HHS Federal Policy for the Protection of Human Subjects (Common Rule) (2017 Final Rule)

Revises the original Common Rule, promulgated in 1991, to modernize, clarify, and strengthen protections for human subjects in research.

Updated last October 9, 2017 for the 01/19/2017 Final Rule.

WHAT IT DOES

The 2017 revisions to the Federal Policy for the Protection of Human Subjects are meant to modernize, strengthen and make more effective the original policy promulgated in 1991. The revisions are intended to better protect human subjects involved in research while facilitating valuable research and reducing burden, delay and ambiguity for investigators. The policy is known as the Common Rule because it was adopted by sixteen Federal departments and agencies. The Department of Labor, which was not a signatory to the previous Common Rule, has adopted the updated version for human subjects’ research. As such, each department and agency has the Common Rule promulgated in its own section of the US Code of Federal Regulations (CFR), as shown here. For the purpose of brevity, references will be made to the portion of the CFR reference that will be consistent across all Common Rule-adopting departments and agencies (for example, §.101).

The final rule (noticed via 82 Federal Register 7149) promulgates the following provisions, annotated according to the final rule notice. These provisions will go into effect on January 19, 2018 – studies approved, waived, or exempted before this date will not be subject to the updated rule. A delayed compliance date for section 46.114(b), which covers cooperative (multi-institutional) research, is set for January 20, 2020.

Summary of Key Changes, As Described in the Final Rule:

- Establishes new requirements regarding the content and presentation of information that must be given to prospective human subjects (defined in the final rule at §.102(e)(1)) as part of the informed consent process, so as to ensure that the information is clear and concise to help the prospective subject decide whether to participate or not;
- Allows the use of broad consent from a subject for storage, maintenance and secondary research use of identifiable private information and identifiable biospecimens (According to §.102(e)(5) and (6), “identifiable” means that “the identity of the subject is or may readily be ascertained by the investigator [i.e., researcher] or associated with the information.”);
- Establishes new exempt categories of research based on the risk profile of the research;
- Creates a requirement for multiple US-based institutions engaged in cooperative research to use a single Institutional Review Board (IRB) for the portion of research that takes place within the US; and
- Removes the requirement to conduct continuing review of ongoing research studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data.

Other Common Rule Revisions, As Described in the Final Rule:

II. Scope and Applicability of the Regulation

- A - IRBs not Operated by an Institution Holding a Federalwide Assurance (FWA) (§.101(a)(1))
  - Common Rule departments and agencies now have the authority to enforce compliance against IRBs without FWAs, also known as independent IRBs.
- D - Department or Agency Discretion in Applying the Policy (§.101(c), (i))
  - Department heads or agency heads retain the final authority to determine the scope of the Common Rule within their purview, but new language requires them to exercise this discretion in a manner consistent with the ethical principles of the
Belmont Report.

- **E - State and Local Laws That Provide Additional Protections for Human Subjects**
  - Clarifies that the Common Rule does not preempt applicable tribal laws passed by the official governing body of an American Indian or Alaska Native tribe.

- **F - Research Covered by this Policy Conducted in Foreign Countries (§.101(h))**
  - Removes the reference to the Declaration of Helsinki as a standard for policy-covered research conducted in foreign countries

- **G - Harmonization of Department and Agency Guidances (§.101(j))**
  - Requires consultation among Common Rule departments and agencies for the purpose of harmonization when developing guidance documents, unless such consultation is not feasible

III. Definitions for the Purpose of This Policy (§.102)

- **B - Clinical Trial (§.102(b))**
  - Clinical Trial: a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes
  - This definition is only applicable to the requirement for posting of consent forms for clinical trials conducted or supported by Federal departments or agencies (§.116(h)).

