GUIDELINE FOR LISTING STUDY TEAM MEMBERS ON A STUDY APPLICATION

The following information is intended to provide guidance for Investigators to determine which study team members should be added to a study application in the online review system.

1. Study Team Members – Definition

For purposes of the application, *study team members* are individuals who:

a) interact with human subjects (e.g., informed consent process, manipulating subject’s environment for research purposes, conduct invasive or non-invasive research procedures),

b) are involved with collecting, reporting or analyzing identifiable subject data,

c) function outside of regular work practice (e.g., student administering research testing), or

d) are faculty advisors providing direct oversight of research involving human subjects, or human subjects’ private information.

If an individual is functioning within his or her regular work practice (e.g., phlebotomist, x-ray technician) and involvement in the research is limited to only those work responsibilities without further contribution to the research, then such individuals do not need to be listed on the application. However, it is appropriate to describe their involvement in the protocol.

*Note: Funding agencies may have their own definition of study team members (i.e., “key personnel”) as it applies to grant or other funding applications.*

2. Whom to Include on the Application

a) Individuals with the following roles must be included:
   - Principal Investigator
   - Co-Principal Investigator
   - Sub-investigator
   - Study Coordinator

b) Individuals who meet the definition of *study team members* as stated above, for example:
   - Staff obtaining consent for research participation
   - Staff collecting, reporting or analyzing identifiable subject data
   - Faculty advisors with direct oversight of the research

c) Individuals listed on a study plan, grant or budget who will have subject contact and/or access to identifiable subject data.
3. **Listing External Unaffiliated Staff**

Whether to list study team members or collaborators not affiliated with the University depends on if there is another IRB serving as the Reviewing IRB for these individuals.

- Do not list external study team members who will receive IRB approval from their own IRB as the Reviewing IRB. Involvement of these individuals should instead be described in the study protocol, as well as the consent if applicable.
- Do not list external study team members who are not engaged in human subject research (e.g., handing out recruitment brochures or flyers at an external facility, providing prospective subjects with information about contacting the Investigator or study team). Involvement of these individuals should instead be described in the study protocol, as well as the consent if applicable.
- When the RSRB will serve as the Reviewing IRB for an external site(s), the process outlined in the *Guideline and Flow Charts When the University of Rochester is the Reviewing IRB* should be followed.
  - The protocol should indicate that RSRB will be the Reviewing IRB for sites.
  - The application should indicate that this is multi-site study and that the RSRB will act as the single IRB of Record for other participating sites.
  - Once the study is approved, participating sites and site PIs will be added to the online review system application by the RSRB.
- In the rare instances where External team members are listed in the online review system application, documentation of human subjects training must be uploaded.
  - See the “Add External Study Team Members” in the [Click IRB Study Staff Manual](#) for additional information.

4. **Training Requirements**

All study team members are required to complete human subjects protection training. Study team members listed in the application at the time of continuing review must have current training certification. Addition of new study team members will only be approved if the proposed individual(s) has completed the required training. See [Policy 201 Education Program](#) for more information regarding training requirements.