**NCI CIRB Oversight Questionnaire**

*[The oversight questionnaire is completed by an institution that identifies as not having an internal IRB.]*

**Institution Name and (CTEP Site Code):**

 **Name of Network Group Membership:** *[Provide membership status (i.e., Main Member, Affiliate Member) Provide the name of Main Member and their CTEP Site Code if your institution is an Affiliate Member.] You must be on a Network Group Membership roster in order to enroll with the CIRB.*

**Person Responsible for Oversight of the Conduct of Research (Department, Name and Title):** *[This person cannot be a Principal Investigator who will open studies with the CIRB or a team member that interacts with study participants. Please describe how this person oversees the conduct of research in question #2.]*

**Oversight Processes:** IDENTIFY INSTITUTION-SPECIFIC PROCEDURES FOR HOW THE FOLLOWING ARE MET *[Provide policies, SOPs, organization chart or other supporting documents that will support your responses.]*

1. **Describe the process for ensuring the initial and ongoing qualifications of the investigators and research staff. *[****Items that address this question include standard operating procedures that detail the process, forms that are required within the institution to document qualifications, or the name of a system at the institution where this information is maintained. Specify what actions the responsible person or designee takes to ensure these processes are followed.]*
2. **Describe the processes and/or procedures used for oversight of the conduct of research at your institution (include your Component and/or Affiliate institutions as applicable). Specify what actions the responsible person or designee takes to ensure these processes are followed.** *[Note: The processes and/or procedures would include:  what studies are open; how many study participants are enrolled at the institution; knowing when an investigator is being audited and the outcome of the external audit; and determining when the study is completed.
This is generally achieved through different communication pathways, including regular meetings, ad hoc meetings, and reports provided to the responsible person or designee. ]*
3. **Describe the processes and/or procedures used to monitor protocol compliance. Specify what actions the responsible person or designee takes to ensure these processes are followed.** *[The monitoring process usually includes, but is not limited to:
 ensuring the correct consent forms are used,  enrolled study participants meet the eligibility criteria, study procedures are conducted per protocol, and  study agent is administered per protocol.
It should also address the frequency of internal audits which should occur at least annually.]*
4. **Describe the methods used to identify any changes to state, local, or institutional requirements and/or regulations related to the protection of human subjects. Identify how changes are communicated to the investigators and research staff.**  *[Note: This response should focus on institutional policy and not study protocols.]*
5. **Describe the mechanism to receive and address concerns from local study participants, members of the research team, and others about the conduct of the research which include complaints or concerns regarding the investigators and/or research study team. Specify what actions the responsible person or designee takes to ensure these complaints or concerns are addressed and resolved.**