- **D - Human Subjects (§.102(e))**
  - Common Rule departments and agencies must reevaluate the definitions of “identifiable” private information and biospecimens (§.102(e)(7)(i)), first within one year and then at least every four years after that; and
  - Common Rule departments and agencies must “assess whether there are analytic technologies or techniques” that generate “identifiable” private information and biospecimens (§.102(e)(7)(ii))
    - One such technology might be whole genome sequencing (both genome and exome)
    - Identified technologies/techniques will be published in the Federal Register and available for comment
  - might evolve due to technological advancements

- **E - Legally Authorized Representative (§.102(l))**
  - In jurisdictions where no applicable law authorizes surrogate decision makers, an individual recognized by institutional policy as acceptable for providing consent in the non-research context to the subject’s participation will now be considered a legally authorized representative for purposes of this rule

- **G - Public Health Authority (§.102(k))**
  - Public Health Authority: an entity (e.g., an agency or authority of the US, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant/contract of authority such public agency) that is responsible for public health matters as part of its official mandate.

- **H - Research (§.102(l))**
  - Accepted four exclusions from the definition of research including:
    1. Scholarly and journalistic activities (e.g., biography, journalism)
    2. Public health surveillance (e.g., disease outbreak monitoring)
    3. Criminal justice/investigative activities (e.g., DNA collection/analysis)
    4. Authorized activities in support of national security missions

V. Exempt Research (§.104)

- **A - Applicability of Exemptions to Subparts B, C, and D**
  - All research exemptions apply to Subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) and none may apply to Subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) unless the research is aimed at a broader population that consists mostly of non-prisoners and only incidentally includes prisoners. Some, but not all, exemptions apply to Subpart D (Additional Protections for Children Involved as Subjects in Research).

- **C - Categories of Exempt Research**
  - Much of this section is taken from the previous Common Rule “To what does this policy apply?” section (§.101(b))
Two new categories were added:
1. Exemptions for storage or maintenance (of identifiable private information or biospecimens) for secondary research for which broad consent is required (§ .104 (d)(7))
2. Secondary research (of identifiable private information or biospecimens) for which broad consent is required (§ .104 (d)(8))

VI. Protection of Identifiable Private Information and Identifiable Biospecimens

- HHS is now required to issue guidance to assist IRBs in appropriately protecting subjects’ privacy and confidentiality (§ .111 (a)(7)(ii))
- Some of the exemptions listed in § .104 (d) are subject to limited IRB review to ensure provisions are in place to protect the safety and privacy of subject information, as required by § .111 (a)(7)
  - Research that only includes interaction, involving educational test, survey procedures, interview procedures, observations of public behavior regardless of identifiability or sensitivity (§ .104 (d)(2))
  - Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written response or video recording (§ .104 (d)(3))
  - Exemptions for the storage or maintenance of identifiable private information or biospecimens for which broad consent is required, when there is a change specific to the research activity in how the identifiable private information is stored and maintained (§ .104 (d)(7))
  - Exemption for secondary research use of identifiable bio specimens for which broad consent is required (§ .104 (d)(8))

VII. IRB Membership and Modification to References to Vulnerability (§§ .107, .111 (a)(3), and .111 (b))

- Terminology Changes
  - IRB Membership Requirements
    - Removed stipulation that “no IRB may consist entirely of members of one profession” and that effort should be made to ensure that “no IRB consists entirely of men or entirely of women”, as other requirements for IRB diversity already accomplish these goals
  - Vulnerability
    - Revised at §111 (a)(3) to reflect that vulnerability of the populations in the research studies should be considered to be a function of the possibility of coercion or undue influence
    - Pregnant women and “handicapped” (physically disabled) persons are no longer considered vulnerable populations in the final rule

IX. IRB Review of Research (§ .109)

- Like other research activities covered by the Common Rule, IRBs have the authority to approve, require modifications in, and disapprove exempt research activities that require limited IRB review
- Continuing review is no longer required for:
  - Many minimal risk studies (defined in § .102 (i)), unless the reviewer documents why continuing review is necessary;
  - Studies that have progressed to such a point that the only activities left are data analysis and/or accessing follow-up clinical data from procedures that subjects would undergo as part of standard care for their medical condition or disease
  - Exempted research that require limited IRB review in order to qualify for an exemption

X. Expedited Review Procedures (§ .110)

- Allow expedited review to occur for research categories identified by the HHS Secretary's list unless the reviewers determine that they involve more than minimal risk, in which case the IRBs should document their rationale

XII. Cooperative Research (§ .114)

- All institutions located in the US engaged in cooperative research should rely on a single IRB
The single IRB rule does not apply to:

- Cooperative research where more than one IRB is required by law
- Research for which the Federal department or agency supporting or conducting the research determines and documents that use of a single IRB is not appropriate
- There will be a three-year transition period so that institutions can adjust to this new model

XIV. General Requirements for Informed Consent (§_.116)

A – General Requirements for Informed Consent (§_.116(a))

Informed consent documents must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in research.

