GUIDELINE FOR REVIEW OF EXTERNAL (NON-UR) INVESTIGATORS

Consistent with Policy 504 IRB Reliance and Collaborative Research, there are requirements when University of Rochester (UR) researchers collaborate with an unaffiliated institution(s) or Investigator(s) to ensure UR ethical, regulatory, and institutional requirements for the protection of human subjects are met. That policy outlines the requirements when a collaborating non-UR individual is part of an institution; this guidance provides general considerations for adding external non-UR investigators when the individual is a sole individual not affiliated with an institution. Additional information regarding the process for reviewing investigators and study team members affiliated with an institution can be found in Policy 504. External individuals who have a **UR sponsored Active Directory account (guest account)** may be required to follow the requirements outlined in this guideline.

Each request will be evaluated using a step-wise approach:

1. **Determine Engagement in Human Subject Research**: Only external investigators engaged in human subject research must be added to the study application per the federal regulatory definition. To determine engagement and evaluate the scope of work for each external investigator, refer to the Identifying Study Team Members in RSRB (IRB) Submissions for additional information.
    a. If the individual is not engaged, ensure the protocol describes the activities this individual will be doing consistent with the scope of work. Additional documentation may be needed (e.g., sharing de-identified data may require a data use agreement (DUA).
    b. If the individual is engaged, continue to step 2.

Note: The following steps will depend on the review level of the study and funding source.

2. **If Study Activities Qualify for Exempt Review:**
   Note: The IRB Specialist will determine the required review level for the study; additional information can be found in the Guideline For Exempt Status Determination.
    a. **Protocol –** Describe the scope of work in the protocol for each external investigator and include how the Principal Investigator (PI) will oversee these activities.

    b. **Department Approval** - Provide *written* documentation from department leadership outlining the department's approval for the external investigator to conduct research activities under the PI's oversight. Upload to the Local Site Documents section, Q3, Other Attachments of the application.

c. **Human Subject Protection (HSP) Training –** Each external investigator must have HSP training consistent with the *External Collaborators and Unaffiliated Researchers* section of Policy 201 Research Education & Training. Also, refer to HSP Training for External Research Personnel.

   Consistent with Policy 901 Investigator Responsibilities, it is the responsibility of the PI to oversee the conduct of all research activities, including the training and education of all study staff.

d. **Include individuals in the IRB Application –** Each individual should be added to the Local Study Team Members section of the IRB application under Question 2: External Team Member Information. See the Click IRB Study Staff Guide for additional information. Additionally, the documentation of completed human subject protection training is to be uploaded in this section.

3. If Study Activities are <u>NOT</u> Exempt, and the Study is <u>NOT</u> Federally Funded.

a. **Protocol -** Describe the scope of work in the protocol for each external investigator and include how the PI will oversee these activities. Refer to the Guideline for Principal Investigator Oversight For Multi-Site Research (RSRB is the Reviewing IRB). Upload the PI Oversight plan in the Local Site Documents section, Q3, Other Attachments of the application.

b. **External Investigator Attestation of Responsibilities** – Depending upon the risk of the study or the determination of the IRB Reviewer/Convened Board, an External Investigator Attestation of Responsibilities may be required. This document outlines the regulatory responsibilities the investigator must follow and will be signed by the external Investigator, the PI, and the Department. If this documentation is required, additional Department Approval is not required. The attestation will be uploaded in the Local Site Documents section, Q3, Other Attachments, in the application.

c. **Department Approval** - Provide ***<u>written</u>*** documentation from department leadership outlining the department's approval for the external investigator to conduct research activities under the PI's oversight. Note: This additional documentation is not required if an External Investigator Attestation of Responsibilities is required.

d. **Human Subject Protection (HSP) Training –** Each external investigator must have HSP training consistent with the *External Collaborators and Unaffiliated Researchers* section of Policy 201 Research Education & Training. Also, refer to HSP Training for External Research Personnel.

Consistent with Policy 901 Investigator Responsibilities, it is the responsibility of the PI to oversee the conduct of all research activities, including the training and education of all study staff.

e. **Include individuals in the IRB Application –** Each external individual should be added to the Local Study Team Members section of the IRB application under Question 2: *External Team Member Information.* See the Click IRB Study Staff Guide for additional information. Also, the documentation of completed human subject protection training will be uploaded in this section.
    i. When the scope of work requires the external investigator to hold professional certifications or meet specific educational requirements, a curriculum vitae (CV) should be uploaded to the application in the External Team Member Information section.

4. **If Study Activities are <u>NOT</u> Exempt and the Study is <u>Federally Funded</u>**.
Refer to Policy 504 IRB Reliance and Collaborative Research and associated Guideline and Flow Charts When the University of Rochester is the Reviewing IRB for further information and instructions on the process for reviewing when a collaborating non-UR individual is part of an institution. A similar process may be used for a collaborating non-UR individual who is **<u>not</u>** part of an institution.
    a. **Protocol -** Describe the scope of work in the protocol for each external investigator and include how the PI will oversee these activities. Refer to the Guideline for Principal Investigator Oversight For Multi-Site Research (RSRB is the Reviewing IRB). Upload the PI Oversight plan to Q3, Other Attachments, in the Local Site Documents section of the application.

    b. **Federalwide Assurance (FWA) or <u>Individual Investigator Agreement</u> (IIA) Required** – In most cases, the external investigator will be required to obtain their own Federalwide Assurance from the Office for Human Research Protections (OHRP). When submitting the FWA, the external investigator will be required to name a Human Protections Administrator and an Institutional Official. Since this is a sole external investigator not affiliated with an institution, the external investigator will likely name themselves in both positions. Approved FWAs can be found in the OHRP Assurance database. Once the external investigator has received the FWA from OHRP, please upload it to the Local Site Documents section Q3, Other Attachments in the application.

    c. **Department Approval** - Provide ***<u>written</u>*** documentation from department leadership outlining the department's approval for the external investigator to conduct research

activities under the PI's oversight. The Department's approval will be uploaded to Q3, Other Attachments, in the Local Site Document section of the application.

d. **Human Subject Protection (HSP) Training –** Each external investigator must have HSP training consistent with the *External Collaborators and Unaffiliated Researchers* section of Policy 201 Research Education & Training. Also, refer to HSP Training for External Research Personnel. Upload their proof of training to the External Study Team Member Q2 section of the Local Study Team in the application. The documentation of completed human subject protection training will be uploaded in this section.

   Consistent with Policy 901 Investigator Responsibilities, it is the responsibility of the PI to oversee the conduct of all research activities, including the training and education of all study staff.

e. **Include individuals in the IRB Application –** The method for including the investigator in the IRB application may vary; however, in most cases:
   i. When the scope of work requires the investigator to hold professional certifications or meet specific educational requirements, a curriculum vitae (CV) should be uploaded to the application in the External Team Member Information section.

   ii. The RSRB application will be updated to reflect a multi-site/collaborative approach (Q4 - Basic Study Information), with an External IRB designation of 'no' (Q5 - Basic Study Information), and the UR will be designated as the Reviewing IRB (Q6 - Basic Study Information). See the Click IRB Study Staff Guide for additional information.

   iii. The RSRB will require an Institutional Authorization Agreement (IAA), also known as a Reliance Agreement, to be executed. This agreement will describe the external collaborator as the Relying Institution. For further assistance, contact the appropriate RSRB specialist or UR_IRB_Reliance@urmc.rochester.edu . The fully executed reliance agreement will be uploaded to the Local Site Documents section, Q3, Other Attachments, in the application.