USC | Office of Research
Office for the Protection of Research Subjects
Institutional Review Board

SMART IRB

SMART IRB Agreement Implementation Checklist and Documentation Tool

Purpose: (1) to highlight the flexible provisions of the SMART IRB Agreement, and (2) to document which options institutions will implement as part of the Ceded Review. Some of the information documented in this form applies to IRB review while other determinations are at an institution-level.

Instructions:

1. The USC IRB will complete the study-specific information in the box at the top of this page. The USC IRB will share this document with the proposed Relying Institutions and discuss any points of disagreement, updating this form as necessary.

2. The Relying Site should fill in any required information (highlighted in yellow) for each selected option, if applicable.

NOTE: The SMART IRB Standard Operating Procedures define the Lead Study Team as the group designated by the Overall PI that works in collaboration with the Reviewing IRB to ensure coordination of communication to and from all Relying Site Study Teams, routing all IRB submissions to the Reviewing IRB and communicating IRB determinations to Site Investigators.

Study Specific Information	
Reviewing IRB:	University of Southern California
Study Title:	
Overall Study PI:	
USC IRB No.	
Relying Site Information	
Legal Name of Relying Institution(s):	
Relying Site PI Name:	
Relying Site PI Phone #:	
Relying Site PI Email:	
Relying Site Study Contact Name:	
Relying Site Study Contact Phone #:	
Relying Site Study Contact Email:	
Completed by:	**Name:** **Title:** **Phone:** **Email:**
Date Tool Completed:	

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Reviewing IRB	
1. Notification of Acceptance or Declination of Ceded Review *SMART IRB Agreement Section 3.4*	**Another party will provide notification** **The Lead Study Team** will notify the Overall PI and the Site Investigator(s) and involved Participating Institution(s) whether the identified study(ies) is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions.
2. Standard operating procedures ("SOPs") *SMART IRB Agreement Section 1.5*	**Using SMART IRB SOPs** The Participating Institutions will follow the SMART IRB SOPs with respect to the identified study(ies). Note: Be sure to review the rules in Section 1.5 of the SMART IRB Agreement regarding the priority of the Agreement terms over any conflicting terms of alternate SOPs (except when alternate SOPs are externally mandated such as by a clinical trial network or other group with authority for the study(ies).
3. HIPAA determinations and actions *SMART IRB Agreement Sections 5.6 and 6.9*	☐ **Not applicable – Ceded study(ies) does not fall under HIPAA Privacy Rule regulations** ☐ **OPTION 1 – Relying Institution(s) are NOT HIPAA Covered Entities** No HIPAA determinations or actions are required for the Relying Institution(s) to use/disclose PHI for the identified study(ies). ☐ **OPTION 2 – One or more Relying Institution(s) are HIPAA Covered Entities and Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions** The Relying Institution(s) will make determinations for themselves as to what pathway under the HIPAA Privacy Rule (authorization / alteration or waiver of authorization / Limited Data Set) is applicable and required for them to use/disclose PHI for the identified study(ies). Note: If a Relying Institution determines that authorization is required, it must use a freestanding authorization form that is separate from (not merged into) the study consent provided by the Reviewing IRB.