Prospective subjects must be provided with the information that a reasonable person would want to have to make an informed decision about research participation.

The information must be organized and presented in a way that does not merely provide lists of isolate facts, but facilitates the prospective subject’s understanding.

B – Basic Elements of Informed Consent

Research with non-identified data will continue to be considered to not involve human subjects.

Any additional elements of informed consent will apply to all research involving private identifiable information.

Subjects must be informed either that:

- Their identifiable private information or biospecimens might be de-identified and used for future research (such research would not require further consent); or
- They will not be used for future research.

C – Additional Elements of Informed Consent [Required When Appropriate] (§_.116(c))

- Statement that prospective subject’s biospecimens may be used for commercial profit and whether the subject will or will not share in this profit.
- Statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subjects and if so under what conditions.
- Subjects must be informed if research on their biospecimen will or might include whole genome sequencing (both genome and exome).

D – Elements of Broad Consent for the Storage, Maintenance, and Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (§_.116(d))

- Broad consent can be obtained for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens (as defined at §_102(e)(5) and (6)).
- Broad consent is only permissible for secondary research and no other types of research.
- A request for broad consent must provide some of the same information required of informed consent requests, to include a description of potential benefits, the extent to which the subject’s confidentiality will be maintained, and the fact that participation is voluntary.
- Broad consent requests must describe:
  - What types of research might be conducted with the prospective subject’s identifiable private information or biospecimens.
  - How identifiability will be handled and who might use the identifiable info or biospecimens.
  - Whether the subject would be informed of details of future research uses or results.
  - A contact for questions regarding the subject’s rights and identifiability.
- Broad consent affords investigators wishing to conduct secondary research on identifiable private information or identifiable biospecimens an additional alternative to obtaining an IRB waiver of consent or to obtaining study-specific consent.

E – Waiver or Alteration of Informed Consent Involving Public Benefit and Service Programs (§_.116(e))

IRBs are prohibited from waiving informed consent for the storage, maintenance, or secondary research use of identifiable biospecimens or identifiable private information if a subject has already refused broad consent for those uses.

F – General Waiver or Alteration of Informed Consent (§_.116(f))

- Can only waive informed consent for the access to or use of identifiable biospecimens or identifiable private information if the research could not be practicably carried out without accessing or using identifiers.
As in preceding section, IRBs are prohibited from waiving informed consent if individuals were previously asked and refused to provide broad consent.

G - IRB Approval of Research Involving Screening, Recruiting or Determining Eligibility or Prospective Subjects (§ 116(g))
- IRBs are authorized to approve a research proposal in which investigators obtain access to information or [stored] biospecimens without the individuals’ informed consent, for the purpose of screening, recruiting or determining the eligibility of prospective human subjects of research.

H - Posting of Consent Forms (§ 116(h))
- A copy of the final version of the consent form of each clinical trial conducted or supported by a Federal department or agency must be posted on a publicly available Federal website that will be established as a repository for such consent forms.

XV. Documentation of Informed Consent (§ 117)
- Alters the language to conform to the new informed consent provisions above

XVI. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects (§ 118)
- For studies with indefinite plans for human subject involvement, IRB review and approval of awards and grants is required before human subjects can be involved in the study, unless the study is excluded, waived or exempted.

XVII. Research Undertaken without the Intention of Involving Human Subjects (§ 119)
- Unless already exempted or waived, studies that do not seek the involvement of human subjects until after being initiated must first be reviewed and approved by an IRB before involving human subjects.
- Reference to department or agency means a Federal department or agency component supporting the research.

XVIII. Conditions (§ 124)
- The head of either the conducting or the supporting Federal department or agency is permitted to impose additional conditions on research, when judged necessary to protect human subjects.

