Update on the Common Rule NPRM
## A Bit of History

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