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4. HIPAA authorization language and consent forms *SMART IRB Agreement Sections 5.6.1.1, 5.6.1.2, and 6.9.1*	☐ **Not applicable – Ceded study(ies) does not fall under HIPAA Privacy Rule regulations** ☐ **Reviewing IRB requires HIPAA authorization language to be incorporated into an authorization form separate from a consent form**. The Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule.
5. Conflicts of interest *SMART IRB Agreement Sections 5.8 and 6.6*	**Relying Institution(s) will perform conflict of interest analyses under their policies** The Relying Institution(s) will perform their own analyses under their relevant policy(ies) with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified study(ies). The Relying Institution's(s') resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.
6. IRB notifications (of decisions, changes, lapses in approval, problems, noncompliance) *SMART IRB Agreement Sections 5.9, 5.10, and 5.11*	**Reviewing IRB will provide notifications through another party** The Reviewing IRB will provide notifications through the **Lead Study Team** to the Overall PI, Site Investigator(s), and Relying Institution(s) of: • the Reviewing IRB's determination(s) (e.g., exemption) or review decision(s) (e.g., approval, disapproval, required modifications) regarding the identified study(ies); • approved changes to the study(ies); • lapses in IRB approval for the study(ies) and any applicable corrective action plans; • the Reviewing IRB's review decisions, findings, and actions (including any suspension or termination of IRB approval) regarding unanticipated problems, subject injuries, and significant subject complaints in the study(ies); and the Reviewing IRB's findings and actions (including any suspension or termination of IRB approval) regarding serious or continuing or apparent serious or continuing noncompliance in the study(ies) and any required

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	remediation actions.
7. IRB-initiated audits/investigations *Smart IRB Agreement Sections 5.12 and 6.13*	**Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis** The Reviewing IRB and the Relying Institution(s) will agree upon a plan for the conduct of any IRB-initiated audit or investigation of a matter relating to the Ceded Review of the identified study(ies) on a case-by-case basis and at the time the matter arises. Note: this section applies only to audits/investigations initiated by the IRB. Institutions will conduct audits under their Human Research Protection Programs according to their HRPP polices. Such audits/investigations are not covered by these options. Sections 5.12 and 6.13 of the SMART IRB Agreement include requirement for mutual notification of such non-IRB audits/investigations.
8. IRB-initiated external reporting *SMART IRB Agreement Sections 5.13 and 6.14*	**Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis** The Reviewing IRB and the Relying Institution(s) will agree upon a plan for the drafting and submission to external parties (e.g., regulatory and funding agencies, sponsors, other oversight authorities) of any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified study(ies) on a case-by-case basis and at the time the matter arises.
9. Congruence of federal grant applications/contract proposals *SMART IRB Agreement Section 5.15*	**Another party will review congruence** The Reviewing IRB will delegate responsibility for review of the congruence of any federal grant application(s) or contract proposal(s) supporting the identified study(ies) with the study protocol(s) submitted to the IRB to **USC Department of Contracts and Grants (DCG) or Clinical Trials Office (CTO) as**

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	applicable (when such review is required by federal regulations or oversight agencies).
Reviewing Institution	
1. Financial agreements (for review costs – indemnification agreements are addressed separately below) *SMART IRB Agreement Section 2.3*	**Reviewing IRB/Institution will not charge Relying Institution(s) for costs of review** The Relying Institution(s) will not be responsible for financial support of the costs of review of the identified study(ies). The Reviewing IRB may charge the sponsor or other third parties for those costs.
2. Quality assurance/quality improvement ("QA/QI") function/program *SMART IRB Agreement Section 4.4*	**QA/QI program access required** Each Participating Institution engaged in or conducting the identified study(ies) must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.
3. Insurance *SMART IRB Agreement Section 4.10*	**Insurance required** Each Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified study(ies), including coverage of its IRB/IRB members when acting as a Reviewing IRB. (State/federal agencies or instrumentalities of state/federal government may provide documentation of self-funded liability coverage or of reliance on applicable law providing immunity from or limiting liability.) Note: Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).
4. Indemnification *SMART IRB Agreement Section 4.11*	☐ **OPTION 1 – Indemnification agreements not required** Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).

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	☐ **OPTION 2 – One or more Participating Institutions require an indemnification agreement** The Reviewing IRB and the following Relying Institution(s) will enter a separate indemnification agreement or agreements or other contractual arrangements for allocation of liability among them with respect to the identified study(ies): [NAMES OF RELEVANT RELYING INSTITUTION(S)]. The executed separate indemnification agreement(s) will be attached to and maintained with this tool.

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