Guidance for Requesting Re-Assessment of Previously Approved Studies Under the Revised Common Rule

This guidance applies to the following studies:

1. **Submitted to the IRB prior to** the implementation of the revised Common Rule on **1/21/19**; AND
2. **Minimal risk as designated by the IRB**, either by the convened board (cat 9) or via an expedited review category(1-7); AND
3. The study **IS NOT a clinical investigation.** Per FDA regulations, a clinical investigation is:
   - Any study that *administers* a drug product* as part of the research procedures;

     AND/OR
   - Any study that is *investigating* a drug or device product*.

   Product = Any product subject to the FD&C Act: drug, biologic, medical device, food, food additive, color additive, electronic product, etc.

If all of the above criteria are met, you may apply for re-review of the study under the revised 2019 Common Rule. Under the revised Common Rule, minimal risk, non-FDA regulated studies are not required to submit applications for continuing review. IRB SOP RR404 describes the types of submissions that are still required when continuing review is not required.

How to Apply for Re-Assessment:

The IRB requires submission of a Modification via HSERA to request re-assessment. The modification must include a completed copy of the Modification form as well as tracked and clean copies of all revised documents. Instructions for submitting modifications is available here - https://irb.upenn.edu/how-submit-penn-irb/how-submit-modifications.

To prepare your modification:

1. Review your protocol, consent forms, and HSERA application to determine:
   a. Whether the research involves collection of any biospecimens
   b. Whether the research involves use of diagnostic devices
   c. A plan for future use of data or (when applicable) biospecimens
2. To determine what changes are necessary based on the design of your research regarding the 3 criteria above, review the Common Rule guidance resources posted on the IRB website:
   a. https://irb.upenn.edu/common-rule-update-2018 - Revised Informed Consent Requirements
   b. Download and review the most recent version of the Biomedical or Social Behavior consent form templates (as applicable). Review the definitions of non-identifiable versus identifiable in the section "What may happen to my information [include if applicable: and samples] collected on this study?"

c. Review Concise Summary Guidance - https://irb.upenn.edu/sites/default/files/ICF%20Concise%20Summary%20Guidance_2019.5-FINAL.pdf

d. Review Health Literacy Guidance - https://irb.upenn.edu/sites/default/files/Health%20Literacy%20Guidance.pdf

3. Make necessary revisions to align your consent forms with the requirements described in the guidance as related to collection of biospecimens, use of diagnostic devices and future use of data/specimens.

4. Upon receipt of your modification submission, the IRB will conduct a screening to confirm the presence of the following information:

NEW REQUIRED Basic Elements of Consent

★ **Consent Summary**—Informed consent must begin with a concise, organized, and focused presentation of the key information that is most likely to assist a prospective subject in understanding why one might or might not want to participate.

- Utilize the template language within the 6/2019 Informed Consent Templates.
- Complex Studies: The IRB recommends that the consent summary be approximately 1 page.
- Uncomplicated Studies: Consent summaries may be approximately ½ page. Alternatively, the study team may request a waiver from this requirement if the consent document itself meets the requirement of being an appropriately concise, organized, and focused presentation of the key information.

★ **Future Use**—A statement about whether the research involves any plans for the future use of the private **information** and/or **specimens** collected.
Only one of the following statements should be included:

★ A statement that data and, if applicable, specimens will not be stored or distributed for future research studies.

OR

★ A statement that data and, if applicable, specimens will be de-identified, and could be stored and distributed for future research studies without additional informed consent.

OR

★ A statement that identifiable (including coded) data and, if applicable, specimens will be stored and distributed for future research studies without additional informed consent.
Additionally, the following elements are required if **identifiable** data and/or specimens may be stored and shared for future use:

★ A statement about which identifiers will be retained and shared with data/specimens.

★ The types of institutions or researchers that might conduct research with the data/specimens.

★ A description of the period of time that the data/ biospecimens may be stored, maintained, and used for research purposes. If indefinite, this should be stated.

★ A general description of the types of research that may be conducted with the data/ specimens.

★ A statement regarding whether subjects will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research.

★ A statement regarding whether clinically relevant research results, will be disclosed to subjects, and if so, under what conditions.

★ Specifically related to the future use: A description of: how confidentiality will be maintained during storage/ sharing, reasonably foreseeable risks and benefits of future

research use, and who to contact with any questions about future use/storage and research related harms.

NEW Elements Of Consent That Are Required When Applicable:

- ★ **Returning Research Results—**A statement regarding whether *clinically relevant* research results, will be disclosed to subjects, and if so, under what conditions.
  - ♦ If your consent already includes language about returning results or incidental findings, please ensure it aligns with CLIA and HIPAA regulations. Please ensure all such language is in this section.

  NOTE: This will apply to research with biospecimens as well as research with any diagnostic devices.
- ★ **Collection of Identifiable Biospecimens—**When the study involves the collection of identifiable biospecimens, the following elements of consent are required:
  - ★ A statement that the biospecimens (even if identifiers are eventually removed) may be used for commercial profit and whether the subject will or will not share in this profit.
  - ★ A statement regarding whether the research will or might include whole genome sequencing.

  NOTE: This will apply to the collection of any biospecimens that are labeled with a study ID code that is linked to identifiers (i.e., coded) or any biospecimens that are labeled with direct identifiers.

NEW General Consent Requirements

- ★ Informed consent must present information in sufficient detail and must be organized and presented in a way that facilitates understanding of why one may or may not want to participate. Please consult the IRB's Health Literacy Guidance to meet this requirement