UNIVERSITY of ROCHESTER

Guideline for Single IRB Plan in an NIH Grant Application

Beginning on January 25th 2018, NIH requires multi-site grant applications to include a plan for the use of a single IRB (sIRB). For details, see Section 3.2 of the PHS Human Subjects and Clinical Trials Information Form Application Guide. The information in this guideline is drawn from the NIH FAQs on the Single IRB Policy for Multi-site Research and the PHA Application Guide.

New "FORMS-E"

A new Human Subjects and Clinical Trial Information form called FORMS-E must be included in grant application packages and contracts for all human subjects and/or clinical trial research applications submitted on or after January 25, 2018. This new form is a "smart" (i.e., branching) webform that consolidates all human subjects and clinical trial-related information into one place, and also expands the information required for studies that meet the NIH definition of a clinical trial.

The sIRB plan is uploaded as an attachment to Question 3.2 of the new FORMS-E. FORMS-E application instructions *are available from NIH on the* How to Apply – Application Guide *website.*

Grant Application

See template language below in Appendix 1, for the following:

- Describe how you will comply with the NIH Single IRB (sIRB) policy. If you are requesting an exception for some or all participating sites, follow the NIH Guidance on Exceptions.
- Provide the name of the IRB that will serve as the sIRB.
- Indicate all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
    - Indicate which sites are included in SMART IRB. Check to see which sites are currently participating.
    - If a participating site is not included in SMART IRB, indicate that they will be requested to join SMART IRB. If they do not join SMART IRB, include language that prior to initiating the study, these sites will sign an Authorization/Reliance Agreement that will clarify roles and responsibilities.

The following information is not included in the template language and will be specific to each study on how the UR PI will oversee the conduct of the research:

- Briefly describe how the UR site will oversee the research activities conducted at the non-UR sites. See Policy 504 IRB Reliance and Collaborative Research and Policy 901 Investigator Responsibilities for further information about creating an oversight plan. Ensure that the plan includes how communication will occur between sites. Additional resources are available on the SMART IRB website under Resources.
- Indicate which institution or entity will maintain records of the Authorization/Reliance agreements and of the communication plan.

Delayed-onset Multi-site Research
Delayed onset refers to NIH applications that are submitted with the intent to conduct human subject research during the period of support; however, definitive plans could not be described in the grant application. If the delayed-onset research is likely to involve multiple sites, the delayed onset justification attachment must:

- Include information about how the study will comply with the sIRB policy, and
- State that a sIRB plan will be provided prior to initiating the study.

FORMS-E has specific questions for delayed-onset studies. The sIRB plan should be uploaded with the answers to those questions.

Letters of Support

- **From the single IRB -** NIH does not specifically require a Letter of Support from the single IRB indicating its willingness to serve as the sIRB, but it is good practice, especially if the sIRB is not the RSRB.
- **From participating sites -** NIH does not require any specific supporting documents, but it states that the sites should agree to a sIRB arrangement prior to the grant submission, and "the applicant should indicate the participating sites willingness to rely on the selected single IRB". A letter of support from each participating site is the standard way to accomplish this. See Appendix 2 for a template letter of support for participating sites and instructions for completion.

Note: Formal, written and signed IRB Reliance Agreements are not required to be in place prior to receiving NIH funding.

Budget

Section 7.0 of the Frequently Asked Questions includes information about costing for sIRB and there are 12 scenarios related to budgeting for the sIRB provided by the NIH. The University of Rochester has developed an initial costing model to be used by Investigators to plan for sIRB costs when the UR RSRB is serving as sIRB. All study teams are required to meet with OHSP staff prior to submission of any federally funded grants involving multi-site human subject research to review the costing model to ensure that grants are budgeted appropriately. See RSRB Fees Structure page for additional information. Please contact OHSP Staff well in advance of your submission date to schedule this meeting,

Additional information can be found in the OHSP seminar held on April 20th 2017 entitled "Preparing Single IRB Grant Submissions Utilizing the RSRB as the Reviewing IRB"

