Instructions to Request USC IRB to Serve as the Single IRB of Record

To facilitate the conduct of multi-site human subjects research, and to comply with NIH grants policy and federal regulations requiring the use of a Single IRB (sIRB) for review of non-exempt collaborative,multi-site research the USC IRB will serve as the IRB of Record (sIRB) for a maximum of 4 external Relying Sites. USC IRB will serve as the IRB of Record when:

- USC is the prime awardee of an NIH award and sIRB is required
- A federally funded multi-site research study requires Single IRB per the funder (45 CFR 46.114)
- USC holds the IND on an investigator-initiated FDA regulated study on a case-by-case basis

These instructions are provided for the USC investigator who wants to serve as the Overall Investigator for a multi-site study. The PI must contact the USC IRB (irb@usc.edu) and request confirmation that the USC IRB is able to serve as the single IRB of record. Please refer to the Single IRB Workflow (Appendix 1).

The following are the responsibilities of the USC Overall Investigator and Lead Study Team:

1. The USC Lead Study Team is responsible for all submissions to the USC IRB including initial study submission, amendments, continuing review of the research, and reportable events.

2. The USC Lead Study Team will create the reliance agreement for Relying Sites in SMART IRB - this generates an invitation to the Relying Sites. Refer to:

   - How to Create a Reliance Agreement in SMART IRB (Appendix 2)
   - SMART IRB Reliance Checklist (Appendix 12)
   - USC SMART IRB Implementation Checklist (Appendix 3)
   - USC Local Context Form and Implementation Checklist for Relying Site (if needed)(Appendix 4)
   - USC SMART IRB Letter of Acknowledgement (when the SMART IRB platform is not used (Appendix 5)
   - USC SMART IRB Overall PI Checklist (Appendix 6)
   - USC Amendment to Add a Relying Site (Appendix 7)

   (Exceptions will be considered for those sites not participating with SMART IRB)

3. The USC Lead study team is responsible for sharing USC IRB approval letters and approved documents with the Relying Sites.

4. The USC Lead Study team is responsible for communicating with Relying Sites about specific USC HRPP Policies and Procedures applicable to the research. All USC investigators and Lead Study team members should be familiar with the USC OPRS website where the USC HRPP Policies and Procedures can be found.

5. The USC Lead Study team must share the Reportable Events: New Information That Requires Reporting guidance (Appendix 8) with Relying Sites. Any reportable events that occur at USC or one

of the Relying Sites must be submitted to the USC IRB by the USC Lead Study Team, via the iStar system. Relying sites must also submit reportable events per local IRB requirements.

6. At the time of continuing review, the USC Lead Study Team is responsible for collecting study progress information from each Relying Site (e.g., number of subjects enrolled, reportable events) and will submit to the USC IRB one continuing review submission for the entire study. Enrollment numbers across all sites (including USC) should be reported in the USC continuing review application.

Step 1: Submit the Initial Study to the IRB via iStar

1. The USC IRB will review the Initial Study

   The initial iStar submission must include the following documents:

   - The Master Protocol that USC and the Relying Site(s) will follow
   - USC site Master Informed Consent Form and Assent Forms (as needed) – All version dates submitted should be the same. Refer to: Relying Site Specific Consent Template Part 2 (2-part consent – Master and Site Specific) (Appendix 9)
   - Any recruitment documents with version dates (if applicable) Refer to: Template Recruitment (as needed) (Appendix 10)
   - Any other study materials (e.g., data collection sheets, questionnaires, etc. with version dates)
   - USC Overall Principal Investigator's Communication Plan (Appendix 11) *(upload to iStar item 40.1)*

   Note: NAMING CONVENTION

   All documents submitted to the USC IRB should be named as follows:

   Document Name_Version Date_Site Name

   (ABC Protocol_MM/DD/YYYY_UCLA)

2. With the initial study approval the USC IRB will create a USC Master Informed Consent Form (Part I), Site Specific Consents Form (Part 2) and Recruitment template (if applicable) for use by the relying sites

3. Depending upon the nature of the study, the USC IRB may refer the study to the USC Office of General Counsel to determine if a **Letter of Indemnification** (Appendix 12) may be required.

