondary research (can be indefinite)
- Statement that participation is voluntary, refusal will involve no loss of benefits, and participant may request to withdraw consent
- Option to decline to inclusion of de-identified data in publically-accessible database

Simplify Consent Processes and Documents

- Informed consent documents may now **only** include specified elements of consent
 - All other documentation (e.g., institutional boilerplate) may only be provided as appendices
- Requires that participants be provided with
 - the information a reasonable person would need to make an informed decision about participation, and
 - an opportunity to discuss that information

Privacy and Security Standards for Biospecimens and Identifiable Data

- Research will be required to comply with:
 - HIPAA standards; OR
 - Standard to be developed by the Secretary
- Sharing permitted for:
 - Other research if equivalent safeguards are in place, research is IRB-approved, and further sharing will not occur
 - Public health purposes
 - Any other purpose with participants' consent

Multi-site Research

- Institutions located in the US engaged in multi-site research must rely upon approval by a single IRB unless:
 - More than single IRB review is required by law
 - Federal Department or Agency determines that a single IRB would not be appropriate for a particular study
- IRBs, rather than research institutions, will be held responsible

Transition Provisions

- Biospecimens collected before the effective date are grandfathered
- Effective date is 1 year after publication of the final rule
- Compliance date of 3 years after publication allowed for:
 - New consent requirement for biospecimens
 - Mandate for single IRB in multi-site studies

Next Steps

- Publication in the September 8, 2015 Federal Register for a 90-day comment period (to December 7, 2015)
 - Docket number: HHS-OPHS-2015-0008
- Stakeholder engagement will be conducted
- Consideration of public comments
- Development of final rule
- Publication of final rule

