214.1 Communication among IRBs in Multi-Site and Collaborative Research

The UH IRB is responsible for the review of all UH research that involves human research participants, whether the research is done at UH, a UH affiliate institution, or another site outside of UH.

When UH is conducting research at an external site (e.g., school, hospital) and is not the coordinating site or lead Investigator, and that site is engaged in research, the UH IRB requires contact information for the coordinating/lead site, whether the site has an IRB, and if so, confirmation of the IRB’s permission to conduct the research.

UH’s IRB relies on the IRBs of other sites and also agrees to have other sites rely on UH’s IRB on occasion. Currently, the UH IRB relies on the Western IRBs (WIRB), Queens Medical Center IRB (QMC IRB), and the National Cancer Institute’s IRBs (CIRB) on human participant research that meet certain criteria. Additionally, UH’s IRB may rely on other external IRBs for single research projects.

If UH agrees to serve as the IRB of Record for an external site, that site obtains an FWA through OHRP which subsequently cites UH’s IRBs registration number(s). OHRP notifies UH of this addition. An IRB Authorization Agreement is signed by the institutional officials of UH and the external site, authorizing UH to serve as IRB of Record for that site.

PI’s Responsibilities for Research in which UH Serves as a Participating Institution

When UH is a participating institution (i.e., sending data or biospecimen samples out of UH), the PI is responsible for submitting data to the coordinating institution, reporting unanticipated problems (UPs), and other reportable events in a timely manner to the coordinating institution and the UH IRB. The PI is also responsible for ensuring that the PI’s research team has the current approved version of the protocol, consent form and other pertinent study documents (e.g., recruitment material, data collection instruments).

214.2 Managing Information in Multi-Site Research

UH Serving as the Coordinating Institution

When UH is serving as the coordinating institution, the PI must include a protocol for communicating information relevant to the protection of participants among participating site and institutions as part of
the **APP 04: New Research for Initial Approval, Non-Exempt Application**, including communication of adverse outcomes, protocol modifications, and interim results.

When completing the eProtocol Application, PIs must indicate if UH is serving as the coordinating institution. The PI must list all other sites involved with the proposed research, the contact person at each site and contact information, such as phone number and email address. The PI must also indicate if each participating site has an IRB and if that IRB has reviewed and approved the research.

When UH is the coordinating institution receiving data or tissue sample from other sites the PI must submit the following documentation for each of the other participating sites along with the Protocol Application to the IRB before receiving any data or tissue sample from a site:

- IRB approval letter from each participating site that includes the type of review, the date of approval, and
- When appropriate, the IRB-approved consent forms from all participating sites.

The UH IRB will keep this information on file for all internal and external reviews.

By submitting the protocol application form, the PI documents his/her acceptance of the responsibility of ensuring that all participating sites have obtained IRB approval prior to initiation of the research at that site. The participating sites must have written procedures that define the scope of studies subject to review by their IRB. The HSP staff will review and confirm that each protocol application for a UH coordinating site project includes the appropriate documentation from all participating institutions.

If a participating site does not have an IRB, that site may request that the UH IRB serve as the IRB of Record. A written agreement (aka Memorandum of Agreement) must be reached between the participating site and the UH IRB that clearly outlines the review and approval procedures. This written agreement must be reviewed, approved and signed by the Institutional Official. See **SOP 120.2: Collaborative Research for information on establishing an IRB Authorization Agreement** and Memorandum of Agreement.

For a prospective clinical trial, the consent forms used at all sites must indicate that data or samples are being sent to UH. Data or tissue sample, even though they are anonymous, may not be received from an outside institution whose consent form prohibits data or tissue from going outside the institution.

There must be documentation of regular communication with the participating sites to update and inform all participating sites about progress of the study.

**Reporting to the IRBs in Multi-Site Research**

As the lead Investigator at the coordinating institution, the PI is responsible for receiving data and reports from the external sites in a timely manner and distributing this information to the UH IRB as required (see **Section 203.7**). UH IRBs give the same considerations to such reports in multi-site research as they do to internal reports.
Identifying Material Changes in Multi-Site Protocols

The PI must report any material changes in the protocol that take place at any of the participating research sites. The IRB may require independent verification to ensure that no material changes have occurred in multi-site research or cooperative study protocols since the previous IRB review.

Additional Requirements

Additional requirements might apply, (such as a formal agreement to specify the roles and responsibilities of each party), depending on the source of support/funding. See GUIDE 617: Other Federal Agencies - Additional Requirements.