

## 2018 Revised Common Rule Transition Information

### Applicability

On January 21, 2019, regulations governing human subjects research are changing. The new 2018 Common Rule is applicable to research funded or supported by the following Federal agencies:

1. Department of Homeland Security
2. Department of Agriculture
3. Department of Energy
4. National Aeronautics and Space Administration
5. Department of Commerce (including National Institute of Standards and Technology)
6. Social Security Administration
7. Agency for International Development
8. Department of Housing and Urban Development
9. Department of Labor
10. Department of Defense
11. Department of Education
12. Department of Veterans Affairs
13. Environmental Protection Agency
14. Department of Health and Human Services
15. National Science Foundation
16. Department of Transportation
17. Office of the Director of National Intelligence
18. Central Intelligence Agency

The following agencies intend to become signatories to the 2018 Common Rule

1. Department of Justice (including National Institute of Justice)
2. Consumer Product Safety Commission

Research funded by other Federal agencies, or clinical investigations of products regulated by the Food and Drug Administration, is subject to different regulatory requirements. Additionally, ISU has chosen to limit the scope of its Federalwide Assurance to cover only federally-funded research with the goal of allowing an appropriate level of flexibility for non-federally funded research. These projects will be afforded protections similar to and commensurate with those required by federal regulations, specifically the 2018 Common Rule.

The Iowa State IRB will begin applying components of the 2018 Common Rule as of its compliance date of January 21, 2019. This means that some research submitted prior to January 21, 2019 will be subject to the new requirements.

For studies approved prior to January 21, 2019, the IRB is not required to apply the requirements of the 2018 Common Rule. However, in some cases, transitioning a study to the new regulations may be beneficial for the research team. IRB staff will work closely with research teams to determine the best transition option.

At this time, there is little Federal guidance regarding the 2018 Common Rule. Guidance may be issued that affects these transition plans or interpretations of Common Rule requirements, and corresponding revisions may become necessary.

This document describes key changes and plans to handle review of IRB applications for new and ongoing research during the transition period from the pre-2018 Common Rule to the new 2018 Common Rule.

Table of Changes and ISU Interpretation and Transition Plans

Common Rule Element	Summary of Changes in the <a href="#">New 2018 Common Rule</a>	ISU Interpretation and Plan for Implementation
Expansion of Exemptions	<p>New exemption categories and clarification of existing exemptions. Now the following types of research may be exempt:</p> <ul style="list-style-type: none"> <li>• Research involving benign behavioral interventions that meets certain conditions.</li> <li>• Some research involving use of identifiable secondary information or biospecimens when its use is governed by specific confidentiality protections (e.g., HIPAA).</li> <li>• Surveys and interviews with adults where identifiable sensitive information is collected when adequate privacy and confidentiality protections are in place.</li> </ul> <p>The exemption related to research involving normal educational practices now requires consideration of the effects on students' education and assessment of educators.</p> <p>Some exempt research is subject to "limited IRB review", which is similar to an expedited review process.</p> <p>Research activities otherwise eligible for exemption that focus on a broader subject population, but only <i>incidentally</i> includes prisoners may be deemed exempt.</p>	<p>The changes in allowable exemptions will be incorporated into the IRB review processes. Investigators should expect changes—some previously non-exempt research may become eligible for exemption under the 2018 Common Rule.</p> <p>Updated information about <a href="#">exempt research</a> is available on the IRB website.</p> <p>New Exemptions 7 and 8 will NOT be implemented at ISU at this time and until federal guidance on implementation expectations and practices is provided and can be assessed for feasibility. Exemptions 7 and 8 rely on implementation of a new type of consent process -- "broad consent." Using broad consent requires permanent, pristine record keeping regarding the consent decision of each individual about how their data may be used. Broad consent cannot be waived, and its provisions must be honored by the initial investigators who collect data <u>and</u> any/all future users of the data.</p>
Continuing Review	<p>Continuing review is no longer required for most minimal-risk research including research where remaining activities are limited solely to data analysis or obtaining follow-up clinical information (that would be collected for medical purposes).</p> <p>The IRB may, at its discretion, require continuing review if deemed necessary. This is expected to be rare for minimal risk research.</p>	<p>ISU will implement this change and no longer require continuing review for most minimal risk research that is approved under or formally transitioned to the 2018 Common Rule.</p> <p>ISU is responsible for continued oversight of research. In lieu of continuing review, researchers will be asked for a very brief and simple status update every three years.</p>