RELEVANT SCIENCE

Technological advancements like next generation sequencing have opened the door for large-scale genetic tests that examine large portions or even the entirety of a patient’s genome (the total DNA found in a human cell). Genetic tests are lab tests used to detect an individual’s genetic variants. Genetic variations contribute to the diversity of human appearance (eye color, height, etc.), but they also determine a person’s susceptibility to a number of disorders. Some disorders can be caused by a single mutation, while other disorders might have more complex and multivariate genetic factors. Scientists have developed a number of genetic tests to detect known disease-causing or -associated genetic variations – these typically only examine one or a few of the more than 20,000 genes found in the human genome at a time.

RELEVANT EXPERTS

Misha Angrist, Ph.D, Senior Fellow, Science and Society Associate Professor of the Practice, SSRI Visiting Associate Professor of the Practice, Sanford School of Public Policy at Duke University.

Holly Fernandez-Lynch, JD, MBioethics, Executive Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Relevant Publications:
BACKGROUND

The following provisions were included in the 2015 Notice of Public Rule Making (NPRM) for public comment, but not promulgated in the final rule:

Summary of Key Changes that were Not Promulgated, As Described in the Final Rule:

- Include non-identified biospecimens in the definition of “human subject”, making them subject to the Common Rule’s informed consent rules.
- Extend Common Rule provisions to research without Federal funding
- Propose standardized privacy safeguards for identifiable private information and identifiable biospecimens

Other Common Rule Revisions that were Not Promulgated, As Described in the Final Rule:

II Scope and Applicability of the Regulation

- B - Coverage of Clinical Trials (unadopted changes described here)
  - Extend Common Rule protections to all clinical trials irrespective of funding if:
    - Conducted at a university or institution that receives support from a Federal department or agency
    - Not subject to FDA Protection of Human Subjects
    - Conducted at a US-located institution

III. Definitions for the Purpose of This Policy (§.102, unadopted changes described here)

- D - Human Subject (§.102(e), unadopted changes described here)
  - Modify the existing definition of a human subject to include “research in which an investigator obtains, uses, studies, or analyzes biospecimens, regardless of identifiability
  - Permit IRBs to waive the requirement for informed consent for research use of biospecimens; the requirements for approval of such waivers would be quite strict
  - Alternative proposals for redefining “human subject”
    - Include whole genome sequencing (both genome and exome)
    - Include the research use of information that was produced using a technology applied to a biospecimen that generated information unique to the individual
- F - Minimal Risk (§.102(j), unadopted changes described here)
Modify the definition of minimal risk to include a requirement that the Secretary of HHS create and publish a list of activities that qualify as “minimal risk” to be re-evaluated periodically, at least every 8 years.

V. Exempt Research (§.104, unadopted changes described here)

- B - Exemption Determination
  - All research exemptions must be documented and records maintained including at minimum the name of the research study, the name of the investigator, and the exemption category applied
  - Federal departments and agencies will develop one or more exemption determination tools
  - Institutions have discretion over whether to implement these tools
    - If the institution chooses not to implement the exemption determination tool, such determinations would be required to be made by an individual who is knowledgeable about the exemption categories and who has access to sufficient information to make an informed and reasonable determination

VI. Protection of Identifiable Private Information and Identifiable Biospecimens (unadopted changes described here)

- Privacy and Security Provisions
  - Investigator and institution are required to implement reasonable safeguards for protecting against risks to security or integrity of biospecimens or private identifiable information
  - The Secretary of HHS will publish a list of privacy and safety measure that could be used to satisfy the requirement
  - Safeguards designed by the Secretary would be designed to be readily implemented if necessary
  - HIPAA compliance, if already required, satisfies safety and privacy requirements

XIV. General Requirements for Informed Consent (§.116, unadopted changes described here)

- C - Additional Elements of Informed Consent (§.116(c), unadopted changes described here)
  - Provide subjects or their legally authorized representatives with an option to consent, or refuse to consent, to investigators re-contacting the research subject to obtain additional information or biospecimens for future research
- E - Waiver or Alteration of Informed Consent Involving Public Benefit and Service Programs (§.116(e), unadopted changes described here)
  - Additional criteria for waiver or alteration of consent for biospecimens
    - IRB would be able to waive required informed consent for proposed biospecimens as human subjects if there were compelling scientific reasons to conduct the research and that the research could not be conducted with other biospecimens for which informed consent was obtained or could be obtained
- F - General Waiver or Alteration of Informed Consent (§.116(f), unadopted changes described here)
  - Additional waiver criteria for research involving the use of biospecimens

ENDORSEMENTS & OPPOSITION

A total of 2,172 comments were submitted in response to the NPRM - they can be accessed here.

