

Human Research Protections Program (HRPP)

Relationships with Other Institutions

MCG may choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for the institution to provide this oversight, a formal relationship must be established between the institution and the other institution through either a Cooperative Agreement or a Memorandum of Understanding. This relationship must be formalized before the institution will accept any human research proposals from the other institution.

MCG acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. MCG may enter into a joint review arrangement, rely on the review of another qualified IRB or make similar arrangements for avoiding duplication of effort.

- When MCG relies on another IRB, the HAC Chairperson or designee and the OHRP Director and/or Assistant Director will review the policies and procedures of the other IRB to ensure that they meet MCG standards. If the other IRB is part of an accredited HRPP, then it will be presumed that the MCG standards are being met.
- When MCG reviews research conducted at another institution, the particular characteristics of each institution's local research context must be considered, either (i) through knowledge of its local research context by the MCG HAC or (ii) through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other HAC members.
- When MCG is the coordinating center for a multi-center protocol, the HAC will require the MCG principal investigator to ensure that IRB approval has been obtained at each participating site prior to initiation of the research at that site. At the time of initial review, the HAC will assess the procedures for dissemination of protocol information (e.g. unanticipated involving risks to participants or others, protocol modifications, interim findings) to all participating sites.

The HAC will also request that the principal investigator provide information to the HAC when research will be conducted outside Georgia to determine what other laws may have an impact on the human research protection program. If the research will be conducted outside Georgia, the OHRP Assistant Director will work with the Office of Legal Affairs to determine the individuals noted as “legally authorized representatives,” “children,” or “guardians” as defined by DHHS and FDA regulations. This information will be provided to the HAC.

Relationships with Sponsors

The institution will work with the various types of external sponsors such as federal, state, foundation, industry or others as well as their designees as appropriate to the issue at hand. The institution will include the external sponsors on copies of auditing and compliance reports along with any corrective action plans as needed. The institution will invite participation by the sponsors for education and training opportunities such as web seminars, conferences (audio and video), on-site presentations and other feedback opportunities.

The research team members will work with the sponsors and contract research organizations for industry or corporate sponsored research during the site selection process, the approval process, during the conduct of the study and the close-out requirements. These activities will be

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accomplished via email, telephone, on-site visits by the sponsors/contract research organizations (CROs), conferences, etc.

Other Institutional Components of the MCG HRPP

The other institutional components of the MCG HRPP communicate with each other on a regular basis. However, it is the responsibility of the OHRP Director and Assistant Director to confirm that all approvals required by the institution are met before the protocol may be:

- Approved by the HAC via the Final Approval Checklist or
- Released by the OHRP CRRI Checklist