

In This Issue

- IRB Rosters available on-line
- Updates to IRB Policies, Procedures, Forms and Templates
- Policy Revision: Closure versus Termination

Quick Links

[University Hospitals](#)
[Center For Clinical Research](#)
[Office of Research Compliance](#)
[UHCMC IRB](#)
[UHCMC Grants and Contracts](#)



Questions, Comments, Suggestion?

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

Contact Us

Office of Research Compliance
Lakeside 1400
11100 Euclid Avenue
Cleveland, Ohio 44106
216.844.5576

E-mail us!

Meeting Dates and UHCMC IRB Roster available on-line

The UHCMC Institutional Review Board (IRB) meets every Tuesday (except holidays) at 3:30 pm. There are two Boards and each meets on alternate weeks. The current 2007 IRB Rosters for both Boards are also available on-line.

- [IRB Meeting Dates for 2007](#)
- [IRB Roster M Committee 2007](#) (v. 3.19.2007)
- [IRB Roster J Committee 2007](#) (v. 5.25.2007)

Updates to UHCMC IRB policies, procedures, forms and templates

As you are aware, many of the IRB Policies and Procedures and required submission documents have recently been revised as part of the ongoing quality improvement of the UHCMC Human Research Protection Program. The accompanying document entitled "**Summary of New and Revised IRB Administrative and Investigator Policies and Procedures**" lists the revised documents and provides a summary of the changes. Many of the revisions are minor clarifications to existing IRB requirements to ensure compliance with the federal regulations governing human subjects' protections. However, there are several policies that have significant revisions, and for these the Office of Research Compliance will be providing you with additional education. Specific announcements regarding educational sessions will be communicated to you in forthcoming emails. If you have questions or concerns regarding any of the changes, the staff at the Center for Clinical Research will be available to assist you.

To facilitate the review of all new submissions submitted after **June 30, 2007**, please ensure that all submissions use the most recent version of all submission forms (e.g., protocol submission forms, consent templates, HIPAA Authorization language, etc.) available on-line ([Forms & Templates](#)).

Closure of an IRB Approved Protocol versus Termination of IRB Approval

Closure is an action taken by an investigator to permanently discontinue research activities for a study that has current IRB approval. This action was previously referred to as "Protocol Termination." The change in terminology is due to the regulatory requirements associated with the federal definition of the term "Termination." **Termination is when the IRB permanently stops some or all research procedures.**

When the IRB terminates a study, they are obligated to report the termination to Regulatory Agencies, Department Heads and Institutional Officials as established in the [IRB Policy, Reporting to Regulatory Agencies, Department Heads and Institutional Officials](#).

When Investigators would like to permanently close or discontinue a study, they have the responsibility to formally notify the IRB by completing the [IRB Checklist, Closure of an IRB Approved Protocol \(C\)](#). In addition, any previously unreported adverse events should be reported at the time the Checklist is submitted, together with an explanation of why the project is discontinued and statement of results, if any. Once a protocol is permanently closed, all research activities must cease, including data analysis (unless the data is de-identified). A protocol that has been closed cannot be reopened; to resume research activities a new protocol must be approved by the IRB.

After a study has been permanently closed, the signed consent forms must be available for IRB inspection for three years. In the event of separation of the principal investigator from UHCMC, copies of signed consent forms should be given to a co-investigator or sent to UHCMC archives. The IRB should be notified where signed consent forms are kept.

After a protocol has been closed the IRB does not accept reports of adverse events unless they impact the rights and welfare of enrolled subjects. The investigator should keep all non-reported adverse events on file for review by regulatory agencies.

Please note that for research that has reached its accrual goal and is subsequently closed to subject enrollment, and all enrolled participants have not completed the research-related interventions, or the research remains active for long-term follow-up of participants, the enrollment closure needs to be reported to the IRB at the time of Continuing Review.