AAH RSPP GUIDANCE

Continuing Review

PURPOSE
The purpose of this guidance is to outline the procedure for properly completing an Application for Continuing Review. Federal regulations found at 45 CFR 46.117(e) (DHHS) and 21 CFR 56.109(f) (FDA) require that IRBs conduct continuing review of research at intervals appropriate to the degree of risk but no less than once per year for certain studies. For studies requiring continuing review, investigators are required to submit an Application for Continuing Review prior to the expiration of the study or as specified by the IRB. Continuing review includes a reassessment of the totality of the project to assure that, among other things, risks to participants are being minimized and are still reasonable in relation to anticipated benefits, if any, to the participants and the knowledge that is expected to result.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

GUIDANCE
How will I know if continuing review is required for my study?
The IRB approval letter provided at the initial approval of the study will indicate if continuing review is required for your study. If continuing review is required, the letter will also state the expiration date. NOTE the status of the study may affect the need for continuing review. You will be told at continuing review if further continuing review is needed.

What is the process for submitting a continuing review application?
If required, a Continuing Review Application must be submitted, reviewed and approved prior to the expiration date of the study – this includes the rectification of any conditions of approval issued by the IRB.

If the study is not re-approved by the IRB by 1159 pm of the study expiration date, research activities in that study must stop. See RSPP guidance IRB approval dates and Expiration of Approval for more information on lapse of IRB approval.

The Continuing Review application must be submitted in IRBNet. It is the study team’s responsibility to ensure that the Continuing Review application is provided to the RSPP Office/IRB with sufficient time for the office to conduct a pre-review, as well as obtain IRB approval. It is recommended that the Continuing Review application be submitted to the RSPP Office six weeks before the last IRB meeting prior to study expiration. This timeline will allow the RSPP Office time to review the application and get any questions/issues addressed prior to IRB review.

Depending on study status/type there is maybe an opportunity for the RSPP Office to conduct an expedited continuing review. However, this may not be known until the RSPP Office review
has been completed. Therefore, it is in the study team’s best interest to assume convened board review is necessary, and submit the continuing review application according to the 6 week timeline noted above. The list of IRB meeting dates can be found on the RSPP website as well as in the IRBNet library.

As a courtesy, the IRBNet system sends continuing review notifications to study team members who have been ‘shared’ Full access in IRBNet. Notifications are sent to the study team’s email address included in the IRBnet system. IRBNet notifications are sent at 75, 45, and 15 days prior to study expiration. A ‘cease research activity’ notification is sent by IRBNet on the date of study expiration if the continuing review application has not been received and approved by the IRB by study expiration. No reminders are sent directly from RSPP staff.

Is continuing review required for all studies?
Continuing Review is generally not required for:

- **Exempt Research:** There are no expiration dates for studies that the IRB determined to be exempt. (However, the IRB may require continuing review based on the research, if there is sufficient rationale to require additional monitoring.) if necessary, the need for continuing review will be outlined in your IRB Exempt Determination letter.

- **Expedited Review:** There are no expiration dates for research eligible for expedited review in accordance with 45 CFR 46.110, unless the IRB determines otherwise and such determination will be described in the approval letter. 45 CFR 46.109(f)(1)(i) and 45 CFR 46.115(a)#3. If the expedited research is FDA-regulated, it is still required to undergo continuing review in accordance with 21 CFR 45.109(f).

- **Research in Data Analysis/Clinical Follow Up:** There are no expiration dates for research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - 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; unless the IRB determines otherwise and such determination will be described in the approval letter. 45 CFR 46.109(f)(1)(iii) and 45 CFR 46.115(a)(3).

  If the research is FDA-regulated, it still required to undergo continuing review in accordance with 21 CFR 45.109(f).

Can changes to the study be made at the time of continuing review?
Sometimes, while completing the Continuing Review Application, it is noticed that there have been unreported changes. If a change is noticed it should be mentioned on the Continuing review Application AND submitted to the IRB using the Change Form. The IRB can review both submissions concurrently.
The Continuing Review Application asks for a brief summary of the research using lay language. Why is this necessary when the original submission application and protocol are on file in the IRB office?

The IRB is composed of both scientific and non-scientific (lay) members. The non-scientific members have a different vantage point than scientific members. This viewpoint is valuable to the committee and offers another level of protection for human subjects in research. A simply written, succinct summary ensures that all IRB committee members have an understanding of the protocol at the time of continuing review. It would be a tedious and burdensome task for each member of the committee to read the full protocol. A well-written summary refreshes the veteran committee members’ memories and helps new members become familiar with the study.

**What does ‘open to subject accrual’ mean?**

The status of ‘open to subject accrual’ means that the study can allow for new subject recruitment/enrollment and is approved to allow new recruitment/enrollment.

**What does ‘enrolled’ mean?**

An enrolled subject is one that has signed the consent document. At times there are different levels of enrollment. Some studies require a subject to be enrolled before a more detailed level of screening occurs. In these types of studies an enrolled subject can screen fail and not be invited to go any further in the study. This would still be reported as an enrolled subject on the Continuing Review Application. Details about the status of the enrolled subjects will be explained in the section of the Continuing Review Application that asks submitters to ‘briefly summarize local subject participation.’

**What considerations are needed when Advocate Aurora’s IRB is the IRB of record for outside sites/personnel?**

When Advocate Aurora’s IRB is the IRB of record for sites and or personnel outside of Advocate Aurora the activity at those sites must also be reported at the time of continuing review.

**REQUIREMENTS**

- Common Rule Regulations: 45 CFR 46.110
- FDA Regulations: 21 CFR 45.109(f)