Purpose of the form: The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution(s) and intend to use a single IRB for oversight of this study:

- ☐ You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:
  - ⇢ Discuss whether your home institution's IRB can act as the single IRB for all or some institutions participating in this study or whether another external IRB would be appropriate.
  - ⇢ Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
  - ⇢ Provide them with details about the study, including the studywide protocol and template consent document(s), which will help facilitate the discussion with your local IRB/HRPP.
  - ⇢ Identify all sites that will be engaged in human subjects' research and thus need IRB coverage.
- ☐ If your institution agrees to single IRB for the study, you will need to ensure the Lead Study Team:
  - ☐ Provides a reliance request to the Overall PI's home institution using the process required by that institution.
  - ☐ Works in collaboration with the Reviewing IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; 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).
  - ☐ Promptly responds to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.
  - ☐ Participates in meetings regarding a study as requested by the Reviewing IRB, Relying Site Study Team, or home institution.
  - ☐ Provides the Site Investigators with the IRB policies of the Reviewing IRB. This includes, but is not limited to, providing the Site Investigators with the IRB policies applicable to the study for reporting unanticipated problems, noncompliance, and subject complaints.
  - ☐ Provides participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).

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- ☐ Prepares and submits IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and studywide information for continuing review.
  - ☐ As part of preparing the IRB application, the Lead Study Team (or designee) must
    - ⇢ Have a mechanism in place to obtain and collate information from Relying Site Study Teams and/or Relying Site Points of Contacts (POCs), depending on who is designated to provide that information at the Relying Institution, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
    - ⇢ Assist Relying Site Study Teams and/or POCs at the Relying Institution(s), depending on who is designated to provide that information, in ensuring consent documents follow the Reviewing IRB's template form and include applicable site-specific required language from each Relying Institution.
- ☐ Ensure Site Investigators are notified of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events, as applicable.
- ☐ When agreed upon in coordination with the Reviewing IRB, promptly reports to the Site Investigator (or designee on the Relying Site Study Team) 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 (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution.
- ☐ If a Relying Site Study Team does not provide the Lead Study Team (or designee) with the required information before the continuing review application is submitted to the Reviewing IRB, reports the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.
- ☐ Provide access, upon request, to study records for audit by the Relying Institution, the Reviewing IRB, and other regulatory or monitoring entities.
- ☐ Follow all ceded review requirements of the Relying Institution such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.