Title	**Multisite Process for Initial Submissions**
Related SOP	403 – Initial Review - Criteria for REB Approval
Effective Date	01 February 2018

When the same research protocol is undertaken at two or more sites, and will receive ethics review through HREBA, the following multisite process applies.

Submitting Multisite Studies for Initial Review

As the IRISS system currently only allows one principal investigator per submission, each site must have a separate IRISS file.

The Cancer Committee prefers that files for multisite studies be identical except for site-specific information. This results in the quickest turn-around time for study teams as it involves the least amount of duplicate review for committee members and REB administrative staff.

If sites do not wish to work together, files may be reviewed separately. However, as the files will not be linked this will result in a longer turn-around time and, if industry sponsored / funded, extra review fees.

Submission methods and review fees for multisite studies are as follows:

A. Parallel Submission

- Sites work together to submit the study for review and discussion at the same full board meeting; the IRISS applications are identical other than site-specific information.
- Review fees for industry funded studies: $4000.00 for one of the sites, $1000.00 for each other site.

B. Sequential Submission

- Once an initial site application is approved, subsequent site(s) will copy the initial site application and modify it for site-specific information.
- Review fees for industry funded studies: $4000.00 for the initial site, $1000.00 for each subsequent site.

C. Separate Submission

- Sites submit their IRISS applications for review without collaborating with each other.
- Review fees for industry funded studies: $4000.00 each site.

A. Parallel Submission

Sites will work together to create their applications and submit the study to the REB for review at the same meeting. "(Multisite – Parallel)" should be added to the end of the Short Study Title and all information and documents, other than site-specific information, must be identical. See "Sequential Submission" below for a list of application sections and documents which may vary due to site-specific information.

If the study is industry funded review fees are required; therefore, sites must decide which site will pay the $4000.00 review fee and which will pay the $1000.00 review fee. The site which will be paying the larger review fee should "Log Comment to REB Admin" indicating that they will be paying the $4000.00 review fee.

To facilitate review the committee requires the submission of tracked changes versions of documents shared between the sites which differ only in site-specific information. Sites must decide which site will submit clean versions of the documents; the other site(s) will be required to submit tracked changes versions, in addition to clean versions, of these documents. The tracked changes documents will show the differences between sites.

If, after the initial review, the committee requires changes, the sites must continue to work together to provide a coordinated response unless questions are site specific. Once all sites are ready to be approved, the committee will issue ethics approval certificates.

B. Sequential Submission

Initial Site Submission and Approval

One of the sites will submit their application as per the standard process for submitting a study for review. If, at the time of submission, the initial site is aware that another site will be submitting the same protocol for review, add "(Multisite – Sequential)" to the end of the Short Study Title.

Subsequent Site Submission

Once the initial site is approved, the subsequent site(s) can start its application(s). The easiest way to do so is to have one of the study coordinators for the subsequent site added as a coordinator to the initial site. He or she can then take a copy of the initial site's approved file and use it as the basis for the subsequent submission. Once a copy is made, the coordinator can be removed from the initial site's file, if desired.

The subsequent site's application should be identical to the initial site's application, except for site-specific information. As applicable, the following information should be updated:

- Add "(Multisite – Sequential)" to the end of the Short Study Title
- Principal Investigator, Co-Investigators and Study Team Members
- Conflict of Interest (if any)

- In question 4.0 of the "Impact and Operational Approvals" section, list the initial site's ethics ID (e.g. HREBA.CC-xx-xxxx)
- Anticipated start and end date of research and interaction with participants
- Number of participants to be recruited
- "Recruit Potential Participants" section
- "Reimbursements and Incentives" section
- "Data Collection", "Data Identifiers", "Data Confidentiality and Privacy" and "Data Storage, Retention and Disposal" sections
- The following documents in the "Documentation" section. (Include tracked changes versions for any documents which differ from the initial site's documents due to site-specific information.)
    - Informed consent / assent forms
    - Recruitment materials and initial contact letters
    - Budget
    - Billing Information Form (for industry funded studies)
    - Departmental Approval Form
- Any other information that differs from the initial site's application

Subsequent Site Review

If the sequential submission process is used, additional sites are eligible to have their site-specific information reviewed and approved by delegated review if: a) the initial site has not yet submitted any amendments to the protocol or consent forms and b) such review is permitted by the sponsor.

If the additional site is not eligible for delegated review the application will be reviewed at a subsequent full board meeting.

Subsequent Site Approval Dating

If the subsequent site is approved by delegated review, the ethics approval certificate will include the date study-wide information was approved, and the date site-specific information was approved.

If the subsequent site was approved by full board review, the approval will be the date the submission was approved by the full board.

Regardless of the method of review, the ethics expiry date will be set to a maximum of one year from the date of the **initial site's** approval. This ensures that all annual renewals for one protocol are reviewed at the same time.

C. Separate Submission

Each site will submit their application as per the standard process for submitting a study for review. Each application will be reviewed as a new submission.

Multisite Studies after Initial Approval

Ongoing Review Activities

The coordination of submissions for amendments, reportable events, etc. will be left to the discretion of the sites. If the sites decide to coordinate after initial approval, standard processes for these submissions should still be followed.

Continuing Review Activities

The coordination of submissions of renewals will be left to the discretion of the sites. If the sites decide to coordinate after initial approval, standard processes for renewing a study should still be followed.

SOP Code	Effective Date	Summary of Changes
SOP403.002G(b)	01-Feb-2018	Original version