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	Note: Annual continuing review is still required for FDA-regulated studies.	Researchers remain responsible for ensuring all changes receive prior approval, any problems or noncompliance are reported to the IRB, and studies are formally “closed” when complete.
Informed Consent Form	<p>Changes include:</p> <ul style="list-style-type: none"> <li>• Informed consent must now begin <i>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 the research.</i></li> <li>• New focus on how consent forms are written and how information is presented to participants to facilitate understanding;</li> <li>• New <u>universally-required</u> element related to use of data beyond the current study</li> <li>• New required elements (<u>when applicable</u>) to inform participants about the potential for their bio-specimens to be used for commercial profit, whether the research involves whole genome sequencing, and whether clinically-relevant results may be returned to the participant.</li> </ul>	<p>Updated consent form <a href="#">templates</a> and guidance on <a href="#">elements of consent</a> are available on the IRB website. IRB staff will work with researchers to ensure consent forms meet new requirements.</p> <p>In general, consent forms that are already concise (e.g., 4 or fewer pages) do not need to include the new concise and focused summary.</p>
Informed Consent Process	<p>Consent is not required prior to screening/assessing eligibility when the procedures are limited to obtaining information through oral or written communication from subjects (e.g., screening interviews or surveys), or obtaining data from records or stored bio-specimens.</p> <p>To waive informed consent for use of identifiable private information or bio-specimens, researchers must justify why the research could not be carried out without using <i>identifiable</i> information.</p> <p>Electronic signatures are allowed to document informed consent. However, it is unclear at this time whether electronic signatures must meet state and federal authentication requirements.</p>	<p>The new requirements will be addressed as IRB application forms are updated in IRBManager (the electronic submission system).</p> <p>Updated guidance about <a href="#">informed consent-related waivers/exceptions</a> is available on the IRB website.</p>

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Posting of Clinical Trial Consent Forms	<p>For federally-funded clinical trials, one IRB-approved informed consent form used to enroll subjects must be posted on a publicly available Federal website that will be established as a repository.</p> <p>Posting must occur after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.</p> <p>In some cases, redactions to the information posted may be allowed.</p>	<p>The Office for Human Research Protections has identified two websites that will satisfy the posting requirement:</p> <ol style="list-style-type: none"> <li>1. <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a>; and</li> <li>2. <a href="http://www.Regulations.gov">www.Regulations.gov</a>, Docket ID: <a href="https://www.fda.gov/oc/ohrt/docket-0021">HHS-OPHS-2018-0021</a></li> </ol> <p>Additional federal websites may be identified in the future.</p> <p>Currently, no instructions regarding posting procedures have been issued.</p>
Review of Federal Grant Proposals for Congruence with IRB Applications	<p>Requirement that the IRB verify congruence between federal grant proposals and IRB applications is removed.</p>	<p>Funding information will continue to be requested in IRB applications, as other agency-specific requirements apply. However, the IRB will no longer review grant proposals to assess congruence with IRB applications. In most cases, submission of federal grant applications with IRB applications is no longer required.</p> <p>Principal investigators are responsible for assuring that all planned procedures are described in IRB applications and are IRB-approved prior to implementation.</p>
Clarification of Activities deemed “Not Research”	<p>The federal definition of <i>research</i> is unchanged. But, the regulations now specify certain activities automatically deemed <u>not</u> to be research, including:</p> <ol style="list-style-type: none"> <li>1. Scholarly and journalistic activities (e.g., oral history, literary criticism, legal research, and historical scholarship), including the collection and use of information, that <u>focus directly on the specific individuals about whom the information is collected.</u></li> <li>2. Public health surveillance activities.....when conducted, supported, requested, ordered, required, or authorized by a public health authority.</li> <li>3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities</li> </ol>	<p>This regulatory change is intended to clarify what activities may be automatically excluded from IRB oversight because they do not constitute federally-defined research. It does not substantially alter how ISU’s IRB currently interprets the federal definition of research (which triggers IRB oversight).</p> <p><b>A note about oral history:</b> There has been long-standing confusion of when oral history projects require IRB oversight. The regulatory wording notes that oral history projects are deemed not research when the focus of the project is <u>directly on the individuals</u> about whom the information is collected.</p> <p>If oral history interviews are obtained for purposes of analyses to draw broadly applicable conclusions (i.e., generalizing to other individuals beyond those who are interviewed), then the project meets the federal definition of research and IRB oversight is required.</p>

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	<p>authorized by law or court order solely for criminal justice or criminal investigative purposes.</p> <p>4. Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.</p>	

## General Transition Provisions

New research proposals reviewed on or after January 21, 2019 will be reviewed in accordance with the 2018 Common Rule and/or applicable Food and Drug Administration or Federal Agency regulations.

