**Single IRB Plan**

**The Ohio State University as Lead Site and sIRB**

**Project Title: [Insert]**

**1. Statement of Compliance with NIH sIRB policy:**

In accordance with the NIH Policy on the Use of sIRB for Multi-site Research, a single IRB will provide IRB review under 45 CFR 46 of all human subjects’ research at all collaborating sites.

**2. Name of the IRB that will serve as the sIRB of record**

The Ohio State University will serve as the sIRB of record

**3. Participating sites agreement to rely on the proposed sIRB**

All sites agree to rely on the Ohio State University IRB as the sIRB. If any additional sites are added after the award, they will also rely on the sIRB.

**4. Communication between sites and the sIRB**

Definitions

* **REVIEWING IRB**: Responsible for addressing questions related to the Reviewing IRB’s policies and procedures and review status for a ceded study
* **LEAD STUDY TEAM – POC:** Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
* **RELYING SITE – POC:** Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel).
* **RELYING SITE STUDY TEAM POC:** Main person responsible for communication with the Lead Study Team regarding the ceded study

Communication Responsibilities are as follows:

# Lead Study Team POC Responsibilities:

The Lead Study Team will be the primary POC for communication to and from the Reviewing IRB. Site-specific information from the relying sites will be provided to the lead study team and then submitted to the Reviewing IRB. All communication from the Reviewing IRB will flow from the Reviewing IRB to the Lead Study Team POC to the Relying Study Team POC. This includes (but is not limited to) the following:

* + Preparing and submitting the study-wide application for initial IRB review and study- wide amendments to the Reviewing IRB
	+ Preparing and submitting the site-specific applications and site-specific amendments to the Reviewing IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements (if applicable), subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research
	+ Providing documentation of IRB determinations to relying site study teams
	+ Providing copies of IRB-approved materials to the lead study team
	+ Providing copies of the most current versions of IRB-approved materials to relying site study teams in a timely manner
	+ Providing the consent form template to relying site study teams
	+ Providing relevant Reviewing IRB policies to the study teams
	+ Obtaining and collating study-wide information for continuing review to the Reviewing IRB
	+ Submitting continuing review progress report to the Reviewing IRB
	+ Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints)
	+ Providing the Reviewing IRB with required information when a study is closed.

# Relying Study Team POC Responsibilities:

Relying Study Team POC will be responsible for communicating with the Relying Site POC for:

* + Site-specific research applications (if any)
	+ Obtaining site-specific approvals (if any)

# Relying Site POC Responsibilities:

The following information will be communicated to the Reviewing IRB from the Relying IRB:

* + Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study,
	+ Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research,
	+ Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB
	+ Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB

**5. Requirement to sign an authorization/reliance agreement which clarifies the roles and responsibilities of the sIRB and participating sites prior to initiating the study**

Each site will sign an IRB Authorization Agreement, which will outline the roles and responsibilities of the Reviewing IRB (sIRB) and the Relying Sites. As Ohio State University is a participating SMART IRB institution, an additional authorization agreement will not be required with sites who are also participating institutions with SMART IRB.

**6. Institution(s)/entity(ies) responsible for maintaining records of the authorization/reliance agreements and communication plan**

The Reviewing IRB and the Relying Sites will maintain records of the signed IRB Authorization Agreements and a copy of the communication plan.