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**To:** Institute and Center (IC) Clinical and Scientific Directors  
All NIH Intramural Research Program (IRP) Clinical and Basic Research Investigators  
IC Protocol Navigators

**Subject:** Policy Memo – Implementation of the 2018 Common Rule and Other Policy Changes

The revised Federal Policy for the Protection of Human Subjects at 45 CFR 46, Subpart A, also known as the 2018 Common Rule, has a general compliance date of January 21, 2019. Many existing intramural NIH human subjects protection policies will be affected by this regulatory update. The NIH Office of Human Subjects Research Protections (OHSRP) is currently updating its policies and procedures regarding human subjects research protections for the NIH Intramural Research Program (IRP), as part of the Institutional Review Board (IRB) centralization and reorganization, and to incorporate requirements of the 2018 Common Rule. As the policy revisions will not be complete prior to the general compliance date of the 2018 Common Rule, this memo serves to inform the NIH IRP research community that certain NIH HRPP policies currently in effect will continue unless the research is subject to the 2018 Common Rule, and there is a conflict between the 2018 Common Rule and existing NIH policy, then the 2018 Common Rule will prevail. Certain additional policy changes listed below will become effective as of January 21, 2019 and supersede the corresponding NIH policies, independent of the Common Rule changes.

## **Policy Statement**

### **1. NIH IRP implementation of the 2018 Common Rule**

For research subject to the 2018 Common Rule at 45 CFR 46, any NIH policies that conflict with the provisions of the 2018 Common Rule will be superseded by requirements of the 2018 Common Rule. If current NIH policy is more restrictive but remains consistent with the 2018 Common Rule requirements, the current NIH policy will prevail.

- a. The 2018 Common Rule requirements will apply only to research that is initiated (i.e., 1) initially approved by an IRB, or 2) for which IRB review is waived pursuant to 45 CFR 46.101(i), or 3) for which a determination is made that the research is exempt) on or after January 21, 2019.

- b. Research initiated prior to January 21, 2019 will remain subject to the pre-2018 Common Rule requirements. (The term "pre-2018 Common Rule" refers to subpart A of 45 CFR part 46 (i.e., the Common Rule) as published in the 2016 edition of the Code of Federal Regulations.)
  - c. At a later time, certain NIH research initiated prior to January 21, 2019 may be transitioned to the 2018 Common Rule requirements; however, this will be determined on a case by case basis by OHSRP or the NIH Intramural IRB. Investigators may not choose to transition research subject to the pre-2018 Common Rule to the 2018 Common Rule without the agreement of OHSRP or the NIH Intramural IRB. Further guidance on this topic will be forthcoming.
2. For all NIH research initiated on or after January 21, 2019, formal determinations by OHSRP that NIH IRP research is not human subjects research will no longer be mandatory for research activities involving only use (including secondary use study or analysis) of coded or de-identified (not individually identifiable) human specimens or data. *This supersedes applicable sections of NIH HRPP SOP 5 NIH Research Activities with Human Data/Specimens, Sections 5.4.B.1 and 3, 5.7 and SOP 6 Determinations Made by the Office of Human Subjects Research Protections (OHSRP), Sections 6.4, and 6.6*
- a. Investigators should assess whether their research meets the regulatory definition of human subjects research (see Implementation Guidance, below). If an investigator is not certain, a request for a formal determination may be made through NIH iRIS, starting January 21, 2019.
  - b. If a formal determination that an activity is not human subjects research is needed or desired, only OHSRP or the Office of IRB Operations (IRBO) can make a formal determination that an NIH IRP activity is not human subjects research.
  - c. Importantly, activities with data and/or specimens that constitutes human subjects research but may be exempt from IRB review under the pre-2018 Common Rule at 45 CFR 46.101(i.e., approved prior to January 21, 2019) or the 2018 Common Rule at 45 CFR 46.104 must still be submitted to OHSRP or IRBO for a formal exempt determination via NIH iRIS.
  - d. This policy change does not supersede other NIH policies or requirements for the review of research, e.g., those involving human fetal tissue or human embryonic stem cells.
3. The new NIH Informed Consent template incorporating the requirements of the 2018 Common Rule is required to be used for all protocols receiving NIH IRB initial approval on or after January 21, 2019 for which a written long form informed consent is required (see memorandum circulated on 1/3/2019 and the Implementation Guidance, below). The NIH Informed Consent template will address requirements of the 2018 Common Rule, for example:
- a. The reasonable person standard, and
  - b. The requirement that Principal Investigators of “clinical trials<sup>1</sup>” post a copy of an IRB-approved informed consent form on a Federal website once the trial is closed to recruitment, and no later than 60 days of the last study visit of any subject.
  - c. The option to use broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of


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<sup>1</sup>“Clinical trial means 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.” [2018 Common Rule, 45 CFR 46.102(b)]

identifiable private information and identifiable biospecimens. *This optional provision is not being implemented within the NIH IRP this time.*

Guidance will be distributed to the NIH IRP community about these and other 2018 Common Rule requirements beginning in January 2019. (Common Rule Bulletins)

