

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	1 of 19

Single IRB Guidance

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	2 of 19

Table of Contents

Section I - Single IRB Reliance Agreement Process Overview	4
Step 1: Identify the IRB that will serve as the IRB of record for all sites (sIRB)	4
Step 2: Establish/negotiate the fee structure	5
Step 3: Identify and/or hire the IRB liaison.....	5
Step 4: Determine who will establish the IRB reliance agreements.....	5
Step 5: Initiate the reliance agreement process for the FCCC’s involvement in the research.....	6
Step 6: Determine the roles and responsibilities related to obtaining IRB approval	6
Step 7: Prepare and submit IRB applications	6
Section II - Grant preparation and selecting sIRB.....	7
Grant application preparation	7
Consult with the FCCC Institutional Review Board (IRB) Office.....	7
Selecting the Single IRB	8
Documenting the SIRB selection	8
Cost of Single IRB Review	8
Single IRB Plan for the Grant Application.....	9
Content	9
Location in the Grant Application.....	10
Delayed-onset Study(ies).....	10
Responsibilities of the Lead Study Team.....	10
Section III- When Fox Chase is a Participating Site (pIRB).....	11
Requesting a Grant Letter of Support.....	11
The Single IRB (sIRB) reliance agreement.....	12
How to initiate a reliance agreement	12
Local Context information	12
Ancillary Approvals	12
Apply for IRB approval.....	13
During the study	13
Section IV - Creating a sIRB Application (eIRB): FCCC IRB of record	14
Creating Consent Template(s).....	14
Create New Study.....	15
Submit Study	15
Add Participating Sites.....	15

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	3 of 19

Modification(s)17

Continuing Review18

Reportable New Information18

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	4 of 19

Section I - Single IRB Reliance Agreement Process Overview

The purpose of this document is to provide guidance when initiating or participating in a study being conducted under a single IRB review.

Please note that FCCC is participating in SMART IRB along with over 500 other sites. Please check the list of participating sites when planning the study at SMART IRB.org

FCCC has signed a master agreement with SMART IRB. It is a preferred mechanism since the SMART IRB Reliance Request System reduces some administrative burdens.

Consult with the Fox Chase Cancer Center Research Compliance and Integrity department, specifically the FCCC– IRB Office for additional guidance, individual training and/or education.

Step 1: Identify the IRB that will serve as the IRB of record for all sites (sIRB)

In some cases, NIH (or another funding sponsor) may specify the sIRB. However, for most grants, NIH expects the Lead PI to identify a specific sIRB in the grant application. Please note that in the NIH [sIRB FAQ](#), it states “The proposed single IRB will not be evaluated as part of the peer review process and will not affect the overall assigned score of an application/proposal or the overall rating of the acceptability of the Protection of Human Subjects section”.

The Lead PI may need to consult with the FCCC IRB Office when selecting a single IRB. The Lead PI should collect preliminary information about the study and the participating sites. That information must be reviewed by the FCCC IRB Office to determine if the FCCC IRB is willing to serve as IRB of Record or cede review to an external IRB based on the details provided.

Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

Requests for exceptions that are not based on a legal, regulatory, or policy requirement may be considered by the NIH. If the exception is approved, please submit that approval notification to the FCCC IRB Office during your consultation and/or when requesting letters of support for other sites.

Please send your request for initial consulting/education or review to IRBOffice@fcc.edu

Consider the following factors when selecting a sIRB:

- IRB’s expertise in relation to the study procedures, populations or other special considerations
- IRB’s turnaround time
- IRB’s fees
- IRB’s history and reputation

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	5 of 19

- IRB's capacity

Fox Chase Cancer Center will only cede IRB oversight to AAHRPP accredited institutions. The FCCC IRB Office will issue a letter of support if the request is approved. See Section III - Requesting a Grant Letter of Support for more details.

Step 2: Establish/negotiate the fee structure

This is a new responsibility for the lead site/PI. The NIH issued a policy permitting the institution that is acting as the IRB of Record on a sIRB project to charge the Relying Site for their service. These fees should be included in the grant budget.

There is no nationwide standard for how IRB fees are assessed or how much they are. You should obtain fee information from the sIRB that is specific to the study you are proposing. This may require asking the IRB office for a study-specific fee estimate.

NIH has provided detailed information about [specific cost guidance](#). Please see this [cost guidance](#) for where to put sIRB cost information on the budget forms.

For more information, please refer to Section II of this document for more detailed instructions.