The following is an itemized list of the endorsements and critiques given to each section of the NPRM, with quotes from commenters interspersed.

II Scope and Applicability of the Regulation (§.101)

- A - IRBs not Operated by an Institution Holding a Federalwide Assurance (FWA) (§.101 (a)(1))
  - Endorsement (E): Will increase IRB accountability and protect institutions
  - Opposition (O): Independent IRBs without FWA should not exist
- D - Department of Agency Discretion in Applying the Policy (§.101(c), (i))
○ E: Belmont Report is a good standard
○ O: the department or agency head should not have discretion in applying the policy

● F - Research Covered by this Policy Conducted in Foreign Countries (§.101(h))
  ○ O: Removing the reference of the Declaration of Helsinki implies we do not endorse it, which is untrue.

● G - Harmonization of Department and Agency Guidances (§.101(j))
  ○ E: Provision will help to stop conflicting guidance and rules
  ○ O: This provision will mean fewer provisions and a slower government process for developing and promulgating guidance

III. Definitions for the Purpose of This Policy (§.102)

● B - Clinical Trial (§.102(b))
  ○ Yale University: “We are concerned that the definition of “clinical trials”, to which the Common Rule would be extended, would sweep in activities not normally viewed as clinical trials, such as research outside the biomedical context and on low-risk interventions” (Full comment here)

● H - Research (§.102(l))
  ○ O: added a layer of unnecessary complexity in determining what was excluded research

V. Exempt Research (§.104)

● American College of Cardiology: “ACR agrees with the appropriateness of excluding from the Common Rule requirements, data collection and analysis for an institution’s own internal operational monitoring and program improvement purposes. We also urge that the use of clinical data registries and other third party vendors for the purpose of operational monitoring and program improvement be explicitly recognized as encompassed within this exclusion. None of the identified principles - respect for persons, beneficence, or justice - are appreciably affected by an institution’s use of third party vendors for program improvement activities.” (Full comment here)

● Yale University: “In particular, we welcome the proposed exclusion of journalism, oral history, history and quality assurance, as activities that are low-risk or have other appropriate safeguards and therefore are not deemed to be human subjects research. We also support changing the requirement for annual continuing review of eligible minimal risk research, the Institutional Review Board (IRB) review of grant proposals, and the creation of minimal risk categories” (Full comment here)

● Tufts University: “Prisoners are a vulnerable population and prisoner research cannot be exempt from IRB review according to the current regulations. Allowing prisoner research to fall under an exclusion seems like it would remove the extra protections they are currently being given under the current regulations.” (Full comment here)

● Boston Public Health Commission: “Public health agencies often design and implement novel public health programs to address community needs based on experience and local knowledge and not always based on accepted practice. Innovation and evaluation of innovative programs drive change. We recommend HHS exempt all public health quality assurance and improvement activities, not just those based on accepted practice.” (Full comment here)

● Duke University School of Medicine: “Duke does not feel that any exclusion categories are necessary other than the current "not research", "not human subjects' research", and "institution not engaged in research" activities.” (Full comment here)

● IMS Health: “We generally support the idea of creating specific exclusions from the scope of the Common Rule. We believe this is an appropriate balancing of the interests identified in the rule that will permit effective use of data for beneficial purposes without adversely affecting patient interests” (Full comment here)

● Society for Women's Health Research: “SWHR strongly believes investigators should not be responsible for making self-determinations for these types of activities [exclusions]. Investigators should at least informally consult with their IRB staff member/representative to determine exclusion. Some sort of written documentation, such as an email response, should be generated and retained prior to commencing research.” (Full comment here)

