

In This Issue

- Prompt Reporting of Protocol Amendments
- Requirements for Continuing Review Submissions

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If you have questions /comments or have a suggestion about how we can improve our human research protection program (HRPP) here at UH, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

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Prompt Reporting of Protocol Amendments

Federal regulations (DHHS and FDA) and UHCMC IRB Policy require that all proposed changes to an approved research study be promptly submitted to the IRB for review and approval. Any change to a currently approved research protocol, including alterations to study procedures, risks, and study population, may **not be initiated prior to IRB approval**.

The only exception to this requirement is when the changes are necessary to eliminate apparent immediate hazards to the subject (21 CFR 56.108(a)(4) and 45 CFR 46.103 (b)(4)(iii)) (see UHCMC IRB Protocol Amendment Policy [page 152]). Changes in approved research initiated without IRB approval to eliminate apparent immediate hazards to the participant must be promptly reported and justified to the IRB using the [Unanticipated Problem or Protocol Deviation Checklist \(U/D\)](#). This report must contain a description of the changes/Protocol Deviations and the number of subjects involved. In addition, an amendment to the approved protocol must also be submitted with a copy of all revised documents. The IRB will review the report of the changes/deviation to determine that its implementation was consistent with ensuring the participants' continued welfare.

Requirements for Continuing Review Submissions

The DHHS requires an IRB to conduct continuing reviews (CR) of approved research at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109(e)). The reviews must be **meaningful and substantive** and must continue until data analysis is complete (if data is not de-identified meaning anonymized).

The following information must be submitted to the IRB as part of the continuing review submission:

- 1) Copy of the current approved protocol (inclusive of approved amendments) and informed consent forms (stamped with the IRB approval stamp).
- 2) Protocol abstract: brief description of the research, including study purpose; and aims and objectives.
- 3) Status Report: summary of the progress of the study including:
 - Summary of enrollment activity;
 - A summary of all adverse events, unanticipated problems, subject withdrawals, complaints and terminations noted during the year covered by this review (See [IRB Policy, Event Reporting - Adverse Events, Unanticipated Problems, and Protocol Deviations](#)) The IRB encourages the use of the [Summary Log of Internal/External Adverse Events](#));
 - Summary of study findings, including results and publications, and an assessment as to whether the risks and benefits of the research have changed;
 - Data and Safety Monitoring Committee/Board and Data and Safety Monitors' reports, including interim findings and recommendations;
 - Trial reports from multi-center sites;
 - Description of approved amendments since the last review; and
 - Description of the plans for the coming year
 - Discussion of previously unidentified conflict of interest (if applicable)
- 4) If changes are requested as part of the continuing review, a description of the changes being requested is required, along with a "tracked changes" and clean copy of all revised documents
- 5) Approval letter from Department Research Review Committee(s).

In preparing the CR submission, subjects must not be identified by name. **The original and one copy of all documents must be provided to the IRB Office.** The IRB suggests submitting all requests for continuing review at least 6 weeks prior to the study expiration date.