Important Changes to Human Research Regulations

Revised Common Rule

Compliance for the revised Common Rule is in effect as of January 21, 2019

- ✓ The U.S. Department of Health and Human Services and other Federal Departments and Agencies issued final revisions to the Federal Policy for the Protection of Human Subjects (also known as the Common Rule). The **substantive revisions** are intended to "modernize, strengthen, and make more effective" the current system of oversight that has been the federal "Common Rule" since 1991. The revisions are intended to:
  - ➢ Better protect human subjects involved in research
  - ➢ Facilitate research
  - ➢ Remove ambiguity
  - ➢ Reduce regulatory burden

What research is impacted by the revised Common Rule?

- ✓ All new research initially approved (or deemed exempt) **on or after January 21, 2019** (except for FDA and DOJ research).
- ✓ The term **2018 Requirements** refers to the revised Common Rule as published in the July 19, 2018 edition of the e-Code of Federal Regulations. The 2018 Requirements may also be referred to as the "revised Common Rule" or "final rule."

What research is NOT impacted by the revised Common Rule?

- ✓ Research initially approved (or deemed exempt) **prior to January 21, 2019**. These studies will continue to be subject to the **Pre-2018 Requirements** (as published in the 2016 edition of the Code of Federal Regulations - PDF). The Pre-2018 Requirements were originally promulgated in 1991, and subsequently amended in 2005. The Pre-2018 Requirements may also be referred to as the "Pre-2018 Common Rule."
- ✓ Research funded or supported by the Department of Justice. DOJ has not yet signed on to the revised Common Rule.
- ✓ Research subject to FDA regulations.

What are the most significant changes to the revised Common Rule?

- ✓ **Elimination of an annual continuing review requirement for expedited studies**
  - While annual continuing review is not required for expedited studies, investigators must still comply with the existing requirements for submitting modifications, reportable new information (e.g., unanticipated problems), and final reports to the UMass Boston IRB. Investigators must still submit any modifications to the UMass Boston IRB for review and approval prior to implementation.
- ✓ **Expansion of exempt categories and new exempt categories**
  - Categories 2, 4, and 5 have expanded to include more research. Category 3 has been replaced with a new category for benign behavioral interventions.
  - Some categories of exemption (2 and 3) involve a new process where an IRB member will conduct a "Limited IRB review" (i.e., via the expedited review mechanism) to determine if there are adequate provisions in the research to protect the privacy of subjects and to maintain the confidentiality of data.
- ✓ **New restriction to the applicability of exempt category 1 (educational practices)**
  - Research under category 1 exemptions must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.
- ✓ **Informed consent changes**
  - For all studies that involve the collection of identifiable private information or identifiable biospecimens, include a statement on whether or not the information or biospecimens if subsequently de-identified will be used for future research by other investigators.
  - Lengthy consent documents (e.g., more than a few pages long) will need to include a summary of key information up front.
  - For "clinical trials" conducted or supported by a Common Rule department or agency, investigators are responsible for posting one IRB-approved consent form after recruitment permanently closes and no later than 60 days after the last study visit to a public Federal online repository for consent forms (clinicaltrials.gov; regulations.gov). Investigators will be responsible for posting.
  - Additional criterion for a waiver or alteration of the informed consent process where the IRB must determine that the research could not practicably be carried out without using the information or biospecimens in an identifiable form.
- ✓ **sIRB (Single IRB mandate) for federally funded cooperative research**
  - Effective January 20, 2020, all federally funded cooperative research will use a single IRB for the portion conducted in the U.S., unless otherwise precluded (e.g., by tribal law and other exceptions) or deemed by the sponsoring agency as not required.

Will studies approved under the Pre-2018 Requirements automatically transition to the 2018 Requirements?

- ✓ **No.** The UMass Boston IRB may determine on a case-by-case basis whether a pre-2018 study can be transitioned. If the UMass Boston IRB does transition a pre-2018 study to the 2018 Requirements, the UMass Boston IRB will explicitly communicate this to the PI, and the transition will be documented. There are no plans at this time to transition pre-2018 studies to the 2018 Requirements if it would create additional work for the UMass Boston IRB and the investigator to meet the new requirements.

How will I know if my research needs continuing review?

- ✓ The UMass Boston IRB will continue to send courtesy reminders in advance of study expiration dates, but it is ultimately the PI's responsibility to keep track of expiration dates.
- ✓ The PI is responsible for reviewing and maintaining all IRB approval letters which will indicate whether or not continuing review is required.
- ✓ The UMass Boston IRB has the ability to determine if an expedited study under the revised Common Rule should have continuing review (even if this is not a Federal requirement). If so, this will be noted in the IRB approval letter.
- ✓ For studies that do not require continuing review, the initial IRB approval letter will only include an approval date. There will be no expiration date. **Investigators must still notify the UMass Boston IRB when a non-exempt study closes by submitting a final report.**

What else do I need to know about the revised Common Rule?

- ✓ UMass Boston will **not** be implementing the new option of "Broad Consent" or any of the new exemptions for Broad Consent. Few, if any, institutions have the technological or tracking ability to implement Broad Consent.
- ✓ This summary only describes most significant changes impacting UMass Boston researchers. The revisions include **many other changes** such as the following.
    - ➢ IRB is no longer required to review copies of grant documents for congruency with the IRB protocol.
    - ➢ Research on the expedited review list is presumed to be minimal risk.
    - ➢ 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 are explicitly deemed not to be research.
    - ➢ "Clinical trial" is defined as 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 of a clinical trial aligns with NIH's definition.

Revised Common Rule Resources

- ✓ For more information and a comprehensive list of revisions, visit the **Office for Human Research Protections** web site at:

  https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-resources/index.html

- ✓ Contact the **UMass Boston IRB** for questions:

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