Step 3: Identify and/or hire the IRB liaison

It is anticipated that studies with a large number of sites will require additional staffing resources to manage the complex communications, coordination and document management associated with the use of a sIRB across sites. It is strongly encouraged to identify or hire a study staff member to fill this role. This role is typically a staff member on the Lead Study Team.

Step 4: Determine who will establish the IRB reliance agreements

Any letters of support about sIRB review that you provided for the grant application are not IRB reliance agreements.

FCCC has signed a master agreement with SMART IRB, if a study site has not joined SMART IRB then that site must negotiate and sign a formal written agreement with the sIRB, this is referred to as a reliance agreement or an institutional authorization agreement (IAA). These agreements document the arrangement between the sites and also establish expectations about communication, reporting and other procedures/processes.

Investigators are not authorized to sign reliance agreements. Each agreement must be signed by the sIRB and by an appropriate institutional official/ signatory official for each site.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	6 of 19

Study leadership should decide who will initiate, manage, and track the IRB reliance agreement process.

Establishing reliance agreements between the sIRB and each site can be slow. It is advised that PI's initiate and manage this process to ensure that it does not get drawn out longer than need be.

Step 5: Initiate the reliance agreement process for the FCCC's involvement in the research

FCCC must have a reliance agreement with the sIRB if ceding IRB review or with all participating sites if FCCC is serving as the IRB of record. Please note that a joiner reliance agreement has already been executed with SMART IRB.

There may be additional contractual agreements needed for your study. Please work with Research & Development Alliance for contracts, the Office of Sponsored Research for Grants and for Data Use Agreements, contact, [Nora McCann](#).

Step 6: Determine the roles and responsibilities related to obtaining IRB approval

For most multi-site studies, IRB review and approval will be a two-step process:

1. Submitting the generic protocol and consent materials for review by the sIRB.
2. Submitting site-specific information such as investigator qualifications, site specific recruitment and consent information, and other local context information (e.g., state laws about the age of majority) for review by the sIRB. Participating site applications can usually be submitted at any time concurrent with, or after, the generic application.

Study leadership should decide who will initiate, manage, and track the IRB applications for each of these two steps, and who is responsible for providing what information for the applications. The lead investigator is responsible for obtaining any additional approvals from Department of Health and Human Services (DHHS) when the research involves pregnant women, fetuses and neonates; or children; or prisoners. The lead PI is also responsible for obtaining Certificates of Confidentiality or establishing the NIH Genomic Sharing policy if applicable.

See Section II – Responsibilities of the Lead Study Team and Section III – During the study for more detailed information on sIRB and pIRB responsibility assignments.

Step 7: Prepare and submit IRB applications

Use the forms, systems and processes required by the sIRB.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	7 of 19

Section II - Grant preparation and selecting sIRB

Grant application preparation

The NIH requirements for the lead PI:

1. Select the IRB that will serve as the single IRB (sIRB)
2. Include any sIRB fees and sIRB-related personnel costs in the grant budget, as well as appropriate budget justification information. See the [PHS G.300 – R&R Budget Form](#) for information about where in the budget form to put this information.
3. Obtain confirmation from the participating site investigator that his/her institution is willing to rely upon the specific identified IRB.
 - a. The participating site PI is responsible for contacting the appropriate office at his/her institution, obtaining confirmation of the institution's willingness to rely on the sIRB, and communicating the confirmation to the lead PI in the form of an acceptance letter.
 - b. The FCCC lead PI may wish to provide participating site PIs with a template letter of support, to assist in obtaining and documenting the confirmation. Note that NIH does not require letters of support from participating institutions about their use of sIRB.
4. Prepare a Single IRB Plan for the grant/contract application.
5. Fill out the grant application forms as required by NIH. See Section D "NIH Grant Application/Contract Proposal Preparation" of [the NIH FAQ Single IRB Policy and Multi-site Research](#) and (for specific details) [Section 3.2 of the PHS Human Subjects and Clinical Trials Information Form Application Guide](#).

Consult with the FCCC Institutional Review Board (IRB) Office about selecting the sIRB prior to submitting the grant.

FCCC IRB office recommends that this is completed, prior to obtaining conformation from participating sites about their willingness to rely on the selected IRB. FCCC IRB Office cannot guarantee its willingness to support the use of a sIRB that has been selected without its consultation and approval.