● New York State Bar Association - Health Law Section - Committee on Medical Research and Biotechnology: “Any modification to the Common Rule must be understood and adequately implemented by local Investigational Review Boards (IRBs) and protocol management review committees that protect human subjects. We are concerned that a study may be deemed exempt or excluded under the proposed changes to the Common Rule, may still be subject to an institutional full review due to a lack of familiarity with such changes. This may result in delays in protocol review and approval of protocols and reeducation of human subjects prior to approval. We request that the final regulations require education of local IRBs and other local protocol
management review committees to ensure that the new regulations, meant to streamline the review process by excluding certain research from extensive internal IRB review, is implemented effectively.” (Full comment here)

VII. IRB Membership and Modification to References to Vulnerability (§§ 107(a), 111(a)(3), and 111(b))

- O: the term mentally disabled should be replaced by the term “person lacking decision-making capacity”
- O: a disability does not always = vulnerability or coercion

VIII. IRB Functions and Operations (§108)

- E: Changes will reduce the administrative burden

IX. IRB Review of Research (§109)

- **Boston Children's Hospital:** “Boston Children's Hospital fully supports the proposed elimination of continuing review for minimal risk studies that qualify for expedited review. Additionally, we support the elimination of continuing review for studies initially reviewed by a convened IRB, unless specifically mandated by the IRB, after the study reaches the stage where it involves one or both of the following: (1) analyzing data, or (2) accessing follow-up clinical data from procedures that subjects would undergo as part of standard of care for their medical condition or disease.” (Full comment here)

XII. Cooperative Research (§114)

- **Boston University:** “Reliance on a single IRB for cooperative research should be incentivized rather than mandated, so that unanticipated consequences can be addressed during a more orderly transition. To incentivize the use of a single IRB, the development of a model agreement would be beneficial.” (Full comment here).
- **Boston Children's Hospital:** “Boston Children’s Hospital does not support a mandate for a single IRB for all Federally-funded research including the extension to clinical trials. While the use of single IRBs may prove to be effective and efficient in many circumstances, it is premature at this time to mandate single IRB use in Federally-funded domestic multi-center trials.” (Full comment here).
- **American College of Cardiology:** “Single IRB review for multi-site research is sufficient and urges the HHS to adopt its proposal to require that all institutions located in the US engaged in cooperative research rely on a single IRB as the reviewing IRB for that study. In that vein, the ACC also supports the extension of HHS’s authority over IRBs to ensure compliance with the requirements of the Common Rule.” (Full comment here).
- **Columbia University in the City of New York:** “Columbia is supportive of the concept of single, or central, IRB review for multicenter studies; however, as proposed in the NPRM, the mandate is premature and the scope is unreasonable.” (Full comment here).
- **Public Responsibility in Medicine and Research (PRIM&R):** “No support is offered, however, for the conclusion that mandating the use of a single IRB in all multi-site research—rather than on a case-by-case basis—is the right policy... Rather than eliminating unnecessary administrative burden, reliance on single IRB review in many cases may give rise to unnecessary demands, delays, and distractions from the work of human subject protection.” (Full comment here).
- **Federation of American Societies for Experimental Biology:** “FASEB believes that this mandate is a realistic option at this time, as many institutions already use reliance agreements to facilitate single IRB use for multisite studies.” (Full comment here).

XIII. IRB Record (§115)

- O: These changes merely shift burden and do not eliminate it

XIV. General Requirements for Informed Consent (§116)

- **General Requirements for Informed Consent**
  - **Yale University:** “By not only retaining these elements in their current form but also adding new basic and additional elements
of informed consent, the NPRM is unlikely to reduce the length or complexity of informed consent documents.” (Full comment here)

- **Boston University:** “The proposed changes to the consent form may not increase protection of subjects as multiple consent forms may be cumbersome for subjects.” (Full comment here)

- **American Psychiatric Association:** “The APA supports ensuring the informed consent process and forms are focused on key concepts including communicating the study’s purpose, potential risks, potential benefits, the voluntary nature of participation, and what the patient should do if he/she withdraws from the study.” (Full comment here)

- **B - Basic Elements of Informed Consent**
  - O: this provision will increase the length of the form without increasing prospective subject understanding

