IRB Authorization Agreement Implementation Checklist and Documentation Tool

This is the preferred selections version. If more flexible terms are needed, download the blank version from the IRB website.

Instructions:

1. The Reviewing IRB should complete the study-specific information in Section 1. This document is to be shared with the proposed Relying Institutions so that any points of disagreement may be discussed and updated where necessary.
2. For each provision identified below, Reviewing IRB POCs should work with relevant individuals at their institutions to identify and record the appropriate option and any sub-options as agreed upon by the involved Participating Institutions for the identified study(ies).

NOTE:

- The UTHSA IRB uses SMART IRB Standard Operating Procedures to 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.

Section 1

Study Title:	
Overall PI:	
Site Investigator(s)	
Study ID No.	
Reviewing IRB:	
Relying Institution(s):	
Lead Study Team (if applicable):	
Date Tool Completed:	

This information was obtained from SMART IRB Agreement Implementation Checklist and Documentation Tool as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

Section 2

Reviewing IRB	
1. Notification of Acceptance or Declination of Ceded Review	☒ **OPTION 1** – **Reviewing IRB will provide notification** The Reviewing IRB will notify the Overall PI (or designee), 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. This can be accomplished through the SMART IRB Online Reliance System or another mechanism. ☐ **OPTION 2** – **Another party will provide notification** 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. ☐ **OPTION 3 – Requirements/processes for determining the Reviewing IRB are mandated by an external group with authority for the study(ies)** The Participating Institutions are members of / participants in and must follow its requirements and procedures for ceding IRB review and determining the Reviewing IRB with respect to the identified study(ies).
2. Standard operating procedures ("SOPs")	☒ **OPTION 1 – Using SMART IRB SOPs** The Participating Institutions will follow the SMART IRB SOPs with respect to the identified study(ies). UT Health San Antonio Exception regarding Research Personnel: Training for Research personnel from ceding will be verified and confirmed upon initial review and throughout the life of the study by the ceding institution unless the individual conducts research at UT Health San Antonio or an affiliated study site; the research or a research procedure

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	requires specialized skills and/or training by the IRB; the individual has a conflict of interest; the individual will be listed in the informed consent document; site principal investigators; and/or will be listed as the overall principal investigator. In these situations, UT Health San Antonio requires that the individual be named in the research application. ☐ **OPTION 2 – Using other SOPs as mandated by an external group with authority for the study(ies)** The Participating Institutions are members of / participants in and must follow the Standard Operating Procedures with respect to the identified study(ies). ☐ **OPTION 3 – Using other SOPs** (not otherwise mandated) The Participating Institutions will follow the SOPs with respect to the identified study(ies). These SOPs ☐ are available at ☐ will be distributed by
3. HIPAA determinations and actions	☐ **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 Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (select appropriate option(s) below)** The Reviewing IRB will make determinations as to what pathway under the

	HIPAA Privacy Rule (authorization / alteration or waiver of authorization / Limited Data Set) is applicable and required for the Relying Institution(s) to use/disclose PHI for the identified study(ies). • If an authorization is required, the Reviewing IRB will determine the form of the authorization (e.g., incorporated into a consent form vs. freestanding) in collaboration with the Relying Institution(s). • If alteration or waiver of authorization is requested the Reviewing IRB will perform the alteration/waiver analysis and be responsible for granting waivers or alterations of authorization • If the Limited Data Set pathway is applicable, the Reviewing IRB will confirm that the PHI constitute a Limited Data Set and that a Data Use Agreement is or will be put into place. Note: Apart from the determinations and actions referenced above, the Relying Institution(s) are responsible for performance of all of their other applicable HIPAA obligations in connection with the study(ies) (e.g., accounting of disclosures of PHI they make under a waiver of authorization). ☐ **OPTION 3 – One or more Relying Institution(s) are HIPAA Covered Entities and Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions** As a matter of policy or otherwise, the Reviewing IRB does not make 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	☐ **Not applicable – Ceded study(ies) does not fall under HIPAA Privacy Rule regulations**

