

OHR-2 SUBMISSION GUIDELINES

NEW STUDIES

When submitting a new study that requires an OHR-2, always use the OHR-2 version currently available on the website.

Answer all questions. If a question does not apply to your research, reply with “Not Applicable” or “NA.” If a whole Part does not apply, you may indicate “Not Applicable” at the start of the Part.

CONTINUING REVIEWS

To determine whether a continuing review requires an updated OHR-2, see the document “Overview of IRB Submissions for New Studies” on the IRB website at <http://www.jefferson.edu/ohr/irb/forms/index.cfm>.

When submitting a continuing review that requires an updated OHR-2, adhere to the following guidelines:

When submitting a continuing review for a study open for **follow-up and/or data analysis only**, use the most recent version (i.e., includes all prior protocol amendments) of the OHR-2/OHR-2A that is in your file.

When submitting a continuing review for a study that currently has **active enrollment, active study treatments and/or active study procedures**, follow the below guidelines:

- If the most current version of the OHR-2 in your file is dated prior to 9/2002, you must revise the OHR-2 to the most current version available on the website.
- If the most current version of the OHR-2 in your file is dated 9/2002 to 2007, you must complete the OHR-2A addendum and include it with your current OHR-2 from your file in the continuing review application.
- If the most current version of the OHR-2 in your file is dated 2008 or after, include this version from your file in the continuing review application.

By following the above guidelines, you assure that the IRB has the most complete information regarding your study when conducting its review.

Continuing review applications that do not adhere to the above guidelines **will not be accepted for review**, and will be returned to the PI.

AMENDMENTS

Most amendments require inclusion of the OHR-2, whether they are protocol or consent form amendments. For amendments to the consent form only, you should include the most current version of the OHR-2/OHR-2A from your file.

OHR-2: Amendments to the OHR-2 should be made to the most current version in your file, unless the amendment affects new sections of the OHR-2 not in the version in your file. In this instance, you should follow the guidelines in the continuing review section and make appropriate revisions in either the current IRB version of the OHR-2 or the OHR-2A. (If updating to the current OHR-2, hi-lite only the study-specific revisions. Indicate on the OHR-12 that the OHR-2 also has been updated to the current version.)

Sponsor protocol: Amendments to the sponsor protocol involving only clarifications, grammar and/or syntax changes in most cases do not require revision to the OHR-2. Amendments to the sponsor protocol that **substantially affect the content of the OHR-2 require revision to the OHR-2**. In this case, you should make the revisions to the current version of the OHR-2 that is in your file, unless the amendment affects new sections of the OHR-2 not in the version in your file. In this instance, you should follow the guidelines in the continuing review section and make appropriate revisions in either the current IRB version of the OHR-2 or the OHR-2A. (If updating to the current OHR-2, hi-lite only the study-specific revisions. Indicate on the OHR-12 that the OHR-2 also has been updated to the current version.)