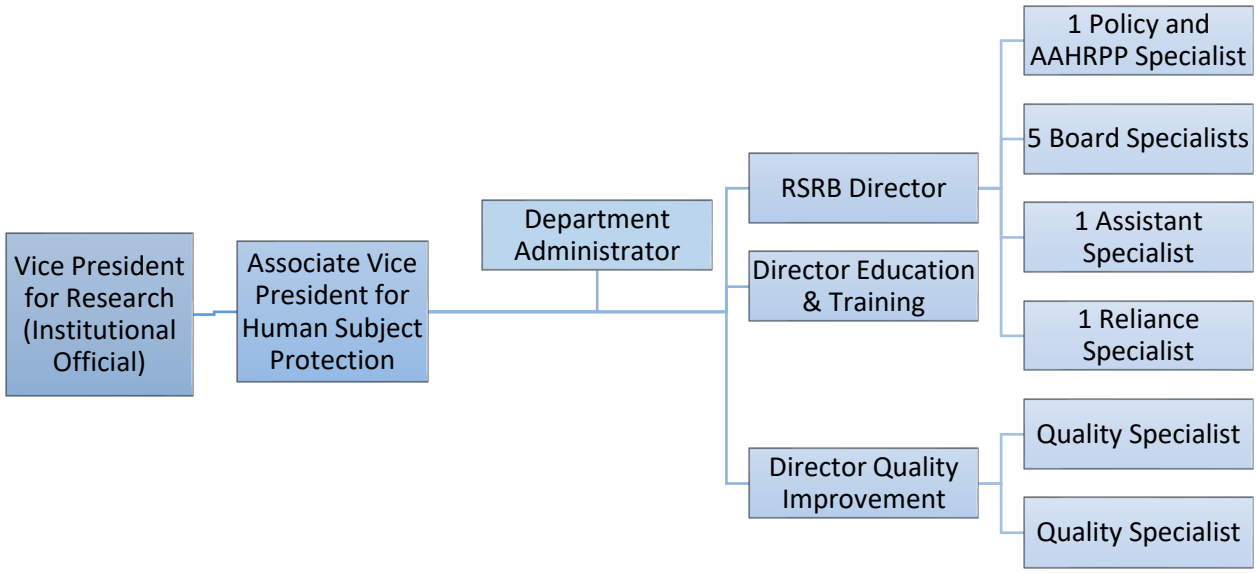
Appendix 1 – Template Language for Grant Applications When the RSRB Will Serve as the Reviewing IRB for Multi-site Research

Single IRB

To maximize efficiency and consistency across participating sites, we will utilize a single IRB (sIRB) to streamline the IRB review and approval of the research. The University of Rochester Research Subject Review Board will act as the sIRB for all sites. The Research Subjects Review Board (RSRB), which serves as the University of Rochester's (UR) institutional review board, is part of the Office for Human Subject Protection. The Office for Human Subject Protection (OHSP) oversees the University's Human Research Protection Program (HRPP) to promote compliance with regulatory and ethical guidelines to protect human research subjects. The Vice Provost for Research, Richard Waugh, is the Institutional Official (IO) for the University's Federalwide Assurance (FWA00009386). The day-to-day direction of the HRPP is delegated to the Associate Vice President for Human Subject Research, who reports directly to the IO. The University of Rochester's HRPP has been accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since July of 2007, with current accreditation to expire in December of 2025.

The Office for Human Subject Protection is made up of three specific divisions:

1. Research Education & Training - provides educational opportunities and resources in research ethics and human subject safety, with an emphasis on proper and responsible conduct of human subject research.
2. Research Subjects Review Board (RSRB) – reviews research to determine that the rights and welfare of the human subjects are adequately protected. The RSRB is guided by the ethical principles described in the Belmont Report and by the regulations of the U.S. Food and Drug Administration (21 CFR 50 and 56) and the U.S. Department of Health and Human Services (45 CFR 46). The RSRB is managed by the Director and includes five institutional review boards (RSRBs). Each of the five RSRBs is chaired by a senior UR faculty member and staffed by a dedicated specialist, who reports to the RSRB Director. The RSRB office also includes a Senior Specialist who oversees policies and AAHRPP accreditation, an Assistant Specialist who manages Exempt Research requests, a Reliance Specialist who manages Reliance Agreements and oversees the Reliance Process, and office support staff.
3. Quality Improvement – conducts routine and directed quality improvement reviews of active research to evaluate compliance with ethical principles, IRB approved protocols, applicable federal and state regulations, UR policies and guidelines, and OHSP policies and guidelines.



