What Does “Approved Not Expiring” Mean?

The new Federal Policy for the Protection of Human Subjects (the “2018 Requirements”) eliminates the requirement for continuing review for minimal risk research approved under expedited procedures. If your research is eligible, and COMIRB approves your research without a requirement for continuing review, it will receive an approval status of “Approved Not Expiring.” In that case your approval letter will not list an expiration date, and any COMIRB approval stamps on consent forms will not have an expiration date.

If your approval letter lists an expiration date, you must submit for continuing review as usual.

It is important to note that if research does not need to be submitted for continuing review, PIs are still responsible for conducting their research in compliance with all other federal regulations and COMIRB policies and terms of approval.

What do I need to do as an Investigator?

Ensure your study is always conducted according to the terms of COMIRB’s approval. This includes ensuring that:

- Human subjects training (as well as HIPAA and/or GCP training, as applicable) is up-to-date for you, all co-investigators, and study staff,
- No changes to the study design, documents, or investigators are made without prior COMIRB review and approval,
- Informed consent is obtained from each subject prior to study enrollment unless specifically waived by COMIRB.
- Only the COMIRB-approved consent documents are used, and subjects are provided copies of these,
- Any unanticipated problems and/or noncompliance that must be reported are submitted to COMIRB, and
- You, all co-investigators, and study staff submit annual Conflict of Interest disclosures.

Links to more information:

Investigator Responsibilities

Training Requirements

Instructions for submitting amendments

Instructions for submitting unanticipated problems

Instructions for closing a study

Conflicts of Interest

Changes to Continuing Review Requirements

Contact COMIRB

If you have any questions, please contact COMIRB. We are happy to answer your questions and discuss your study.