Continuing Review Requirements

The new Common Rule (the "2018 Requirements") does not require continuing review for expedited research. Expedited research reviewed under the previous Common Rule still requires at least annual continuing review. Exempt research does not require continuing review under either Common Rule.

Eligibility: Unless COMIRB determines otherwise, continuing review of research is not required for research reviewed under the "2018 Requirements" in following circumstances:

- Research eligible for expedited review.
- Research that has progressed to the point that it involves only one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Continuing Review Required: Continuing review will be required under the following circumstances, even if for research falling into the categories above:

- Research requiring full board review.
- Non-exempt research subject to pre-2018 requirements of the Common Rule.
- Research subject to FDA or DoD oversight, in compliance with FDA regulations and DoD policies. See "DoD Requirements" below for more information.
- Research in which COMIRB is serving as a sIRB for non-affiliated sites, to ensure ongoing and appropriate oversight of the multicenter research.
- Research involving especially large amounts of PHI, in order to ensure ongoing and appropriate oversight of PHI.
- Research involving data subject to GDPR, to ensure ongoing compliance with GDPR.
- Any other study for which the IRB has identified a reason for requiring continuing review.

Amendments, UAPs, Study Closure: Regardless of continuing review requirements, IRB approval is required for changes to approved non-exempt human subject research. Investigators are required to submit reports of unanticipated problems and serious or continuing non-compliance. COMIRB requires investigators to submit a study closure report at the completion of the study.

Reinstatement: The requirement for continuing review may be reinstated if COMIRB reviews an amendment that increases risks to subjects or adds involvement of the FDA or DOD, or if deemed necessary following submission of an unanticipated problem or serious or continuing noncompliance.

Approval letters: COMIRB approval letters will document the requirement for continuing review. If continuing review is not required, a determination of "Approved not expiring" will be

indicated and no expiration date will be specified. If continuing review is required, an expiration date will be specified.

Continuing Review Notices: For studies requiring continuing review, reminder notices are sent to PI's and Primary Contacts 60 days and 45 days prior to expiration.

Annual Reminders: For studies that do not require continuing review, COMIRB will send out an annual notice to PIs and Primary Contacts to remind them of their ongoing responsibilities for the conduct of the research. These reminders are sent 45 days prior to the anniversary of the last IRB approval. Response to these reminders is not required unless the study is closed. These notices will continue to be sent until COMIRB has been notified of study closure.

Expiration Notices: An expiration notice will be sent to the PI and Primary Contact for any study that is not re-approved by the expiration date.

DoD Requirements: Investigators are responsible for obtaining HRPO approval after IRB approval. Documentation of HRPO approval must be submitted to COMIRB as soon as possible after it is obtained, and by no later than the first Continuing Review.