Changes to Continuing Review Requirements – Transitioning research to the 2018 Requirements of the Federal Policy for the Protection of Human Subjects

The general compliance date for the Federal Policy for the Protection of Human Subjects (the “2018 Requirements”) has been delayed to January 21, 2019. However, beginning July 19, 2018, institutions are allowed to implement three “burden reducing” provisions. One of those provisions is the removal of the requirement for continuing review for some research. COMIRB will begin to implement this on July 19, 2018.

Eligibility: Unless COMIRB determines otherwise, continuing review of research is not required in the 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.

Exceptions: The FDA, VA and DOD require at least annual continuing review of human subjects research. Studies involving these agencies will continue to be reviewed under Pre-2018 Requirements.

In addition, due to uncertainty regarding the new broad consent provisions in the 2018 Requirements, COMIRB will continue to review research involving informed consent for future unspecified research (e.g., banking) under the Pre-2018 Requirements.

Protocol-by-Protocol Basis: All currently approved research still requires continuing review. COMIRB will make determinations about removing the requirement for continuing review on a protocol-by-protocol basis. These determinations will be made only during initial or continuing reviews.

Transition: Studies that no longer require continuing review begin transitioning to the “2018 Requirements” effective the date of approval. PIs must comply with all other Pre-2018 Requirements until January 21, 2019, at which time full compliance with the 2018 Requirements is required.

Amendments, UAPs, Study Closure: IRB approval is still required for changes to approved research. Investigators are still required to submit reports of unanticipated problems and serious or continuing non-compliance. COMIRB still requires investigators to submit a study closure report.

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

**Approval letters:** COMIRB approval letters will document the transition and compliance with the 2018 Requirements and/or the Pre-2018 Requirements as appropriate. A determination of “Approved not expiring” will be indicated where appropriate.

**Expiration Dates:** If continuing review is not required, your study will be approved without an expiration date. Stamped documents will not include an expiration date.

**Informed consent changes:** The 2018 Requirements include new requirements for informed consent. COMIRB may require changes to consent forms when we transition research to the 2018 Requirements. For example, consent forms that do not include a HIPAA section will need the following new section:

**What happens to data collected in this study?**

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

Other consent changes will become necessary on January 21, 2019. If COMIRB determines that your consent form does not currently comply with new *Key Information* provisions of the 2018 Requirements, COMIRB will review the study under the Pre-2018 Requirements.

**Re-consent:** COMIRB does not anticipate that re-consent will be necessary for these changes.

**Annual Reminders:** Until COMIRB has been notified of study closure, COMIRB will send out an annual notice to PI’s to remind them of their ongoing responsibilities for the conduct of the research. Response to these reminders is not required unless the study is closed.

**Study Status:** Later this summer, COMIRB will implement a change to require investigators to indicate the status of their study (e.g., enrolling, enrollment is complete, etc.) with every amendment.

**Links:** Additional guidance about the 2018 Requirements will be made available as we near the general compliance date.

- [Investigator Responsibilities](#)
- [6 Month Delay](#)
- [2018 Requirements](#)