After assessing the acceptability of the proposed IRB, FCCC IRB Office will provide the FCCC investigator with an emailed letter of support, '*Invitation Decisions Letter*' (HRP-851). This should be retained for study records.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	8 of 19

Selecting the Single IRB

Any IRB with a Federal wide assurance (FWA) and is AAHRPP accredited, can serve as a sIRB, if NIH has not specified the sIRB in its funding announcements.

The lead PI will need to determine the following:

- Ensure that the IRB is willing to serve as the sIRB;
- The IRB charges fees and obtain cost estimate for the grant budget.

Documenting the sIRB selection

The Single IRB Plan in the funding proposal must name the proposed sIRB and contain a statement that each participating site is willing to rely on the proposed IRB.

Cost of Single IRB Review

The costs for single IRB review had typically been considered an indirect cost covered under an institution's Facilities and Administration (F&A) rate (except for industry-initiated-and-sponsored studies).

However, NIH expects that many sIRBs will charge fees to review other sites. The fees are the responsibility of the lead site and should be included in the grant budget. **This is a new responsibility.**

Each IRB determines whether or not it will charge study-specific fees.

In general:

- NIH-operated IRB **will not** charge fees
- Commercial IRB (WIRB, Advarra, etc.) **will** charge fees
- IRB affiliated with a university, academic medical center or research institute **may or may not** charge fees
- FCCC has a fee schedule available upon request

There is no standard for how IRB fees are assessed or how much they are. Some IRBs charge for each review activity they complete (initial approval, modifications, continuing reviews) for each site and some IRBs charge annual fees for the study based on the number of sites.

You should obtain fee information from the IRB that is specific to the study you are proposing. This may require asking the IRB office for a study-specific fee estimate.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	9 of 19

NIH has provided detailed information at the [sIRB FAQ](#) and a [specific costs guidance document](#), including topics such as:

- Which budget category on the SF424 (R&R) form should be used
- Which costs should be charged as direct vs. indirect costs under different IRB review scenarios
- The relationship with the \$500,000 cap on direct costs
- [Where to put the sIRB cost information on the budget forms](#)

If you have questions, contact:

- The NIH financial officer identified in your FOA or RFP and/or
- The FCCC Office of Sponsored Research

Single IRB Plan for the Grant Application

Since [January 25, 2018](#), NIH requires most multi-site grant applications to include a plan for the use of a sIRB. For details, see [Section 3.2 of the PHS Human Subjects and Clinical Trials Form Information Application Guide](#).

Content

The sIRB should include the following elements:

- Describe how you will comply with the NIH Single IRB (sIRB) policy. If you are requesting an exception for some or all participating sites, follow the NIH Guidance [Requesting an Exception](#).
- Provide the name of the IRB that will serve as the sIRB of record.
- Indicate that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
- Briefly describe how communication between sites and the sIRB will be handled.
- Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.

Some IRBs, such as commercial IRBs like WIRB and Advarra, will provide you with this information prepared in a letter of support along with any fee estimates you have requested. If the IRB has not provided this information, you will need to compile it yourself.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	10 of 19

Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your grant application.

Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study in the [delayed onset study justification](#).

- Justification attachment must include:
 - Information regarding how the study will comply with the sIRB policy, **and**
 - State that a sIRB plan will be provided prior to initiating the study.

Location in the Grant Application

New FORMS-E

NIH created a new application form that consolidates all Human Subjects and Clinical Trial related information into one place, and also expands the information required for studies that meet [the NIH definition of a clinical trial](#). This new form is included in the [FORMS-E](#) Application Packages to be used for all due dates on or after January 25, 2018 and should be used for all human subject contract proposals responding to Requests for Proposals issued as of January 25, 2018. The sIRB plan is uploaded as an attachment to Question 3.2 of the new FORMS-E.

[FORMS-E application instructions](#) are available from NIH on the [How to Apply – Application Guide](#) website.

Delayed-onset Study(ies)

FORMS-E has specific questions for delayed-onset studies. The sIRB plan should be uploaded with the answers to those questions.

Responsibilities of the Lead Study Team

The Lead Study Team has new responsibilities associated with the use of a sIRB. You can find a list of many of these described in the [Overall Principal Investigator/Lead Study Team Guidance and Checklist](#) provided by SMART IRB.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	11 of 19

Section III- When Fox Chase is a Participating Site (pIRB)

This means that FCCC relies on an External IRB to perform sIRB review to ensure that the protocol meets the regulatory criteria for approval. The sIRB is also responsible for the ongoing review of the study, this includes continuing review, review of modifications, and review of reportable events. When FCCC IRB cedes to a sIRB, FCCC IRB Office is still responsible for ensuring certain institutional policies and practices established by the FCCC Human Research Protection Program are being followed.

