

BCH Overall/Lead Principal Investigator Guidance

The Overall PI holds the responsibility to function as the PI for all involved sites, communicating with the Reviewing IRB on behalf of all involved. Investigators will need to determine who among collaborators who will serve as the Overall Principal Investigator (PI) and whose institution will serve as the Reviewing IRB (Lead PI). In this document the BCH PI serves as both Overall and Lead PI.

As the Overall Principal Investigator for a study when **BCH will serve as the single IRB (sIRB) for research at multiple sites**, you should be aware of your additional responsibilities in assuming that role. Please consider these extra responsibilities carefully before agreeing to serve as the Overall PI for multiple institutions.

- If you are considering serving as the Overall PI for multiple institutions you should first contact the BCH IRB reliance specialist to:
 - Discuss whether the BCH IRB can act as the sIRB for all or some institutions participating in this study or whether an external IRB would be more appropriate.
 - Decide which reliance agreement will be utilized between BCH and the Relying Sites.
 - Identify who will act in the role of coordinating the additional activities when other sites will rely on BCH. Please note your workload will increase because you are responsible for conducting activities on behalf of the Relying Sites.
 - Provide the BCH IRB reliance specialist with details about the study, including the study-wide protocol and consent/assent document(s), which will help facilitate the discussion.
 - Identify all sites that will be engaged in human subjects research and thus require BCH IRB coverage.

- If the BCH IRB agrees to serve as the sIRB for the study, you will need to first have the 'master' protocol reviewed and approved by the BCH IRB. Once all materials are approved (protocol, consent, recruitment materials, etc.) you can begin to submit reliance requests for each site.

- As part of preparing the reliance requests you need to provide each site with a "Reliance Packet" including copies of the initial protocol approval letter, approved protocol document, template consent/assent form(s), any pertinent materials to be used locally (e.g. recruitment fliers, surveys), and reliance documentation, as applicable. You will also need to have a mechanism in place to obtain information from Relying Sites regarding local variations in study conduct, such as updated recruitment materials and process, required institutional consent language and process, and state and local law variances. Each Relying Site needs to be submitted individually and will be "approved" separately. This is accomplished via the 'Reliance on BCH' activity within the approved protocol submission in CHERP.

- You are responsible for developing specific roles and responsibilities for communicating and coordinating key information to Relying Sites; this includes developing a plan for communicating with collaborators across the lifetime

of the study (i.e. regular conference calls, site initiation procedures and training materials, updated protocols, web based systems).

- You need to provide Relying Site study teams with the BCH IRB policies. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints. [BCH IRB Guidelines and Policies](#)
- You will need to promptly respond to questions or requests for information from Relying sites and IRB/Human Research Protection Program (HRPP) personnel at institutions that are relying on the BCH IRB. This may require that you refer these questions to the BCH reliance specialist on behalf of the relying site.
- You will need to prepare and submit IRB materials on behalf of all Relying Sites that include local amendments, local reportable events, and study-wide information for continuing review.
- You will need to notify Relying Sites of all BCH IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
- When necessary and agreed upon in coordination with the BCH IRB, you will need to promptly report to the Relying Site any unanticipated problems involving risks to subjects or others, research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research at the Relying Site.
- You will need to providing access, upon request, to study records for audit by the Relying Institution, the BCH IRB, and other regulatory or monitoring entities.
- You will need to follow all requirements of the BCH Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.