

Application of Final Common Rule (2018 Requirements): Protection of Human Subject's (45CFR46)	Effective:	1.21.2019
	Revised:	11.28.2023

1.0 Purpose: The purpose of this standard operating practice (SOP) is to describe how the revised federal regulations for the protection of human subjects in research will be carried out at ECU by the University and Medical Center Institutional Review Board (UMCIRB).

2.0 Persons Affected:

- 2.1 Individuals engaged in human research activities approved by the UMCIRB
- 2.2 UMCIRB Chairperson (or designees) and members
- 2.3 UMCIRB staff and administrators

3.0 SOP: The federal regulations related to the protection for human subjects in research have been revised. The revisions to the regulations take effect January 21, 2019. These changes were significant enough to warrant an SOP to assist investigators and study team members in navigating how the changes will affect their human research after the effective date as well as how existing studies will be affected. Significantly updated definitions have been provided from the new regulations and a description of each change that could affect the life of a research study have been provided in the Procedures section below. Currently, these changes apply to non-FDA regulated human research only.

4.0 Relevant Federal Definitions:

- 4.1 **Human subject** is a living individual about whom an investigator (whether professional or student) conducting research:
 - 4.1.1 Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - 4.1.2 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- 4.2 **Research** means 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. Based on the revised regulations, the following activities are deemed not to be research:
 - 4.2.1 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.
 - 4.2.2 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

(including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- 4.2.3 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.
- 4.2.4 Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- 4.3 **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.
- 4.4 **Pre-2018** requirements are those requirements for human research per the federal regulations as they were written prior to the effective date for the revised regulations.
- 4.5 **Post-2018** requirements are those requirements for human search found in the revised federal regulations effective January 21, 2019.

5.0 Responsibilities:

5.1 **Principal Investigators** are responsible for:

- 5.1.1 Reviewing their current studies to determine whether any action is required to ensure compliance with the revised regulations.
- 5.1.2 Inquiring with the UMCIRB office when questions arise about their existing studies and the revised regulations.

5.2 **UMCIRB Chairperson (or designee) and members** are responsible for:

- 5.2.1 Understanding the revisions to the human research regulations.
- 5.2.2 Applying the revised regulations appropriately during their reviews.

5.3 **UMCIRB office** is responsible for:

- 5.3.1 Providing education and training materials to investigators and study team members regarding the changes to the federal regulations.
- 5.3.2 Training IRB members on the new requirements related to the human research they will be reviewing.
- 5.3.3 Modifying the electronic IRB application and website accordingly.

6.0 Procedures:

6.1 The requirement of a Federal Wide Assurance (FWA) needed for all institutions accepting federal funds has been modified to no longer ask institutions to check a box on the FWA application indicating the Common Rule would be applied to all research regardless of the funding source. After the effective date for the revised Common Rule, only those studies supported or funded by a Federal agency will need to apply the Common Rule regulations. It is up to the institutions to inform investigators and study team members whether the Common Rule will be applied to all human research regardless of the support/funding. ECU will apply the revised Common Rule to all human research regardless of support/funding except for the following:

- 6.1.1 For research that is not federally funded, a concise and focused presentation of key information is not required within the informed consent document.

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- 6.1.2** For research that is not federally funded, IRB reliance agreements are not required for Exempt categories of research that include a “limited review”.
- 6.2 Exempt categories of research** that are certified as such before January 21, 2019 will comply with the pre-2018 requirements. These research studies may continue as approved without any required changes. If the PI makes changes to these existing studies that would change the Exempt category the study had originally been approved under, the researcher may need to submit a new research study application and the revised regulations would apply (see Exempt Research SOP).
- 6.2.1** Broad consent for the storage and maintenance of identifiable data or biospecimens will not be utilized at ECU. The Exemptions relating to this type of secondary research are not available to users within the electronic IRB application.
- 6.3 Expedited categories of research** will no longer have an expiration date set by the IRB after January 21, 2019. The Expected End Date provided by the study team within the IRB application will become a more important and mandatory field for these studies. While no more Continuing Review applications will be necessary to renew the study, a Final Report will be required once the study has been completed. Notification to complete the Final Report will be generated based on the Expected End Date provided in the application. If the study team receives a notice to complete a Final Report but they are not yet done with the study, an Amendment would need to be submitted to update the Expected End Date. Amendments and Reportable Events will need to be submitted as usual—no changes have been made to these procedures under the revised regulations.
- 6.3.1** Existing expedited studies approved prior to January 21, 2019 will continue to follow pre-2018 requirements including required renewal at least annually.
- 6.3.1.1** Upon request by the investigator and after discussion with UMCIRB, an existing study may be revised to meet the new federal requirements. An Amendment (to meet the revised regulatory requirements) would need to be submitted and approved within the electronic IRB submission system to document this transition.
- 6.3.2** As long as justification is provided and documented, the IRB can still require expedited studies approved after January 21, 2019 to undergo annual renewal (see Expedited Review Procedures SOP and Continuing Review SOP).
- 6.4 More flexibility for when a research study can be closed** has been provided in the revised regulations. Research studies can be closed when the study is in:
- 6.4.1** Data analysis—now includes analysis of identifiable data; or
- 6.4.2** Follow-up—when the only data being collected is from procedures that participants would undergo as part of clinical care (medical record).
- 6.5** Informed consent requirements have also been modified to include more elements. These changes can be found in the Informed Consent SOP, Waiver or Alteration of Informed Consent SOP and Waiver of Documentation of Informed Consent SOP.
- 6.5.1** If a research study approved under the pre-2018 requirements has been modified to meet the post-2018 requirements and had a consent that was modified accordingly, then the IRB, along with the investigator and UMCIRB, will determine if re-consent would be necessary for those participants enrolled under the pre-2018 study requirements. Re-consent would likely only be necessary when there are changes to procedures, risk information or other elements that may affect the participant’s decision to continue in the study.

Revision History:

Date	Change	Reference Section(s)
11.28.2023	Added language about requirement for IRB reliance agreement for Exempt research with a limited review only when federally funded/sponsored. Updated office name to UMCIRB.	6.1, throughout.

References:

DHHS. Revised Common Rule (45CFR46): Protection of Human Subjects. January 19, 2017.