The FCCC Study PI is responsible for obtaining all sIRB approved study materials (approved protocol, approved consent documents, etc.) from the ‘Overall PI’ or ‘Lead PI’. The FCCC study team will be responsible for providing information needed at the time of continuing review or if any unanticipated problems involving risks to subjects are to be reported to the sIRB.

Requesting a Grant Letter of Support

The NIH sIRB policy requires the Lead PI to identify the sIRB in the grant application and to state that conformation has been obtained from each participating site that each site is willing to rely upon the identified sIRB.

To provide written confirmation, a FCCC participating investigator must first obtain a **Letter of Support**. The FCCC IRB Office is the only office that can make this commitment on behalf of Fox Chase Cancer Center.

To request for FCCC IRB to cede review to an external IRB, **complete HRP- 881 Reliance Request form** and email it to the IRB Office IRBOffice@FCCC.edu. The IRB cannot provide confirmation without this information.

After the IRB office assesses the acceptability of the proposed IRB, FCCC IRB will provide the participating site investigator with an emailed letter of support. This should be retained for study records.

NIH requirements:

1. Provide the lead (overall) PI with confirmation that FCCC is willing to rely upon the specific single IRB identified by the lead PI. FCCC will provide you with an emailed letter of support that you can use for this purpose.
2. Fill out the grant application forms as required by NIH. See Section D “NIH Grant Application/Contract Proposal Preparation” of the [NIH FAQ Single IRB Policy and Multi-site Research](#) and (for specific details) Section 3.2 of the [PHS Human Subjects and Clinical Trials Information Form Application Guide](#).

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	12 of 19

***Note:** Reliance Agreements for sIRB review are used to cede only the IRB review of the study. All institutionally-required ancillary reviews must still be obtained locally. Fox Chase Cancer Center will cede IRB review only to AAHRPP credited institutions.

The Single IRB (sIRB) reliance agreement

Any letter of support from FCCC IRB about sIRB review that you are provided is **not** an IRB reliance agreement. After the grant is awarded, each participating site must negotiate and sign a formal written agreement with the single IRB. The reliance agreement documents the arrangement and also established expectations about communication, reporting and procedures.

How to initiate a reliance agreement

The FCCC IRB participates in SMART IRB. This is an NIH funded initiative that has over 500 sites which allows participating sites to minimize the administrative burden of executing multiple reliance agreements. If the Lead Site is participating in Smart IRB inquire if a separate reliance agreement is needed. If approved by the Lead Site follow the ***FAQ SMART IRB Agreement Reliance System*** guidance document for further information about the reliance system.

If an individual reliance agreement is required complete the document HRP-901 **Reliance request form** and submit it in eIRB. As part of your submission, you will need to provide a copy of the protocol, template consent materials, and any documents you received from the reviewing IRB that are to be filled out by the FCCC IRB Office. You may need to contact the reviewing IRB or lead site in order to obtain any missing materials.

Local Context information

Local context information is information about state laws and mandatory institutional policies that is important for the sIRB to know when it reviews the FCCC site's application.

If the lead site or single IRB asks for you for local context information (for example, by sending you a form or webpage to complete), contact FCCC IRB for help at IRBOffice@FCCC.edu.

Ancillary Approvals

The sIRB does not perform local ancillary reviews. FCCC requires feasibility, scientific review, privacy (HIPAA) review, conflict of interest compliance review, institutional biosafety (IBC) review, if applicable and a few others. These reviews must be completed PRIOR to submission to sIRB. You may be asked to provide approvals or verification of completion of these ancillary reviews to the sIRB. Local Ancillary Review is the responsibility of the FCCC study team, not the IRB. The IRB does help facilitate some of these local reviews.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	13 of 19

Examples include:

- Any relevant Financial Conflict of Interest Management Plan
- Documentation of completed human subjects training for all key personnel
- Documentation of completed GCP training for all key personnel
- Radiation Safety Approval
- Institutional Biosafety (IBC) approval

Apply for IRB approval

Each participating site must apply for the approval of the sIRB. There is currently no national standardization or consistency regarding who prepares and submits the IRB application for each participating site – it could be the local PI (you), the lead site, or the coordinating center. The lead site or coordinating center will inform you:

- Who should prepare and submit the IRB application for Fox Chase
- If it is you: what application forms and submission system you should use
- If it is not you: what information you will need to provide to the individuals preparing the application for the Fox Chase site

During the study

The FCCC participating site PI is responsible for following the policies of the sIRB. This includes using the sIRB forms and processes, following the sIRB reporting requirements about unanticipated problems and other issues, and complying with the stipulations of the sIRB's approval in addition to following some local policies as well.

