University of Southern California (USC) IRB Local Context Form and Implementation Checklist for Relying Site

Your site is participating in a study where the USC IRB will be the IRB of record. When relying on the USC IRB, Relying Institutions must agree to provide the following important information to help the USC IRB conduct its review:

- The requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution.
- Site-specific consent information for this study using the template provided by the USC IRB.

Please seek guidance from your HRPP/Research Office/IRB regarding how to complete the local context review process at your institution. Most IRBs require a local submission in order to initiate the local context review process.

We strongly recommend that the local context form be completed as a collaborative effort. Information from the local site PI, in addition to the IRB/Institutional contact is required to ensure all necessary information is captured. Please Note: Signatures by both the local site PI and the IRB/Institutional Contact are required. Please be as careful as possible in completing this form so that the document does not need to be re-signed.

The local context form contains three important sections:

- Part 1: Relying Site Study Team Information and Operating Procedures
- Part 2: Applicable Local Requirements and Implementation Checklist
- Part 3: Signatures/Attestations

Part 1 of this form must be completed by the Relying Site Study Team, as this section addresses any procedures conducted at the local site that may not be outlined in and/or may differ from the multi-site protocol. Please carefully review the approved protocol and approved master template consent form and complete the local context form below and provide any locally required consent form language using the site-specific template provided.

Part 2 of this form must be completed by the Relying Site IRB, as applicable, as this section addresses state laws and local policies, as they relate to the procedures outlined in Part 1.

Part 3 of this form must be signed by *both* the Relying Site Principal Investigator and the Relying Site IRB representative, as *both* parties are attesting to the completion of this form and the local consent document (if applicable).

Questions regarding completion of this form should be sent to mariatbr@usc.edu.

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Study-Specific Information

Study Title:

Overall Study PI:

USC IRB No.:

Part 1 – To be completed by Relying Site Study Team

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:	
Is your site conducting all of the study activities in the approved protocol?	Yes ☐ No ☐ ***If no, please describe the differences.***
Are there any differences to the study population(s) that you are enrolling at your site from those described in the protocol?	Yes ☐ No ☐ ***If yes, please describe the differences.***
Do all Relying Site study members have the appropriate credentials and/or permits to conduct the proposed research procedures?	I confirm that all involved individuals are credentialed and/or appropriately qualified ☐ ***Note: This form should not be submitted for central IRB review unless all individuals are credentialed and/or appropriately qualified.***
Are there sufficient resources available at your site to carry out the research as planned?	Yes ☐ No ☐ ***(Please note: the answer to this must be YES prior to submission to the central IRB)*** *If any changes are required to the study plan related to the resources available at your site, please outline the required changes.*

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Does your recruitment plan differ from those described in the protocol or associated documents?	Yes ☐ No ☐ N/A ☐ **If yes, please describe**
Does your consent process differ from those described in the protocol or associated documents? *(NOTE: If you are required to use a translated consent form. Please provide translated site-specific consent information sheet(s) **after** the English version has been approved.)*	Yes ☐ No ☐ N/A ☐ **If yes, please describe**
Are there any site-specific ancillary reviews that are required to be completed at your site? *[e.g., radiation safety review, review for research with bio-specimens, drug/device safety review, contracts, etc.]*	Yes ☐ No ☐ N/A ☐ ***If yes, please describe and provide the ancillary review outcome(s) and attach any relevant documentation.***

Part 2 – To be completed by Relying Site IRB Representative

Relying IRB Information

Name of Relying Site IRB Contact:	
Relying Site IRB Contact Phone #:	
Relying Site IRB Contact Email:	
FWA #(s):	
FWA Expiration Date(s):	
List all institutions that are considered components under your FWA:	
Is your site AAHRPP accredited?	Yes ☐ No ☐ ***If no, please describe your institution's human subjects protection training requirements for researchers and study staff.***
Does your institution have a post-approval monitoring system?	Yes ☐ No ☐ ***If yes, provide a description of the monitoring program and/or provide a link to your website.***
Are there any state or local laws that the Reviewing IRB will need to consider when reviewing <u>for this particular research study or study population</u>?	Yes ☐ No ☐ N/A ☐ ***If yes, please describe.***

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Are there any community or cultural differences for the local population of subjects that require consideration for this particular research study?	Yes ☐ No ☐ N/A ☐ ***If yes, please describe.***
Have all Relying Site study team members completed required research training at your site?	Training Completed ☐ ***Note: This form should not be submitted for central IRB review if training has not been completed.***
Did the institution determine there is a relevant individual or institutional financial COI for this protocol?	Yes ☐ No ☐ ***If Yes:*** (1) Provide a summary of the conflict and management plan or attach documentation: (2) Provide an institutional Point of Contact for questions related to the local management plan [This person should be someone in the office/entity who prepared the management plan]:
Please confirm that any local ancillary reviews required for this research study have been completed. *[e.g., radiation safety review, review for research with bio-specimens, drug/device safety review, contracts, etc.]*	☐ N/A – no ancillary reviews required ☐ Ancillary reviews completed
Please confirm that the local study team's plan for recruitment and recruitment materials aligns with local Institutional policy.	☐ Not applicable to this research study or relying site study activities. ☐ I confirm that the local study team's plan for recruitment and recruitment materials aligns with local Institutional policy.
Please confirm that local study team's plan for informed consent process and documentation aligns with local Institutional policy.	☐ Not applicable to this research study or relying site study activities. ☐ I confirm that the local study team's plan for informed consent process and documentation aligns with local Institutional policy.

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Please review and confirm to ensure that the local consent, assent, and/or HIPAA authorization forms (1) include all local language and (2) documents align with local policy.	☐ Not applicable to this research study or relying site study activities. ☐ I confirm that all local language has been included and documents align with local policy.

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 share this document with the proposed Relying Institutions and discuss any points of disagreement, updating this form as necessary.
2. The Relying Site IRB 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.

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*	**Using SMART IRB SOPs** The Participating Institutions will follow the SMART IRB SOPs with respect to the identified study(ies).

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Section 1.5	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.
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,

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	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 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.

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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 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*	**Insurance required** Each Participating Institution must maintain insurance coverage of

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Section 4.10	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). ☐ **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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Part 3 - Signatures/Attestations – To be completed by Relying Site Investigator *and* IRB Representative

By signing below, the signatories attest to the following:

- They have reviewed the SMART Master Reciprocal Agreement/USC Reliance Agreement and Letter of Indemnification, if applicable.
- The information provided in this Local Context Form and Implementation Checklist is complete, accurate, and meets all other applicable federal, state, and local legal and policy requirements.
- The information provided in the Local Consent, assent, and HIPAA authorization form is complete, accurate, and meets all other applicable federal, state, and local legal and policy requirements.

Relying Site Investigator

Signature:	Date:
Printed name:	

Relying Site IRB Representative

Signature:	Date:
Printed name: Title:	

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