Step Two: Provide and collect necessary documents from the Relying Sites

1. The Lead Study Team will collect from the Relying Site all necessary documents and submit an amendment to add the site (One Relying Site per amendment)(Appendix 7). Do not submit any Relying Site documents via amendment until all of the documents are available and complete for a site. *(Upload to iStar item 40.1 when other options are not provided)*

   The Lead Study Team will distribute and collect as applicable from each Relying Site the:
   - USC SMART IRB Letter of Acknowledgement (provided by the SMART IRB platform if needed)
   - USC IRB Implementation Checklist (Appendix 3)
   - USC Local Context Form and Implementation Checklist (if requested) (Appendix 3 or 4)
   - USC Overall Principal Investigator's Communication Plan (Appendix 11)
   - USC Master Informed Consent Form Template (Part 1 and 2) (Appendix 9)
   - USC Reportable Events: New Information Requiring Reporting to USC IRB (distribute only) (Appendix 8)
   - Responsibilities of Relying Site Teams (distribute only)(Appendix 13)

2. The amendment to add a Relying Site will include:

   - All informed consent forms and recruitment materials with the Relying Site's local context specific edits
     - The Relying Site may make local context changes to the recruitment material and Part 2 of the informed consent form
     - The USC Lead Study Team must compare each of the Relying Site's informed consent forms and recruitment materials against the USC Master ICF templates, USC Recruitment Templates, and the information included in the Relying Sites completed Local Context Form (if applicable). This is necessary to ensure only local context specific edits were made by the Relying Site. Please assure that no changes have been made to the Master USC ICF Part 1 or the USC Recruitment Template language
   - Completed and signed USC IRB Implementation Checklist or the Local Context Form and IRB Implementation Checklist for the Relying Site (as applicable)
   - The SMART IRB Determination Letter or USC IRB Authorization Agreement signed by the Relying Site (Relying sites will be required to use SMART IRB for agreements if they have joined SMART IRB. Exceptions will be considered for those sites not participating in SMART IRB.)
   - Conflict Management Plan for Relying Site study team personnel (if applicable}
   - Any other documentation from the Relying Site's local IRB (e.g., ceded acknowledgment letter)
   - Ancillary Committee approvals of the Relying Site (e.g., radiation safety review, review for research with bio-specimens, drug/device safety review, contracts, etc.)

3. When a Relying Site is approved, the USC IRB will issue the following documents to the USC Overall Principal Investigator who will forward these documents to the Relying Site:
    - USC IRB Approval Letter of the Relying Site
    - USC IRB approved site-specific ICF forms and site specific recruitment materials (as applicable)
    - Signed IRB Authorization Agreement (IAA) for non-SMART IRB Relying Sites.

Related Documents

Appendix 1	Single IRB Workflow
Appendix 2	How to Create a Reliance Agreement in SMART IRB
Appendix 3	USC SMART IRB Implementation Checklist
Appendix 4	USC Local Context Form and Implementation Checklist for Relying Site (if needed)
Appendix 5	USC SMART IRB Letter of Acknowledgement (when the SMART IRB platform is not used)
Appendix 6	USC SMART IRB Overall PI Checklist
Appendix 7	USC Amendment to Add a Relying Site
Appendix 8	USC Reportable Events: New Information Requiring Reporting to the USC IRB
Appendix 9	Relying Site Specific Consent Template Part 2 (2-part consent – Master and Site Specific)
Appendix 10	Template Recruitment (as needed)
Appendix 11	USC Overall PI Communication Plan
Appendix 12	SMART IRB Reliance Checklist
Appendix 13	Responsibility of Relying Site Teams