Continuing Review

IRBs are required to regularly review previously-approved research to ensure human subjects protections remain appropriate over the life of a study. This process is called “continuing review.” Continuing review of non-exempt research is required at intervals appropriate to the degree of risk, but not less than annually, unless the research fits within one of the exceptions described below.

When required, continuing review must be substantive and meaningful, and it must address any new information or changes that relate to risk/discomfort, benefits, safeguards for participants, and informed consent. Informed consent forms(s) are reviewed to assess whether the information provided in the currently approved or proposed consent form is still accurate and complete, and whether any new information that may relate to the subject’s willingness to continue participation should be included in the document.

Continuing Review Submission Requirements

When continuing review is required, investigators should submit an amendment in IRBManager three to four weeks in advance of the approval expiration date. The application will request a progress report on activities conducted for the research during the review period, including the following:

- Summary of study progress;
- Accrual of study participants;
- Enrollment status of participants including the number of withdrawals;
- Summary of any new information that may be relevant to the research or participants’ willingness to stay enrolled in the study;
- Summary of any modifications implemented since last IRB review; and
- Summary of any unreported adverse events, unanticipated problems, or subject complaints.
- Verification of the continued use and accuracy of informed consent form(s) and recruitment materials.

Supplemental information or materials should be provided when applicable, including the following:

- Description of any proposed modifications;
- An updated investigator’s brochure, if available, for FDA regulated studies; and/or
- Any other significant information/documents, if applicable, such as reports from a Data Safety and Monitoring Board.

Extended Approval Periods

Some research that requires continuing review (i.e., does not fall into one of the exceptions, or the IRB determines continuing review is necessary) may be granted an extended approval period of up to three years. The longer approval period eliminates the need for principal investigators (PIs) to submit continuing review applications on an annual basis.
To be eligible for extended approval, the research must present no more than minimal risk to human subjects (as determined by the ISU IRB via convened or expedited review), and it must not include any of the following:

- Federal funding, including federal training and program project grants, federal no-cost extensions, federal flow-through funding, etc.;
- FDA regulated components (i.e., food products or additives, dietary supplements, medical devices [including activity monitors], drugs, vaccines, biologics);
- Contractual obligations or restrictions that preclude eligibility for extended approval (i.e., a non-federal sponsor or funder requires annual IRB review);
- Prisoners as subjects, unless the study is eligible for exemption or review via expedited procedures;
- Any findings of serious or continuing noncompliance related to the study or the principal investigator within the past two years;
- Any incidents that meet the definition of an unanticipated problem involving risks to subjects or others within the past two years.

The IRB (including the IRB Chairs/Co-Chairs), at its discretion, may make exceptions to this policy and require more frequent review.

During the approval period, principal investigators are responsible for

- reporting to the IRB any changes in funding or sponsorship that involve federal sources; and
- obtaining approval for any change(s) to the IRB-approved protocol, prior to implementation of the change(s), unless the change is necessary to eliminate apparent immediate hazards to participants;
- reporting any unanticipated problems or serious adverse events.

Exceptions to the Continuing Review Requirement

Continuing review is generally not required for research that falls into one of the three exceptions listed below. However, for any research, the IRB or IRB reviewer may determine that continuing review is required for research that would not otherwise require it. Typically, this will be to assure protection of human subjects or to address compliance concerns. In these instances, the IRB or IRB reviewer must document the rationale for requiring continuing review.

**Note:** These exceptions DO NOT APPLY to FDA-regulated research (e.g., studies of medical devices, drugs, vaccines, food additives, etc.). FDA-regulated research must undergo annual continuing review until the research no longer requires IRB oversight (see Study Closure for details).

**Exception 1:** Non-exempt research approved on or after January 21, 2019 that falls into one of the following:

a. New research protocols approved via expedited review procedures; or

b. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved protocol:
   i. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
ii. Accessing follow-up clinical data from procedures subjects would undergo as part of clinical care.

**Exception 2:** Non-exempt research approved before January 21, 2019 (“ongoing research”), but is formally transitioned *by the IRB or IRB reviewer* to comply with the 2018 Common Rule, when one of the following applies:

a. The research is approved via expedited review procedures, or

b. The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved protocol:
   i. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
   ii. Accessing follow-up clinical data from procedures subjects would undergo for clinical care.

**Note:** Continuing review is required for non-exempt research approved before January 21, 2019 until it is formally transitioned to comply with the new 2018 Common Rule. Upon submission of an application for modification or continuing review, ongoing research protocols will be assessed on a case-by-case basis by the IRB or IRB reviewer to determine whether transitioning the study to comply with the 2018 Common Rule is appropriate. Transitioning to the 2018 Common Rule may require modifications to the study (e.g., revisions to the informed consent document, etc.).

**Exception 3:** Research reviewed by the convened IRB may be excluded from continuing review requirements when all of the following are true:

a. The research has no federal funding, is not regulated by the Food and Drug Administration, and is not subject to contractual obligations that require annual review;

b. The convened IRB determines that the study presents only minimal risk to participants; and

c. The convened IRB determines that continuing review is not a necessary measure to ensure protection of human subjects or determines that the study is eligible for expedited review.

**Status Check in lieu of Continuing Review**

ISU is responsible for continued oversight of all human subjects research, even when formal continuing review is not required. Toward this end, the IRB has implemented a brief “status check” process to ascertain the status of each protocol and verify that no unapproved changes or unreported problems have occurred.

The status check occurs at rolling three-year intervals. The first three-year period is established at the time of initial approval. A new three-year period is established upon approval of any subsequent modifications to the project. To facilitate the rolling three-year intervals, study status verification questions are included in all modification applications.

Researchers receive notification of an upcoming status check electronically via IRBManager in advance of the three-year period end-date.

To complete the status check, researchers provide the following information via a brief form in IRBManager:

1. Whether data collection has begun, is ongoing, or has ended.
2. Verification, via simple yes/no questions, that there is/are no
   a. New information relevant to risks or that may impact participants’ willingness to continue participating,
   b. Unreported serious adverse events or unanticipated problems.
   c. New federal funding sources, or
   d. Unapproved changes to the protocol.

The status-check form directs researchers to complete additional actions when needed based on responses (e.g., submission of a modification application, reporting an adverse event, etc.).

If no additional actions are needed, another three-year period is established.

Document History

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