As previously announced, new regulations regarding human subjects will go into effect January 21, 2019.

**Studies submitted prior to January 21, 2019** may continue through completion under the Current Common Rule and will not be expected to comply with all of the changes generated by the Revised Rule. However, if a Principal Investigator (PI) wishes to transition an existing study to the Revised Common Rule, contact Research Ethics and Compliance (REC) to discuss options since the study would have to comply with all applicable revised common rule requirements.

**Studies submitted on or after January 21, 2019 must comply with the Revised Common Rule.** While much of the revised regulations apply to IRB review and management, changes impacting researchers will be reflected in the Cayuse IRB submission forms. SOPs, policies, FAQs, etc., are being revised, but some revisions are pending guidance from OHRP, the federal agency overseeing human subjects research, that may require additional revisions.

This document provides an overview of the 2019 primary changes of importance to researchers. Key regulatory changes include:

- the redefinition of activities that are not considered human subjects research,
- changes to the informed consent documentation and process,
- new exempt categories, and
- changes to the requirements for continuing review.

PIs are encouraged to consult REC’s website for more information and contact REC with any questions. Updates will be provided with additional information and answers to frequently asked questions (FAQs) as OHRP provides federal guidance on interpretation and practical application of the new rule.

**Processing:** There has been no change in the process for determining what activities meet the federal of research and human subject and require IRB review. Submissions are still routed through Cayuse IRB, and CITI training requirements have not changed.

**Activities deemed not to be research that do not require IRB review:** The revised rule has provided determinations on select activities that are considered “not human research and do not require IRB review” as long as they are done exactly as described below. These include:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the
collection and use of information, that focus directly on the specific individuals about whom the information is collected.

• Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

• Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

• Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

If the data collected is used more broadly than defined above, IRB review may be required. Please contact REC for guidance.

**Informed Consent Documentation & Process:** The revised rule shifts the focus of informed consent to consider the perspective of the potential subject with:

• Information that a “Reasonable Person” would want in order to make an informed decision;

• Changes to facilitate subject’s understanding of the key reasons he/she would or would not choose to participate in research; and

• Requirements that Key Information essential to that decision be presented first in the document and discussion.

Templates and FAQs are being prepared to assist researchers in making revisions to their informed consent documents. Researchers are expected to adapt templates to fit the context of the study and the population. Researchers are also expected to comply with readability standards, using the recommended 8th grade reading level for the general adult population.

For studies that collect identifiable information or identifiable specimens, there is a new required element that informs subjects regarding intent to conduct future research with the identifiable information or specimens collected as part of the initial research. Participants must be told whether or not identifiers will be removed and material used or shared with others for future research, without the subject’s additional consent. There are also three additional elements, which the investigator must include when applicable. The three elements inform subjects regarding potential commercial profit, whole genome sequencing, and return of research results. To ensure consent documents include all required elements, please refer to the Informed Consent Checklist in the Cayuse IRB Initial Submission Template or on the REC website.
General Waiver or Alteration of Informed Consent: The revised rule adds a fifth condition to meet to be eligible for a waiver or alteration of informed consent: that the research could not practicably be carried out without accessing or using information or biospecimens in an identifiable format. This is consistent with the participant-focused revisions in that it requires PIs to justify why they believe it is necessary to retain identifiable data instead of deidentifying it.

Waiver of Documentation of Informed Consent: The only change to this section is that the revised regulations recognize that in some international contexts, requiring a written signature may be culturally inappropriate. Waivers are now allowable for this situation.

Screening or Determining Eligibility: An IRB may approve a research proposal in which an investigator will review information or results from previously collected biospecimens for the purpose of screening or determining the eligibility of prospective subjects without obtaining informed consent if either of the following conditions are met:

1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or,
2) The investigator will use identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Exempt Review: Exempt Category 1 contains additional criteria that must be met to be eligible for the exemption. Exempt Categories 2 now allows research that has identifiers and risk to be exempted if the data and security provisions are approved through a limited IRB review. There is a new Exempt Category 3 covering benign behavioral interventions (with some limitations), also potentially subject to limited IRB review. Exempt Category 4 now allows for both prospective and retrospective review of records instead of just retrospective review. Exempt Categories 5 and 6 are relatively unchanged. ISU has chosen not to implement new Exempt Categories 7 and 8 until further guidance is issued related to Broad Consent. New requirements have been incorporated into the Cayuse IRB submission templates.

Expedited Review: The expedited categories remain the same for now. Select Social Behavioral Education research that required initial Expedited Review will be eligible for Exempt review (see above) under the revised rule.

Continuing Review: Continuing review provides the IRB with an opportunity to determine whether there is new information that represents a significant new findings or risks and whether these need to be communicated to subjects already enrolled in the research. Comprehensive Continuing Review is no longer required in select minimal risk research initially reviewed under Expedited Review, however PIs should report any
adverse events or unanticipated events as well as the closure of the protocol. Full Board Review protocols will still complete a continuing review application to allow for substantive IRB review.

**Clinical Trials Definition:** In order to harmonize with other agencies, the revised rule definition is, “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”. At this time, ISU is not engaged in clinical trial research.

**Staying Informed:** Information contained in this document will be updated as additional information is available, and if/when OHRP issues guidance or announcements regarding the revised Common Rule. Information will be posted on the REC website and be disseminated through emails and education/information sessions. Email general questions to irb@ilstu.edu or contact the REC main line at 309-438-5527. For protocol specific questions, the Cayuse IRB protocol number should be referenced in order to assist in responding to questions in a timely manner.