PBRC AS LEAD

FIRST STEPS- PI

☐ The PI or study coordinator submits a Reliance Request Form xform in IRBManager

☐ Wait for communication from the IRB stating the reliance request has been approved or denied by the committee (this could take up to 3 weeks)

☐ Once your request has been approved, submit the Initial Review Application xform in IRBManager if you have not already done so. **Be sure to not include any relying sites or investigators in these documents yet. This will be done at a later time via a modification.**

☐ Wait for notice of full study approval from the IRB (depending on whether your study is expedited or full board, this may take 2-6 weeks) if not already approved.

ONCE YOU RECEIVE IRB APPROVAL- IREx STEPS

☐ IRB staff will create a study profile for your study in IREx, the platform we use to manage reliance studies https://www.irbexchange.org/p/. All initial study documents will be added by IRB staff.

☐ The PI will assign a study manager (usually a study coordinator) and let the IRB staff know to give this person access to the study in IREx. The study team may need to register for an IREx account if they don't already have one.

☐ The study manager will add the relying sites and their contact information in IREx and "notifies" the relying sites to complete the IREx steps. Resources for using IREx can be found here https://www.irbexchange.org/p/irexstudymanager/

☐ The relying sites will need to complete 3 surveys in IREx. The study manager or PI may need to communicate to the relying sites that they need to complete these in IREx.

ONCE RELYING SITES COMPLETE ALL SURVEYS- IRBMANAGER STEPS

☐ Study manager downloads and saves all 3 IREx surveys for each relying site (these should also be added to the regulatory binder)

☐ Study manager should also obtain any site-specific documents (consent forms, recruitment materials, etc.) from relying sites, if applicable

☐ A Modification xform should be initiated in IRBManager to add sites/investigators through reliance

   ☐ Include IREx surveys, relying site ICF/documents, and tracked/clean versions of any study documents that need to be amended to include the relying sites or investigator names (such as the protocol)

☐ Wait for notification of IRB approval of the modification (this should take approximately 2-3 weeks), and then upload the approval and site-specific documents to IREx for the relying sites to access

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FOR THE DURATION OF THE STUDY

☐ Modifications should be submitted per usual practice in IRBManager and approved documents should always be uploaded to IREx for relying sites to access

☐ Continuing Review should be submitted per usual practice in IRBManager and approved documents should always be uploaded to IREx for relying sites to access. Be sure to include relying site information, such as enrollment numbers, SAEs, Deviations, Unanticipated Problems, etc.

☐ When/if relying sites have any local subject materials and/or reportable events, they must be submitted for review through IRBManager

PBRC RELYING

FIRST STEPS- PI

☐ The PI or study coordinator submits a Reliance Request Form xform in IRBManager

☐ Wait for communication from the IRB stating the reliance request has been approved or denied by the committee (this could take up to 3 weeks)

☐ Once your request has been approved, you will work with the Lead IRB to develop local consent forms (if applicable). You will most likely use the Lead IRB's templates for this, rather than PBRC templates.

☐ Once developed, please send these local documents to the PBRC IRB office (irb@pbrc.edu) to review and ensure that all required local context language is included.

STEPS FOR IRB STAFF WITH HELP OF PI

☐ Once the PBRC IRB agrees to rely and lead site initiates reliance, IRB staff will indicate willingness to rely in IREx, SmartIRB, or other and will provide local considerations required by the Lead IRB. The PI may be asked to complete some of this information.

☐ If there is communication from the Lead IRB to the PI or study coordinator regarding steps needing to be complete- **please relay this information to the PBRC IRB office (irb@pbrc.edu).**

☐ IRB staff will create a study page for the study in IRBManager. The study number will be sent to the PI via email and can be found on the PI's dashboard. **If you do not see the study on your dashboard and have not received communication from IRB staff that the study page was created, **please let us know**.**

ONCE LEAD SITE APPROVES PBRC AS A SITE- PI/COORDINATOR STEPS

☐ Study coordinator or PI will obtain all site approval documents from the Lead IRB including approval letter and any local consent forms, etc.

☐ Using the "Reliance - Initial Study Documents Approved by the Lead IRB" xform in IRBManager, study staff will upload all of the approval documents from the Lead IRB.

☐ IRB staff will acknowledge these documents and release a Site Activation/ Study Acknowledgement letter to the PI (can take up to 2 weeks).

☐ No study activities should commence until this letter is received! If you have not received a Site Activation letter or Study Acknowledgement letter after submitting initial approval documents via IRBManager within 2 weeks, please contact the PBRC IRB office.

FOR THE DURATION OF THE STUDY

☐ PBRC specific subject materials, including recruitment documents, should be submitted via Subject Materials xform as normal, however you MUST have Lead IRB approval first and attach the approval letter to the submission! If you would like it pre-reviewed, send an email to irb@pbrc.edu.

☐ Continuing Review should be submitted using the "Reliance Continuing Review Approval from the Lead IRB" xform once approval documents are received from the Lead IRB.

☐ Modifications should be submitted using the "Reliance Modification Approval Documents from Lead IRB" xform once approval documents are received from the Lead IRB. *You should always wait for PBRC IRB acknowledgement before moving forward with any protocol modifications.*