TRANSITIONING TO THE FINAL COMMON RULE

Background

The federal government changed the Common Rule (45 CFR 46) that governs human subjects research, with an effective date of January 21, 2019. Studies initiated before January 21, 2019, will be grandfathered and continue to be subject to the pre-2018 Common Rule regardless of funding. The UUIRB will allow for a non-FDA regulated, grandfathered study to transition to comply with the Final Common Rule. Transitioned studies must adhere to all aspects of the Final Common Rule, not individual components. For example, in order to take advantage of the elimination of the requirement for annual continuing review for certain studies, the study would need to transition entirely to the Final Common Rule.

Studies that are ideal to transition include but are not limited to:

- Studies with closed enrollment
- Studies that are in long-term follow-up
- Chart reviews
- Expedited studies with no consent document

A study may be transitioned at the time of continuing review. An amendment with the continuing review should be created and indicate the intent to transition to the Final Common Rule. The IRB Staff will evaluate continuing reviews to determine if a study is ideal for transition. Investigators will not be compelled to transition to the Final Common Rule and may decline to transition the study.

What Changes Need to be Made?

A. If your study has a consent process, the consent document must include:

Note: If enrollment is closed, the consent does not need to be updated. Re-consent of currently enrolled participants using an updated consent form is not required. For sample language and more detailed description of these consent requirements, please see the Informed Consent guidance on the UUIRB website. ***Studies still open to enrollment are not ideal to transition to the Final Common Rule.***

1. **A concise and focused presentation of key information.** The beginning of an informed consent must include a concise explanation of the key information most likely to assist a reasonable person in understanding why one might or might not want to participate in the research. In general, a concise summary would include the following:
    - The fact that consent is being sought for research, and participation is voluntary.
    - Purpose of the research, expected duration, and procedures.
    - Reasonably foreseeable risks.
    - Benefits that may be reasonably expected.
    - Appropriate alternative procedures or courses of treatment, if any.

    Learn more on the Concise Summary page on the UUIRB website.

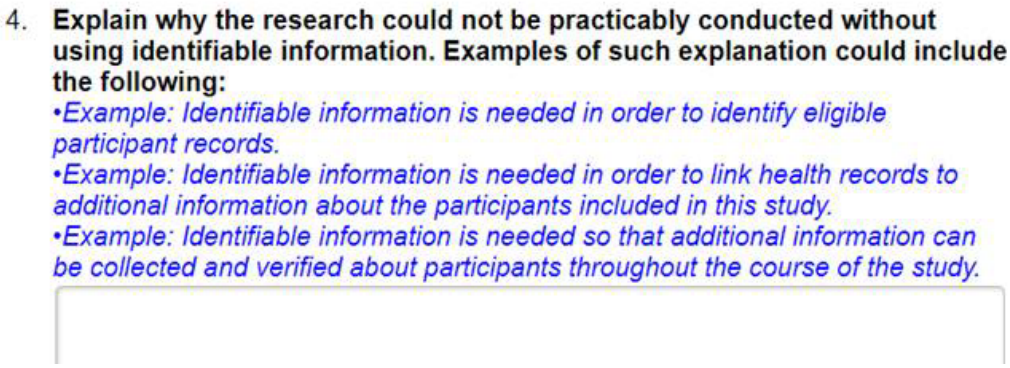
2. **A statement about whether or not the collection of identifiable private information or identifiable biospecimens will be used in the future.**

3. **A statement about whether the participant's biospecimens may be used for commercial profit.**

4. **A statement about whether clinically relevant research results will be disclosed to participants.**

5. **For research involving biospecimens, a statement about whether the research may include whole genome sequencing.**

B. **If a Waiver or Alteration of Consent is in place for this project, the Request for Waiver or Alteration of Consent must be updated.** In the ERICA application, answer the new question (4) on the Request for Waiver or Alteration of Consent page. A screenshot is provided below that shows the new question and examples of how to answer the question:



C. **If the project registered as a clinical trial that is conducted or supported by a Common Rule department or agency, an informed consent must be posted on a public federal website.** If the study transitions to the Final Common Rule, the informed consent form should be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit. For additional guidance, refer to OHRP FAQs on Informed Consent. This requirement is the investigator's responsibility and no submission to the IRB is required.

D. **If a VA study has a waiver of consent for recruitment, it should be requested in the application that the IRB staff remove the Waiver of Consent for recruitment.** A waiver of authorization still applies and should not be removed. The application should still retain the description of how information or biospecimens are obtained for the purpose of determining eligibility where describing recruitment.

References & Links

IRB SOP 106: Implementation of the Final Rule	*https://irb.utah.edu/guidelines/irb-sops.php*
Informed Consent Guidance	*https://irb.utah.edu/informed-consent/index.php*
Concise Summary Guidance	*https://irb.utah.edu/informed-consent/concise-summary.php*