**SMART IRB Agreement Addendum**

**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**:

For each provision identified below, Relying IRB Point of Contacts (POCs) should work with relevant individuals at their institutions to review the options and any sub-options below as indicated by the Icahn School of Medicine at Mount Sinai (ISMMS) Program for the Protection of Human Subjects (PPHS).

1. Additional notations can be included to clarify unique situations as long as they do not contradict the terms of the SMART IRB Agreement. Suggestions revisions should be marked and returned to ISMMS for review.
2. Each Relying Institution should review the proposed terms and return this document signed by the appropriate Insitutional Signatory Official.

NOTE:

* Capitalized words and terms reflect the same language as found in the terms of the [SMART IRB Agreement](https://joinder.smartirb.org/download_mra).
* The [SMART IRB Standard Operating Procedures](https://smartirb.org/sites/default/files/SMART_IRB_SOP-090816.pdf) 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.

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| **Study Title:** |  | |
| **Overall PI:** |  | |
| **Site Investigator(s)** |  | |
| **Study ID No.** |  | |
| **Reviewing IRB:** | Icahn School of Medicine at Mount Sinai | |
| **Relying Institution(s):** |  | |
| **Lead Study Team (if applicable):** |  | |
| **Date Tool Completed:** |  | |
| **Reviewing IRB** | | | |
| 1. **Notification of Acceptance or Declination of Ceded Review**   *SMART IRB Agreement Section 3.4* | | **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. | |
| 1. **Standard operating procedures (“SOPs”)**   *SMART IRB Agreement 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) – see Option 2). | | **Using SMART IRB SOPs**  The Participating Institutions will follow the [SMART IRB SOPs](https://smartirb.org/sites/default/files/SMART_IRB_SOP-090816.pdf) with respect to the identified study(ies). | |
| 1. **HIPAA determinations and actions**   *SMART IRB Agreement Sections 5.6 and 6.9* | | **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). | |
| 1. **HIPAA authorization language and consent forms**   *SMART IRB Agreement Sections 5.6.1.1, 5.6.1.2, and 6.9.1* | | **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). | |
| 1. **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. | |
| 1. **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. | |
| 1. **IRB-initiated audits/investigations**   *Smart IRB Agreement Sections 5.12 and 6.13*  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. | | **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. | |
| 1. **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. | |
| 1. **Congruence of federal grant applications/contract proposals**   *SMART IRB Agreement Section 5.15* | | **Reviewing IRB will review congruence**  The Reviewing IRB will review 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 (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. | |
| 1. **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. | |
| 1. **Insurance**   *SMART IRB Agreement Section 4.10* | | Relying Institution shall maintain and provide Icahn School of Medicine at Mount Sinai documentation of its insurance coverage or self-funded liability coverage for its respective activities under this Agreement as follows:   * 1. Medical and/or other Professional/Errors & Omissions liability insurance with limits of at least $5,000,000 per occurrence and $5,000,000 in the annual aggregate;   2. Commercial General Liability, including broad form contractual and personal injury liability, with limits of at least $1,000,000 per occurrence and $3,000,000 in the annual aggregate.   3. Workers’ Compensation with statutory limits and Employers Liability with limits of $1,000,000 each accident, each employee, and each disease.   4. Network security and privacy liability of not less than $5,000,000 per occurrence and in the annual aggregate.   Should any of the insurance policies be written on a claims-made basis, insurance requirements shall survive the expiration of this Agreement, and extended coverage shall be afforded for at least two (2) years after the expiration of this Agreement. Icahn School of Medicine at Mount Sinai shall be named as an additional insured on the Commercial General Liability insurance and on the Network security and privacy policies. The Relying Institution agrees to provide Icahn School of Medicine at Mount Sinai with certificates of insurance evidencing aforementioned insurance coverages upon signing the agreement and annually thereafter. The certificates of insurance shall state that the issuing company will endeavor to provide (30) days prior written notice to the certificate holder should any of the policies be cancelled prior to the expiration date. Icahn School of Medicine at Mount Sinai shall have the right to terminate this Agreement in the event of changes to the Contractor’s insurance that are unacceptable. | |
| 1. **Indemnification**   *SMART IRB Agreement Section 4.11* | | Each party (the “Indemnifying Party”) agrees to defend and indemnify the other party(ies) and such party’s respective trustees, officers, directors, employees, faculty, IRB members, volunteers, agents, and contractors (collectively the “Indemnified Party”, from and against any and all third-party claims, lawsuits and demands and the associated liabilities, damages, costs and expenses (including reasonable court costs and attorneys’ fees) arising out of or relating to: (i) Indemnifying Party’s material breach of this Agreement, or (ii) the negligent acts and omissions, willful misconduct, or negligent violation of applicable laws or regulations made by the Indemnifying Institution, Indemnifying Party’s IRB, as applicable, or any trustees, directors, officers, , employees or volunteers, of Indemnifying Party in their performance of this Agreement, including without limitation, negligent use or disclosure of any information, except to the extent that such harm results from the negligence or willful misconduct of the Indemnified Party. The Indemnified Party shall, at the Indemnifying Party’s sole cost and expense, have the duty to cooperate with all reasonable requests in the investigation and defense of claims. Notwithstanding the foregoing, the Indemnifying Party shall not dispose or settle any claim admitting liability on the part of, or impose any obligation on the Indemnified Party without the Indemnified Party’s prior written consent. The obligations contained herein shall survive termination or expiration of the Covered Research. | |

Printed Name of Relying Institution Signatory Official:

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Signature of Relying Institution Signatory Official:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Title*

*Contact Information*

Signature of Reviewing IRB Signatory Official:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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