Reliance Agreements: Whenever possible, the University of Rochester will utilize SMART IRB to document reliance among all participating sites. SMART IRB is a national IRB Reliance Agreement that contains many features to aid in the acceptance, coordination, and implementation of a single IRB review model in a highly cost effective manner. SMART IRB is open to any US institution with an FWA and there is no cost associated with joining. Currently, there are several hundred Participating Institutions. XX of the participating sites have already signed on to SMART IRB, and the remaining XX, which are not already members of SMART IRB, will be encouraged to join for the purposes of ceding IRB review to the University of Rochester RSRB. For those who are not part of SMART IRB, Reliance Agreements will be executed.

Informatics Platform: The University of Rochester has utilized the Huron Research Suite (formerly Click), a web-based IRB review solution, for more than 10 years. The University of Rochester Huron IRB solution offers support for multiple study models, including single-site studies and multi-site studies. This platform enables:

- RSRB Specialists to create profiles for participating sites to manage relationships and track authorization agreement status, communication plans, accreditation status, and points of contact.
- Full support for the sIRB model and entry of participating site (pSite), and will maintain regulatory compliance with the NIH Final Policy on the use of a single IRB of record for

multi-site research. The software has built-in integration with the Huron IRB Exchange, a cloud-based subscription service that facilitates the exchange of data between a sIRB and pSites in multi-site and collaborative research. The structure of the Huron IRB Solution allows for pSite IRB regulatory documentation to be entered by the primary UR site or, if the pSite has the supporting technologic software (Huron or integration with Huron IRB Exchange), for the pSite to utilize their own IRB software to enter directly into the UR platform. The use of this software will significantly reduce the administrative burden and staff time required to maintain multi-site studies.

Support and Coordination for Multi-site Research: A critical element of single IRB review is study coordination across all participating sites and ensuring investigators and study teams understand their responsibilities. A single IRB review does not mean only one IRB is involved in the approval of the study, nor does it mean that investigators only report and submit to a single IRB. The University of Rochester's RSRB follows OHSP Policy 504 IRB Reliance and Collaborative Research and Guideline and Flow Charts When University of Rochester is the Reviewing IRB to document the requirements and procedures for serving as the sIRB. Each institution and site investigator retains responsibility for the conduct of research at their site. As such, investigators at relying sites must provide relevant information to their local IRB for institutional review. Institutional review of each site's local requirements (e.g., human subject training requirements, conflict of interest, and consent forms to ensure locally required language is included for compensation for injury, conflict of interest, etc.) and "non-IRB" institutional reviews by ancillary committees (e.g., institutional biosafety, radiation safety) must be performed by each institution, as applicable.

Appendix 2 – Participating Site Letter of Support

Instructions

- Insert the indicated information in the template below, send to non-UR Investigator(s).
- The non-UR investigator(s) provide it to the appropriate office at their institutions, for review and signature on their institutional letterhead. *For institutions with an IRB*: The IRB office should sign it. *For institutions without an IRB*: The letter should be signed by a compliance office or other person with authority to sign on behalf of the institution.
- The non-UR investigator provides a scanned copy for the grant application.

Date

Name of Participating Site PI
Title
Department / Division
Institution

RFA Number and Title

Dear [INSERT NAME OF PARTICIPATING SITE PI],

I am pleased to write this letter in strong support of a grant application proposing that [INSERT NAME OF INSTITUTION] will become one of the participating sites for [CHOOSE ONE: a multi-site human subjects study OR a research network/consortium] called [INSERT NAME OR TITLE] that will [INSERT BRIEF DESCRIPTION]. The research will be led by [INSERT NAME OF UW PI] at the University of Rochester.

Reliance upon a single IRB. This letter confirms the willingness of [INSERT NAME OF PARTICIPATING INSTITUTION] to rely on another IRB for the review of your activities. [CHOOSE ONE: I understand that [INSERT THE NAME OF THE IRB] is likely to serve as the single IRB for this research, and we are willing to rely upon their review. OR I understand that the single IRB will be identified later by NIH and the lead PI]. INCLUDE IF APPROPRIATE: [INSERT NAME OF PARTICIPATING INSTITUTION] is already a member of the SMART IRB and agree to utilize that system to track reliance for the conduct of this research.

Sincerely,