Review of research initially determined to be exempt, approved, or approved with stipulations prior to January 21, 2019 (i.e., “ongoing research”) will be handled as follows:

1. Ongoing research will not automatically be required to comply with the 2018 Common Rule. It will continue to operate in accordance with the Pre-2018 Common Rule or applicable FDA or Federal Agency regulations for the life of the study, until closure or the study is transitioned to the 2018 Common Rule requirements.
2. Upon submission of an action (a continuing review application or modification application (other than personnel-only)), each ongoing study will be assessed on a case-by-case basis for a determination of whether the project should be transitioned to the 2018 Common Rule requirements. For non-exempt research, the IRB or expedited reviewer must document a determination to transition ongoing research to the 2018 Common Rule. An exempt reviewer may document the determination to transition to the 2018 Common Rule for the following:
  - a. Research granted exemption in accordance with the pre-2018 Common Rule; and
  - b. Research deemed non-exempt in accordance with the pre-2018 Common Rule, but that is eligible for exemption under the 2018 Common Rule. When applicable, newly-exempted research must undergo limited IRB review.

### Transitioning to the 2018 Common Rule

- a. Projects that are eligible for exemption based on the 2018 Common Rule may be granted exemption if a reviewer finds that all requirements are met. This includes limited IRB review when required. For ongoing research that was previously non-exempt, exempt status is effective on the date exemption is granted by the reviewer.
- b. Continuing review requirements for ongoing research that has been formally transitioned to the 2018 Common Rule are as follows:
  - i. Research requiring oversight by the convened IRB (i.e., “full-board”) requires continuing review, except in the following instance:
    1. Research that is not federally-funded and not FDA-regulated may be excluded from continuing review if the convened IRB determines the study presents no greater than minimal risk to participants, and determines that continuing review is not a necessary measure to ensure protection of human subjects.

- ii. Continuing review is no longer required for:
  - 1. Minimal risk research reviewed by expedited procedures under the pre-2018 Common Rule, or
  - 2. Research that is eligible for expedited review under the 2018 Common Rule; or
  - 3. Ongoing research that has progressed to the point that it involves only one or both of the following:
    - a. Data analysis, including analysis of identifiable private information or identifiable biospecimens; or
    - b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
- iii. For any research, the IRB or expedited reviewer may determine that continuing review is required for research that would not otherwise require it. Typically, this will be to assure protection of human subjects or to address compliance concerns. In these instances, the IRB or expedited reviewer must document the rationale for requiring continuing review.
- c. Non-exempt research that has been formally transitioned to the 2018 Common Rule must be modified to align with applicable requirements for informed consent.
  - i. Re-consent of previously-enrolled participants is NOT required, unless the IRB or expedited reviewer determines that the changes may materially affect participants' willingness to continue taking part in the study.
  - ii. In general, previously-granted informed consent waivers or alterations will be allowed to continue to avoid disruption in the ongoing research. The IRB or expedited reviewer may determine that a previously-granted waiver or alteration is no longer appropriate; however, these situations are expected to be rare.
  - iii. In accordance with 45 CFR 46.116(g), the IRB or expedited reviewer may approve activities conducted to assess eligibility without first obtaining informed consent if the following conditions are met:
    - 1. Information is obtained through *oral or written communication* with the prospective subject or their legally authorized representative; or
    - 2. The investigator will obtain identifiable private information or identifiable biospecimens by *accessing records or stored identifiable biospecimens*.
  - iv. Federally-funded clinical trials must comply with requirements to publicly post one IRB-approved informed consent form used to enroll subjects, as required by 45 CFR 46.116(h). This requirement will not apply to research where, at the time of transition, data collection is complete and remaining activities are limited to data analysis.