	☒ **OPTION 1** – **Reviewing IRB requires HIPAA authorization language to be incorporated into the informed consent documents**, unless the Relying Institution obtains agreement from the Reviewing IRB to use a separate authorization form (e.g., separate form is required by State law or institutional policy). If the Relying Institution requires a separate authorization form, the Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule). ☐ **OPTION 2** – **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	☒ **OPTION 1** – **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. ☐ **OPTION 2** – **Reviewing IRB will perform conflict of interest analyses under its policies** The Reviewing IRB will apply its institution's own policies with respect to disclosure and management of the Relying Institution's(s') Research Personnel's conflicts of interest in connection with the identified study(ies). The Reviewing IRB will notify the Relying Institution(s) of the IRB's resulting determinations, prohibitions, management plans, and any changes thereto. Note that the Relying Institution(s) may propose additional prohibitions or conflict management requirements to the Reviewing IRB for approval. ☐ **OPTION 3** – **Relying Institution(s) and Reviewing IRB have agreed on an**

	alternate plan for conflict of interest analyses
6. IRB notifications (of decisions, changes, lapses in approval, problems, noncompliance)	☒ **OPTION 1** – **Reviewing IRB will provide notifications directly** The Reviewing IRB will notify the Overall PI and Relying Institution(s) of: • its 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; • its 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 • its 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. ☐ **OPTION 2** – **Reviewing IRB will provide notifications through another party** The Reviewing IRB will provide notifications through to the Overall PI 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 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.	☐ **OPTION 1** – **Reviewing IRB will conduct any IRB audits or investigations** The Reviewing IRB will conduct any audits or investigations it initiates of matters relating to the Ceded Review of the identified study(ies). ☐ **OPTION 2** – **Relying Institution(s) will conduct any IRB-initiated audits or investigations** The Reviewing IRB will request Relying Institution(s) conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified study(ies). ☒ **OPTION 3** – **Reviewing IRB and Relying Institution(s) will jointly conduct any IRB-initiated audits or investigations** The Reviewing IRB and the Relying Institution(s) will jointly conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified study(ies). ☐ **OPTION 4** – **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.
8. IRB-initiated external reporting	☒ **OPTION 1** – **Reviewing IRB will draft and submit reports to external recipients**

	The Reviewing IRB will draft and submit to external parties (e.g., regulatory and funding agencies, sponsors, other oversight authorities) 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). Note that the Relying Institution(s) have the right to review/comment on the draft report(s) and to make/submit their own report(s) in addition to the Reviewing IRB's report(s). ☐ **OPTION 2** – **Relying Institution(s) will draft and submit reports to external recipients** The Reviewing IRB will request the Relying Institution(s) to draft and submit to external parties (e.g., regulatory and funding agencies, sponsors, other oversight authorities) 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). Note that the Reviewing IRB has the right to review/comment on the draft report(s) and to make/submit its own report(s) in addition to the Relying Institution's(s') report(s). ☐ **OPTION 3** – **Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties** The Reviewing IRB and the Relying Institution(s) will jointly draft and submit to external parties (e.g., regulatory and funding agencies, sponsors, other oversight authorities) 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). ☐ **OPTION 4** – **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.
Reviewing Institution	
1. Financial agreements (for review costs)	☒ **OPTION 1 – 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. ☐ **OPTION 2 – Reviewing IRB/Institution will charge the Relying Institution(s) for costs of review** The Reviewing IRB and the Relying Institution(s) will enter a separate agreement or agreements under which the Relying Institution(s) will provide financial support to the Reviewing IRB for the costs of review of the identified study(ies).
2. Quality assurance/quality improvement ("QA/QI") function/program	☒ **OPTION 1 – 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. ☐ **OPTION 2 – QA/QI program access not required** Participating Institutions engaged in or conducting the identified study(ies) are not required to have or have access to a human subjects research QA/QI program or service.

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Reviewed by:

Name Title UT Health San Antonio	Name: Title: Name of Institution:

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