UNIVERSITY of ROCHESTER

GUIDELINE FOR PRINCIPAL INVESTIGATOR OVERSIGHT FOR MULTI-SITE RESEARCH *(RSRB is the Reviewing IRB)*

The University of Rochester Principal Investigator (UR PI) must provide oversight for all research and research-related activities performed at relying site, or participating sites (pSites) when the UR is the Reviewing IRB. This guideline reviews the topics and information that should be included in the plan and provides a template when creating a PI Oversight plan for multi-site research. While the information below focuses on research where the RSRB is the Reviewing IRB for non-UR sites, these can be adapted for any type of oversight plan.

The following research activities will occur at the participating site (pSite): ***[Insert all research activities: e.g., recruitment, consent, intervention, interview/survey, data sharing, etc. If activities are different across sites, document what may be different, e.g. one site is just getting data.]***

The UR PI will be responsible for the following:

A. Communication: The UR PI will notify the Site PI/study team of the RSRB site approval and provide site approval letter(s) as well as copies of the most current versions of the approved study materials via ***[insert types of communication, e.g., email, shared box account, etc.]*** The UR PI is responsible throughout the course of the study to provide all modified documents and IRB approval letters to the pSite(s).

B. Supervision of study activities at the site: The UR PI will conduct regular meetings with the site PI/study team to review study activities. Meetings will occur ***[insert frequency: e.g., bi-weekly***] by zoom, telephone or in person (when possible). During the meeting, the UR PI will troubleshoot study-related issues, answer study-related questions, and provide verbal/written direction for all study activities. Meetings will be documented via ***[insert type of documentation: e.g., meeting log, meeting minutes in the regulatory binder].***

C. Training: The UR PI will ensure that all study personnel have completed required institution-specific and protocol-specific trainings and that these trainings are documented appropriately via ***[insert type of documentation: e.g., training log].*** While training should be completed and documented in real time, the UR PI will verify that all training is current and appropriately documented on a ***[insert frequency: e.g., quarterly basis]***. When study personnel are added/removed, the UR PI will ensure the pSite submits these changes to their local IRB for institutional review and approval. If applicable, these changes will be appropriately documented on the Delegation of Responsibilities Log.

D. Reporting**:** The UR PI will submit required information for reporting, progress reports, reportable events, non-compliance, ***[insert any other required documentation, e.g., Data and Safety Monitoring reports]*** and provide the site with any RSRB determinations regarding the submitted reports.

E. Site Files and Documentation:

- Regulatory File: As per Policy 901 Investigator Responsibilities, all sites will maintain a regulatory file with current and accurate records of all study documentation as required by applicable regulatory requirements (see OHSP-QI Study Documentation Tool Box for regulatory file guidance). The UR Investigator's regulatory file must contain all versions of the approved protocol, watermarked consent forms, recruitment materials, all IRB approval letters, and other IRB communication. Each pSite must maintain their site-specific approval documents, including all versions of the approved protocol, watermarked consent forms, recruitment materials, all IRB approval letters, and other IRB communication. When documents are updated, change the footer date before sending it to RSRB and mark the older versions as 'superseded' with the new version noted. The regulatory file can be kept in a paper file or electronically on a shared drive.

- Subject Research Charts: All pSites must maintain a file for each subject, which includes at a minimum the consent (as applicable) and associated data. If signed consent is obtained, the signed, original consent form including all pages must be maintained for each subject.

F. Quality Improvement (QI) and Compliance: As part of its responsibilities under the University of Rochester's Human Subject Protection Program, the Office for Human Subject Protection (OHSP) has a QI program, which offers services to the University of Rochester PI, consistent Policy 1001 Quality Improvement Program. The following services are provided:
   a. Study Start Up Consultations: Assessment of documentation to assist Investigators and study staff in their ability to achieve compliance with the regulations, policies, and guidelines applicable to their specific study.
   b. Quality Improvement Reviews: Assessment of compliance with applicable regulations and requirements for ongoing research. Site file content expectations are outlined here and self-audit tools are available here.
   c. Quality Improvement Management Plan Program: Provides resources to encourage, guide, integrate, and enhance continuous quality improvement for a research site, program, or department/division, prioritizing areas of potential risk. Additional information and a program guide is available here.

Appendix A: Oversight Plan for Multi-Site Research (UR Principal Investigator Responsibilities)

When the RSRB will be the Reviewing IRB for non-UR sites, the UR Principal Investigator (PI) must provide a plan to oversee the research conducted at these participating sites (pSites). This plan will, at a minimum:
1) Outline the specific research activities that will occur at the site(s)
2) Outline the training plan in place to provide protocol based education to non-UR sites
and
3) Document how the UR PI will ensure study and regulatory compliance, including notification to the non-UR researchers of RSRB review determinations (e.g. initial approval, modifications, continuing review).
This plan will be included in the protocol and approved by the RSRB as part of the initial approval.

