**SMART-IRB SINGLE IRB REVIEW GRANTS LANGUAGE**

This project will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to support single IRB review [in compliance with NIH [Policy on the Use of a Single Institutional Review Board for Multi-Site Research](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html).] Development of the SMART IRB Agreement was funded by the National Center for Advancing Translational Sciences (“NCATS”) at the National Institutes of Health (NIH) to be responsive to and serve as a roadmap for implementing [single IRB review *or* the NIH sIRB policy]. SMART IRB streamlines and advances collaboration by establishing a common IRB authorization agreement and standardizing the roles and responsibilities of all parties involved in the review and conduct of multisite research. Further, the SMART IRB Agreement outlines the responsibilities of all Participating Institutions, the Reviewing IRB, and Relying Institutions, in addition to detailing the communication plan between the Reviewing IRB and Relying Institutions.

[Include one of the following options below.]

[OPTION 1] Each engaged institution has joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement, thus avoiding the need for protracted negotiations about reliance details. [xx] IRB has agreed to serve as Reviewing IRB, and the following Relying Institutions, have agreed to cede review as noted in the letters of support: [list of sites]

[OPTION 2] To date approximately [xx] of the [xx] planned participating sites already have signed onto the SMART IRB Agreement through the joinder process. It is anticipated that all participating sites will be signatories to the SMART IRB Agreement prior to the planned award date.

[OPTION 3] [X, Y and Z] have each joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement. Use of the SMART IRB Agreement helps reduce the need to negotiate between institutions about reliance details. The other participating institutions have been contacted with a request to join SMART IRB as we await notice of award.

The sites have agreed that IRB review, regulatory oversight, and roles and responsibilities of the parties will be governed by the SMART IRB Agreement and the [SMART-IRB Standard Operating Procedures](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjQ5deewNOAAxUIkYkEHdfmB84QFnoECBcQAQ&url=https%3A%2F%2Fsmartirb.org%2Fassets%2Ffiles%2FSMART_IRB_SOP-090816.pdf&usg=AOvVaw1Lb9EoKKDmtaMkl3GRWZ_P&opi=89978449) throughout the life of the project. In joining SMART IRB, each site has designated a Point of Contact (POC) to provide the Reviewing IRB with knowledge about local context and facilitate coordination among the sites.

In accordance with the SMART IRB Agreement and SOPs:

* [Name] will serve as the Overall PI, and
* [Name], [role] at [lead site], will serve as the primary contact on the Lead Study Team, and will distribute the results of IRB reviews and manage ongoing communications across site study teams.
* The POC for the Reviewing IRB will ensure appropriate communication with Relying Institution POCs.

***Study Team Communication Plan***Study initiation conference calls will include a presentation by the [Overall Principal Investigator *or* identify presenter] to inform all sites about the reliance arrangement as well as the review processes and reporting requirements of the Reviewing IRB. In addition [name or role of person (e.g., coordinating center)] will provide each site with a summary of the Reviewing IRB’s reporting requirements to be distributed to their study teams.

The Lead Study Team will be responsible for ensuring ongoing communication with all participating study teams via teleconferences and regular emails throughout the study. Key communication points will occur to:

* Disseminate IRB determinations and IRB-approved documents
* Educate study teams regarding the approved study and amendments to the study
* Alert study teams to problems that may affect the conduct of the study or the rights and welfare of research participants, such as unanticipated problems and serious noncompliance
* Inform study teams of any changes in study status (e.g., temporary suspensions of recruitment) or new information
* Facilitate submissions to the Reviewing IRB, including:
	+ Inclusion of site-specific requirements in consent documents
	+ Identification of any variability in study implementation across sites that must be communicated to the Reviewing IRB
	+ Collection of information from participating sites to include in continuing review reports to the Reviewing IRB
	+ Site-specific amendments
	+ Personnel updates
	+ Reportable events (e.g., noncompliance, unanticipated problems)
	+ Closure reports
* Ensure revisions to applicable conflict of interest management plans are provided to the Reviewing IRB