4. For all research using a written long form consent at an NIH site (whether initially approved by an IRB before or after January 21, 2019): A witness to the subject's signature of the informed consent document will no longer be required. *This supersedes applicable sections of NIH HRPP SOP 12 Requirements for Informed Consent 12.8.4.B and C, 12.9 and 12.15.* Notably, the requirement to have a witness to the short form oral consent process still remains, as noted below.
  - a. When obtaining long form consent via telephone is approved by an IRB, and when written documentation of consent is required, there is no requirement for the presence of a witness to the consent at the location of the individual obtaining consent. However, no research procedures can commence until the investigator has confirmed that written, legally effective consent has been obtained.
  - b. Investigators are encouraged to have a second person (who is not obtaining informed consent) present during the entire informed consent discussion and, if applicable, the signature process. Investigators are further encouraged to document the presence and identity of that individual in the informed consent note placed in the medical record. This is encouraged for both in person and telephone consent processes.
  - c. The NIH policies on utilizing a witness during the "short form" consent process remain in effect.
5. Expanded access to an investigational product for a single patient *non-emergency* use. *This supersedes applicable portions of NIH HRPP SOP 15 Research Regulated by The Food and Drug Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products), Section 15A.8.*
  - a. FDA allows that a physician submitting a new individual patient expanded access IND may request a waiver from the FDA regarding full IRB review (FDA Form 3926). The FDA concludes that such a waiver is appropriate when the physician obtains concurrence by the IRB chairperson before treatment use begins.
  - b. At the NIH, full IRB review of an individual patient expanded access IND is no longer required if FDA grants a waiver. Consistent with FDA requirements, IRB Chair concurrence in lieu of IRB approval is allowable.
  - c. Physicians wishing to provide an investigational product for a single patient non-emergency use should follow the requirements of the FDA as outlined here <https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf>.
  - d. Physicians should also submit a request to the IRB Chair via iRIS along with a cover memo identifying this as a non-emergency use. Currently, the submission form to use for this is titled "Emergency Use IND form" but will be modified with the revision to the policy.
  - e. The patient-recipient must also be co-enrolled in research (e.g., through 45 CFR 46).

  
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## Implementation Guidance

**Revised Common Rule:** The revised rule contains several new provisions, some of which are listed below. *Note, the following list is not intended to be a complete listing of all the changes in the revised CR):*

### 1. Informed Consent:

- a. A requirement to begin with a concise and focused presentation of the key information (see Common Rule Bulletin #1).
- b. The provision of certain information in the consent must meet a reasonable person standard (see Common Rule Bulletin #4).
- c. One new required element of consent regarding other future research use of biospecimens and data stripped of identifiers (see Common Rule Bulletin #3).
- d. Three new additional elements of consent to be included when appropriate (see Common Rule Bulletin #3).
- e. A requirement that an informed consent document used to enroll participants on a “clinical trial” be posted to a publicly available federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit of any subject (see Common Rule Bulletin #5).
- f. Requirements for institutions who want to use broad consent (i.e., seeking prospective consent to unspecified future research) to allow the storage, maintenance and secondary use of identifiable private information and identifiable biospecimens. *This will not be implemented within the NIH IRB at this time.*

### 2. Exempt research:

- a. There are extensive revisions to the categories of exempt research (see Common Rule Bulletin #2)

### 3. Continuing Review:

- a. For research approved by an IRB on or after January 21, 2019, continuing review will no longer be required for certain categories of minimal risk research, unless specifically required by the IRB.

At a later time, certain NIH research initiated prior to January 21, 2019 may be transitioned to the 2018 Common Rule requirements; however, this will be determined on a case by case basis by OHSRP or the NIH Intramural IRB. **Other NIH Policy changes:**

### 1. Not human subjects research (NHSR) determinations:

- a. Given that researchers are no longer required by NIH policy to obtain a formal NHSR determination as described in the policy statement above, researchers should carefully consider whether their work is human subjects research. If in doubt, researchers should contact the Office of IRB Operations or OHSRP for guidance. Researchers should consider the following when determining whether the research is NHSR.

- Is the activity research? See definition of research in footnote below
  - If yes, consider further questions below. If no, no IRB review required.
- Do the specimens and/or data come from a living individual?
  - If yes, consider further questions below. If no, no IRB review required.
- Will you obtain specimens and/or data through an interaction or intervention with the subject? *If yes to any of the questions below, IRB review may be required. Contact the OHSRP or IRBO.*
  - Interaction includes communication or interpersonal contact between the investigator and subject.
  - Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Will you obtain, use, study, analyze or generate identifiable private information (e.g. data) or identifiable specimens? *If yes to any of the questions below, IRB review may be required. Contact the OHSRP or IRBO.*
  - Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
  - Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
  - An identifiable specimen is a specimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

*Coded data and/or specimens should be considered identifiable if any member of the NIH research team has access to the code key. Additional information about coded specimens can be found at: HHS OHRP's Coded Private Information or Specimens Use in Research, Guidance (2008).*

*Research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research” 45 CFR 46.102(l)*