- **D - Elements of Broad Consent for the Storage, Maintenance, and Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (§.116(d))**
  - **Citizens Council for Health Freedoms** “We do not support the “broad consent” proposal. So many things could be done that the patient would find quite objectionable.” (Full comment here)

  - **Broad Institute of MIT and Harvard:** “The Broad Institute is the largest depositor of genomic data to the National Center for Biotechnology Information’s dbGaP repository (Database of Genotypes and Phenotypes), which has required explicit consent for data sharing obtained from biospecimens collected after January 25, 2015. Many investigators are increasingly requesting broad consent for future use of biospecimens or data derived from specimens in research regardless of funding—a practice we highly encourage. Obtaining prospective consent for future use of specimens facilitates broad sharing and use of specimens in research, while also providing individuals the opportunity to give (or withhold) their express permission for those uses. The creation of uniform standards with respect to broad consent would greatly assist investigators in making these requests and would address a growing concern that inconsistencies in consent forms used from one institution to the next could hinder future data sharing efforts.” (Full comment here)

  - **Duke University School of Medicine:** “Duke believes that if meaningful broad consent for secondary use of biospecimens is obtained under _104(1)(1), that exemption of specific secondary use protocols for biospecimens and identifiable private information should be rapidly established, particularly for research groups that were able to demonstrate appropriate privacy protection measures under the guidelines.” (Full comment here)

  - **Geisinger Health System:** “As a learning health system, Geisinger Health System uses broad consent approaches and discusses the research use of specimens and the wide variety of information collected as part of health care operations with its patients. While the communities served by the Geisinger Health System have demonstrated their general comfort with broad consent for research, this population is unique in many characteristics. We are concerned that a Federal mandate requiring informed consent for biospecimens research would potentially skew data sets and, moreover, generate health disparities among “data rich” and “data poor” patients. We share concerns that requiring broad consent for biospecimens research could exacerbate racial health disparities, as Asian and African American individuals have been noted as being less comfortable with the concept of broad consent.” (Full comment here)

  - **Muscular Dystrophy Association:** “MDA is concerned that the NPRM’s broad consent proposal could result in negative unintended consequences to the NBS [New Born Screening] program and to secondary research efforts that would outweigh the benefits. NPRM’s proposed broad consent requirement would compromise the ability to develop tests and establish the necessary data to add new disorders to the panel.” (Full comment here)

- **G - IRB Approval of Research Involving Screening, Recruiting or Determining Eligibility or Prospective Subjects (§.116(g))**

  - **American College of Cardiology:** “The College supports the proposal to allow IRBs to approve research proposals where investigators obtain identifiable private information from prospective human subjects without informed consent where that information is to be used for the purpose of screening and recruiting subjects for clinical trials.” (Full comment here)

- **H - Posting of Consent Forms (§.116(h))**
  - O: Such a list of informed consent forms could be a target for litigation

  - **Medical Library Association** and **Association of Academic Health Sciences:** “we recommend that ClinicalTrials.gov be used as the repository where the informed consent forms are stored. Using ClinicalTrials.gov ensures that all of the information related to a specific trial is found in one place by the more than 61,000 researchers, clinicians, and public who use the database daily.” (Full comment here)

  - **Boston Children’s Hospital:** “NPRM indicates that the intent is to increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the development of future consent forms. The NPRM provides no explanation as to how this requirement will achieve that goal or simply add a new administrative task. It is unlikely that consent forms
posted on a publicly accessible Federal website will serve as a useful tool by which to improve informed consent.” (Full comment here)

XVIII. Conditions (§ 124)

- O: This will increase variance unduly.

STATUS

The Final Rule was promulgated on January 19, 2017. These provisions will go into effect on January 19, 2018 – studies approved, waived, or exempted before this date will not be subject to the updated rule. A delayed compliance date for section 46.114(b), which covers cooperative (multi-institutional) research, is set for January 20, 2020.

POLICY HISTORY


PRIMARY AUTHOR

Nicole Angelica, MA Candidate

EDITOR(S)

Hira Ahmed, MA Candidate; Alex Robeson, PhD

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