The UR Principal Investigator is responsible for the following:

		Start Up	During Study	Study Close
A	**Communication with All Sites**	Site approval, which includes ensuring each site obtains institutional review for the study.	All associated RSRB-approved items (approval letters, modified documents)	Provide RSRB Acknowledgement of Closure
		Notify the non-UR site(s) of review determinations	Notify the non-UR site(s) of review determinations (modifications, annual review, if applicable)	
B	**Supervision of study activities at each site**	Conduct an initial meeting to clarify expectations of site(s) including communication, documentation expectations, and frequency of meetings*	Conduct regular meetings* with the site PI/study team to review study activities	Provide written guidance and expectations regarding study closure and research records storage
		Note: *All meetings should be documented, including discussion topics, resolutions/changes, date held, and attendance.		
C	**Training**	UR PI will ensure that all study personnel have completed required institution-specific and protocol-specific trainings. Minimal training requirements include the review of Policy 901 Investigator Responsibilities and Policy 801 Reporting Research Events.	Ensure training is current and appropriately documented as per agreement (i.e. quarterly)	
D	**Reporting**		Submit required documentation to the RSRB for reporting, progress reports, reportable events, non-compliance. As applicable, submit reports to regulatory agencies.	Submit required documentation to the RSRB for study closure. As applicable, submit reports to regulatory agencies.
		Start Up	**During Study**	**Study Close**

E	**Site Files and Documentation**	Provide expectations of regulatory files and subject research charts contents and maintenance too the non-UR site(s). Note: Supporting documents are in the OHSP-QI Toolbox.	Ensure maintenance of regulatory files and subject research charts	Complete regulatory file and close subject research charts. Store all study-related materials consistent with IRB-approved protocol, contractual agreements, and institutional policy.
		Provide IRB-approved and associated documents (protocol, consent forms, recruitment items)	Provide modified documents (protocol, consent forms, recruitment items)	Provide study closure documents, as applicable
F	**Quality Improvement and Compliance**	Consider utilizing OHSP Study Start Up Program.	Conduct monitoring of research activities at non-UR site(s), in addition to or in collaboration with the RSRB and OHSP. This could take the form of actual remote or in-person monitoring by the PI's study team or could be self-auditing performed by the Relying site.	
		Consider utilizing OHSP Quality Management Plan Program.	Consider requesting a QI review from OHSP-QI.	

Appendix B: Oversight Plan for Multi-Site Research Guideline (Relying Site Responsibilities)

The Relying Site (pSite) Investigator is responsible for the following:

		Start Up	During Study	Study Close
A	**Communication**	Provide the contact person and contact information for the IRB	Notify the UR-PI of all unexpected events/ issues of non-compliance in a timely manner	Provide UR-PI final, verified data and closure information
B	**Supervision of study activities at site**	Hold an initial local meeting to clarify expectations of site(s) including communication, documentation, and frequency of meetings*	Conduct regular meetings* with the study team(s) to review study activities	Follow written guidance and expectations regarding study closure and research records storage
		Note: *All meetings are expected to be documented, including discussion topics, resolutions/changes, and attendance		
C	**Training**	Ensure study personnel have completed required institution-specific and protocol-specific trainings	Ensure training is current and appropriately documented as per agreement (i.e. quarterly)	
		Establish other minimal training requirements, as applicable	Ensure participation in associated trainings	
D	**Institutional Review**	Ensure the non-UR site provide institutional review, as needed for the study (e.g. COI, Compensation for Injury, Educational requirements, Ancillary review)	Ensure institutional review, as needed, for modifications to the study (e.g. Changes in site study team members, additional ancillary reviews, changes in COI. and Compensation for Injury)	
E	**Reporting**		Submit required information to the UR PI for RSRB reporting, progress reports, reportable events, non-compliance in a timely manner	
F	**Site Files and Documentation**	Initiate a regulatory file with IRB-approved documents (protocol, consent forms, recruitment items) and subject research charts	Maintain regulatory files and subject research charts	Complete regulatory files and closure of subject research charts. Store all study-related materials for the IRB-approved time period. Destroy study files consistent with the protocol and institutional policy.
G	**Quality Improvement and Compliance**		Conduct monitoring of research activities or could be self-auditing performed by the Relying site.	