FCCC's participating site PI's are also responsible for:

- Ensuring that any relevant financial conflicts of interest are disclosed to the sIRB and that conflict of interest management plans issued by the Research Compliance Oversight Committee (RCOC) are submitted to the sIRB for review and approval.
- Providing copies of sIRB approvals available for inspection by monitors and auditors.

See the [Relying Investigator Guidance and Checklist](#) for a detailed list of responsibilities provided by SmartIRB.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	14 of 19

Section IV - Creating a sIRB Application (eIRB): FCCC IRB of record

The purpose of this document is to provide guidance for creating a multi-site application in eIRB when FCCC IRB is the IRB of Record.

When FCCC is serving as the IRB of Record, the initial IRB application must **only** describe the research **being conducted at the FCCC site**. The initial study application may be submitted prior to finalization of Reliance Agreement(s).

Multi-site studies using sIRB includes separate submissions:

- **A Study Submission** that describes the research and the study-related details of the institution serving as the single IRB of record (sIRB)
- **Site Submissions** that describes the study-related details of each participating or relying site (pSite). The multi-site study will appear differently based on whether you are in the FCCC IRB system or the IRB system of a pSite institution.
 - The sIRB system is where the main multi-site study submission is housed. This includes a study submission, and all the sites submissions for every pSite participating in the study. For example, if a multi-site study involves 3 pSites, the sIRB system will have 4 separate submissions: 1 study submission and 3 site submissions. Each of these submissions have their own workspace and their over review process. Each site submission is also linked from the study workspace.
 - The pSite system only includes an abbreviated version of the multi-site study, including 1 study submission and 1 site submission, which is the pSite's own site submission.

Creating Consent Template(s)

Consent templates must be uploaded in the eIRB application. The document(s) will use the same language as the FCCC consent form but will have sections where the participating sites will insert their local language.

The sections of the consent and HIPAA that participating sites are permitted to edit:

- Institutional letterhead
- Local study staff
- Local contact information
- Local compensation for injury language (if applicable)
- Local confidentiality measures
- Compensation language (if applicable)
- Local HIPAA language (Standalone document preferred)

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	15 of 19

Create New Study

The following steps must be completed in eIRB if FCCC IRB is serving as the IRB of record:

1. Create New Study
 - a. Title: Add “sIRB” in front of the title of the study
 - b. Question “What kind of study is this?”
 - i. Answer: Multi-site study
 - c. Question “Will an external IRB act as the IRB of record for this study?”
 - i. Answer: No
2. External team member information
 - a. **DO NOT** list any study personnel from the external sites under this section. This section is used to list study personnel that is conducting study activities under the direction of the **FCCC PI** at an outside location. (example: a statistician from Pittsburgh University)
3. Local Site Documents
 - a. Upload the consent forms, recruitment documents, etc. that are for FCCC site **only**.
4. Study-Related Documents
 - a. Upload the multi-site protocol, consent template(s), DHHS approval of vulnerable populations and Certificates of Confidentiality, Genomic Data Sharing Plans (if applicable) and other documents/templates that will be used by the relying sites.
5. Complete all applicable areas and submit the initial IRB application.

Once the FCCC IRB approved the initial study application, the participating sites can be added to the study.

Submit Study

Once all information and documents are entered into eIRB, the PI will submit the study for initial IRB review. The study team can start adding participating sites at initial IRB review or after study approval.

Add Participating Sites

Participating sites can be added by completing the **Add Participating Sites** activity. Participating sites can be added one at a time or all at once by adding multiple sites.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	16 of 19

The following **must** be completed prior to FCCC IRB reviewing the participating site:

1. The reliance agreement for each pSite has been fully executed
2. The pSite has completed the Local Context survey and add local language to consent form(s). Both must be returned to the FCCC lead study team.

Participating sites will work with their local IRB to complete the local context survey and insert local language in the provided consent templates. Once the lead study team receives the completed review and documents from the participating sites, the FCCC lead team can submit an activity in eIRB to add participating sites. The IRB will review and approve participating site submission. The lead study team will then distribute the FCC IRB approved documents to the participating sites.

