

Guidance on Research Conducted Off-Site or at Multiple Sites

The Case IRB Administrative Office Head (IAO) Head will evaluate whether investigators are complying with policies and procedures and whether further communication or information from multiple sites are required for both expedited and full review protocols. The RI will inform all institutions/sites of all adverse events or unanticipated problems associated with the respective protocol.

Investigators, affiliated with Case, recruiting or conducting research at sites other than Case (i.e., schools, businesses, community centers, clinics) must submit copies of those sites' IRB approval before the Case IRB will finalize approval (unless the research is conducted at an affiliated medical center, see below). The Case IRB will usually accept a common, or shared, informed consent document (i.e., the Case template is not required); however, the investigator must include all required elements of informed consent outlined at 45 CFR 46.116 (unless waived by the IRB), as well as contact information for the Responsible Investigator and the Case IRB.

If the site does not have an IRB, investigators must submit a letter of cooperation from an institutional official to confirm that the institution in question approves the proposed research (see Appendix for example Letters of Cooperation). The letter should be on the site's letterhead, and include a statement indicating that the official understands and approves of the proposed research at his/her institution. This letter should contain an original signature.

Relationship with Case HRPP Institutions' IRBs

Affiliated IRBs of the Case HRPP may rely upon one another via the executed IRB Authorization Agreement (or Inter-Institutional Amendment) in effect between the collaborating institutions (MHS, Case, UHC). The decision of which IRB to rely on for review of a particular protocol is made jointly by the Chairpersons and/or IRB Administrators of the collaborating institution's IRB, and is determined primarily by the place of primary appointment of the PI or place of primary interactions for study related activities. Both parties must agree that it is acceptable to rely upon the respective IRB for initial and continuing review of the research in accordance with the terms and conditions of the IRB Authorization Agreement. When acting as the IRB of record, the IRB sends the site PI and designated institutional representatives copies of IRB correspondence. Copies of relevant IRB Minutes are provided to the designated institutional representative, upon written request.

Relationship between Other Institutions and the Case IRB

Institutions outside Case may rely on the Case IRB if there is an executed IRB Authorization Agreement in effect between the institution and the Case IRB. The decision of whether to rely on the Case IRB for review of a particular protocol is made jointly by the Chairperson and/or Administrator of the IRB and the Chairperson

and/or Administrator of the collaborating institution's IRB. Both parties must agree that it is acceptable to rely upon the Case IRB for initial and continuing review of the research in accordance with the terms and conditions of the IRB Authorization Agreement. When acting as the IRB of record, the Case IRB sends the site Responsible Investigator and designated institutional representatives copies of IRB correspondence. Copies of relevant IRB Minutes are provided to the designated institutional representative, upon written request.

When research reviewed at Case that plans to include research activities at external sites that do not have an IRB, investigators must provide documentation (e.g.; appropriate letter of cooperation on letterhead from that site) that the external site has agreed to host the research activities and also provide contact information for relevant parties and officials related to the conduct of the external site.

Oversight and Review

The Case IRB oversees all human study participants research conducted by Case faculty, staff or students, unless the research involves one of the affiliated medical centers. Specifically, the affiliated hospital IRBs (University Hospitals of Cleveland, The MetroHealth System, Louis Stokes Cleveland Veterans Affairs Medical Center and the Cleveland Clinic Foundation) review all human research projects that originate from: 1) their staff members, 2) the Case departments housed in the School of Medicine*, 3) the School of Nursing, Dentistry or any other department that involves patients or personnel of each hospital, as well as, 4) all projects involving the hospital's patients or personnel, regardless of sponsor, and 5) selected proposals as requested by the Case IRB (University Policy, January 13, 1999).

The Responsible Investigator is responsible for reporting all adverse events and unanticipated problems associated with the protocol in question to the IRB as well as to all institutions/sites involved.

Communication with other IRBs/Institutions/Sites

When *Case* or one of its investigators is functioning as the lead institution/lead on a multi-site study, the Responsible Investigator is required to provide the IRB with a management plan for coordinating data from all sites and disseminating information to all sites that might be relevant to the protection of research participants. The management plan will include: (1) unanticipated problems involving risks to participants or others, (2) interim results, and (3) protocol modifications. As such, the Responsible Investigator will inform all institutions/sites of all adverse events or unanticipated problems associated with the respective protocol.

*Because medical IRBs receive protocols from the School of Medicine that may be more appropriately reviewed by the behaviorally-focused Case IRB, the IRB Advisory Committee (IAC) will allow selected proposals to be referred from an affiliated medical IRBs to the Case IRB. The referral must come to the Case IRB as a written request from the Chairperson of the respective medical IRB (IAC Approved, October 12, 2001).