The local context review include the following tasks:

- Ensuring that the study team has adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of participants.
- Identify if there are any additional requirements that the study must adhere to in order to comply with local institutional policies and requirements.
- Ensure all applicable Ancillary Review (Radiation Safety, Pharmacy, Institutional Biosafety, etc.) have been completed.
- The study team will customize the FCCC IRB approved consent form by inserting site specific language within the documents.
- If members of the study team have potential financial conflicts of interest, they will be reviewed according to the institutions conflict of interest policies.

The following steps must be completed in eIRB to add a participating site:

1. Add Participating Sites
 - a. Choose the site and local PI from the list. If they are not listed, contact the IRB.
2. Edit Site
 - a. Question: Brief description of activities this site will perform
 - i. Answer: Specify what study activities will be completed at the site.
Enter “ALL” if all study activities will be completed at the site.
3. Local Site Documents

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	17 of 19

- a. Upload the template documents that the participating sites inserted their local language into.
4. Answer all other applicable questions.

Once all information and documents are collected, execute the activity ‘Submit Site Materials’. Participating sites may begin the research study once all of the following has occurred:

1. FCCC IRB approved the modification to on board the participating site
2. All local institutional requirements have been met at the pSite
3. Grant/contract executing has been completed through the office of Sponsored Research.

Modification(s)

Modifications study wide, follow the regular study modification process.

Site modifications to the **study team membership or to research locations** follow an abbreviated local review process:

1. The pSite PI creates and submits the site modification, moving it into the **Pre-Review** state.
2. A pSite IRB staff member reviews the modification and either requests clarifications or approves the modification using the **Accept Site Updates** activity.
3. If the pSite staff decides that finalized documents or a letter are required, the modification is sent to **Post-Review**, then to **Review Complete**.

Note: If no documents or letters are required, the modification is directly sent to Review Complete.

Site modifications to **other parts of the site** require sIRB review:

1. After the pSite PI or study team member submits the modification, pSite IRB staff approves the modification on the pSite system using the **Accept Site Updates** activity. The modification is then communicated and uploaded to the sIRB system.
2. On the sIRB side, sIRB staff take the modification through the review process. While this happens, the modification remains in the **Pending sIRB Review** state on the pSite system.
3. Once the sIRB review is completed, pSite IRB staff record the sIRB decision, moving the modification to either **Post Review** (if a letter is required) or **Review Complete** on the pSite system.

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	18 of 19

Note: If modifications are required for approval, the modification submission moves to **Modifications Required**. The pSite PI can then submit a response to the sIRB, which moves the modification submission back to **Pending sIRB Review** until a new determination is received by the pSite and recorded in the pSite system.

Continuing Review

A continuing review (CR) for a multi-site study requires data from the sIRB institution and from all pSites associated with the study. While the pSite is responsible for reporting CR data from their site, the sIRB PI is responsible for creating and submitting a CR that encompasses the entire multi-site study. The Lead Study team must communicate and collect information for the continuing review from all the pSites.

1. The sIRB PI creates a CR from the study workspace and begins to complete the form. Because a CR for a multi-site study requires data from the sIRB institution and all pSites, it's likely that the PI may not have all the information they need at hand. In this case, the PI can exit the CR form and return to it later.
2. When a pSite PI reports continuing review data for their site, the sIRB PI will enter the CR data into the sites **Report Continuing Review Data** activity.
3. The site data is then displayed in the Sites tab. Next to the data, the sIRB PI **must** click the checkbox next to **Report Completed** to indicate that the CR data from that site has been reported. Once this checkbox is selected, the data that was reported complete automatically populates the CR form. When the sIRB PI next opens the CR form to edit it, the PI can see that the form has been automatically populated with the site CR data in the appropriate fields.

Note: the sIRB PI can complete the above activities as they receive CR data from various sites, or they can wait until they have received CR data from all site associated with the study, and complete the activities for multiple sites at once.

4. Last, when the sIRB PI has received and reported CR data from all the pSites, the PI can complete the CR form and submit the CR. Once the CR is submitted, it follows the same review process as a continuing review for a single-site study.

Reportable New Information

Reportable new information (RNI) should be submitted to the FCCC IRB base on FCCC's reporting policy.

The review process for reportable new information (RNI) associated with a multi-site study differs depending on whether the RNI originates from the sIRB or the pSite system, and on

GUIDANCE: SINGLE IRB		
NUMBER	DATE	PAGE
HRP-880	12/16/2019	19 of 19

where the RNI is routed for review. An RNI originating from the sIRB system follows a review process like that of single-site study RNIs.