**IRB Reliance Agreement (Reviewing IRB)**

**Name of Institution or Organization Providing IRB Review** (“Reviewing IRB”): University of Maryland, College Park

Designated IRB Registration Number(s): IRB00000474

Federalwide Assurance (FWA) #: FWA00005856

**Name of Institution Relying on the Designated IRB(s)** (“Relying Institution”): XXXXXXXX

Designated IRB Registration Number(s): IRB0000xxxx

Federalwide Assurance (FWA) #: FWA0000xxxx

# In accordance with this IRB Reliance Agreement, including the terms and conditions in APPENDIX A, attached hereto and incorporated herein by reference, the Officials signing below agree that Relying Institution may rely on the Designated IRB(s) for review and continuing oversight of the human subject research projects described below:

This Agreement applies to all **Scholarship of Teaching and Learning (SoTL)** human subject research conducted by Relying Institution for which Relying Institution submits an application under the **“Broad SoTL Protocol”** at the Reviewing Institution. This Agreement is effective upon the date of last signature and will remain effective for five (5) years at which time the Agreement may be renewed by both parties.

The Reviewing IRB will follow the University of Maryland, College Park Human Research Protections Policies and Procedures for reporting its findings and actions to appropriate officials at the Relying Institution. Relevant minutes of IRB meetings will be made available to the Relying Institution upon request. The Relying Institution remains responsible for ensuring compliance with the Reviewing IRB determinations and with the terms of the Reviewing IRB OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Agreed to by:

**IRB of Record: University of Maryland College Park**

Signature of Signatory Official (IRB):

Date:

Print Full Name: Joseph M. Smith

Institutional Title: Director – Human Research Protection Program

**Relying Institution: XXXXXXX**

Signature of Signatory Official (IRB):

Date:

Print Full Name:

Institutional Title:

# APPENDIX A: Terms and Conditions

1. **Obligations of Reviewing IRB.**
	1. Reviewing IRB Services. For the research described above, the Reviewing IRB agrees to:
		1. Perform initial review, continuing review (if applicable and at intervals appropriate to level of risk), review of amendments, and review of reportable events pursuant to the University of Maryland’s Human Research Protection Program Policies;
		2. Ensure research meets criteria for approval pursuant to 45 CFR § 46.111 and/or 21 CFR §

56.111 as may be subsequently amended, taking into account local context information provided by Relying Institution per Section 2.1(b);

* + 1. Review informed consent forms when IRB has determined that such a consent form is required, and ensure that each informed consent form meets the requirements of 45 CFR §

46.116 and/or 21 CFR § 50.20, as may be amended from time to time;

* + 1. Make determinations upon request pursuant to 45 CFR § 164.512(i)(1)(i)(A) of the Standards for Privacy of Individually Identifiable Health Information (45 CFR Part 160 and Subparts A and E of Part 164 as may be subsequently amended (the "Privacy Rules") promulgated pursuant to the Health Insurance Portability and Accounting Act of 1996 ("HIPAA")), whether to approve an alteration to or waiver of, in whole or in part, the individual authorizations required by 45 CFR § 164.508 of the Privacy Rules for the use or disclosure of Protected Health Information (PHI), as defined in 45 CFR § 164.501, and upon request otherwise ensure that the individual authorizations provided in addition to the informed consents drafted by the various research sponsors are compliant with the Privacy Rules;
		2. Consider any applicable conflict of interest determinations and associated management plans provided by Relying Institution and ensure that any management plan is incorporated into its review as applicable;
		3. Notify the Principal Investigator of its determinations or review decisions, of approval/disapproval of any changes to the research reviewed, and of lapses in IRB approval and any applicable corrective plans (if continuing review is required); and
		4. Maintain records of its membership, its review activities and determinations, and other records as required by applicable laws, rules, and regulations, and make such records available during regular business hours to Relying Institution upon reasonable request.
	1. Notifications. Reviewing IRB will notify Relying Institution through contact provided in Section 3.2 of any of the following as it relates to each research project: (1) serious and/or continuing noncompliance; (2) suspensions, and/or terminations; (3) audits, including findings and corrective actions; (4) required reporting to a regulatory agency (e.g., OHRP, FDA) and/or communication with regulatory agencies.
	2. Performance Standards. In performing IRB Services hereunder, Reviewing IRB shall:
		1. Act in a manner consistent with the Principles of Ethics as set forth in the Report of the National Commission for the Protection of Human Subjects of Bio-Medical Research entitled

Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("Belmont Report") and the Code of Federal Regulations; and

* + 1. Comply with all applicable federal, state, and local laws, rules, and regulations including but not limited to: (1) 45 CFR Part 46, Subpart A (the Common Rule) governing protections for human research subjects; (2) the safety procedures specified in the Federal Food, Drug and Cosmetic Act at 21 U.S.C. § 301 et seq.; and (3) 21 CFR Parts 50, 56, 312, and 812 governing the review of research involving human subjects.
	1. Registration. Reviewing IRB is not responsible for registration of Protocols with clinicaltrials.gov for compliance with 42 U.S.C. § 282 or other applicable laws and is not responsible for any penalties caused by noncompliance with such laws and regulations.
	2. Data Collection and Management. Reviewing IRB is not responsible for compliance with the requirements of any applicable federal, state, and local laws, rules, and regulations regarding electronic data management, including but not limited to: (1) the Privacy Rules at 45 CFR Part 146; and (2) rules governing electronic records at 21 CFR Part 11.
	3. Reviewing IRB is responsible only for providing the IRB Services and other obligations specified in Section I and accepts no additional responsibilities not herein described.
	4. Reviewing IRB certifies that they are an Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)-accredited IRB and will maintain an accreditation status of “Full Accreditation” throughout the term of this Agreement.

# Obligations of Relying Institution.

* 1. For each research project, Relying Institution agrees to:
		1. Relying Institution agrees to submit an application to Reviewing IRB.
		2. Ensure investigators are appropriately qualified and meet Relying Institution’s standards for eligibility to conduct research including, but not limited to, completion of human subjects protection training, and collection and maintenance of conflicts of interest disclosure forms;
		3. Communicate to Reviewing IRB, on the IRB application for each research project, local context information, including requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors relevant to each research project;
		4. Ensure compliance with Reviewing IRB’s determinations, provided there are no legal or policy concerns that would arise with compliance. In the event Relying Institution identifies legal or policy concerns that would arise with compliance, Relying Institution and Reviewing IRB shall address those concerns and make a good faith effort to resolve them. If Relying Institution’s concerns cannot be resolved in a mutually acceptable way, Relying Institution will withdraw its IRB application for that research project. Relying institution will also comply with all applicable federal, state, and local laws, rules, and regulations, including but not limited to: (1) 45 CFR Part 46, Subpart A (the Common Rule) governing protections for human research subjects; (2) the safety procedures specified in the Federal Food, Drug and Cosmetic Act at 21 U.S.C. § 301 et seq.; and (3) 21 CFR Parts 50, 56, 312, and 812 governing the review of research involving human subjects;
		5. Ensure appropriate monitoring of research and conduct internal checklists upon Reviewing IRB’s request, provided there are no legal or policy concerns that would arise with compliance. In the event Relying Institution identifies legal or policy concerns that would arise with compliance, Relying Institution and Reviewing IRB shall address those concerns and make a good faith effort to resolve them. If Relying Institution’s concerns cannot be resolved in a mutually acceptable way, Reviewing IRB may withdraw from that research project;
		6. Maintain policies regarding disclosure and management of conflicts of interest, review and manage conflicts of interest upon disclosure, and communicate resulting conflict of interest determinations, prohibitions, and management plans relating to each research project to Reviewing IRB;
		7. Notify Reviewing IRB of any of the following as it relates to each research project: (1) serious and/or continuing noncompliance; (2) restriction, and/or suspension of research activities; (3) internal audits, including findings and corrective actions; (4) communication with regulatory agencies; (5) legal claims; (6) personnel disciplinary action; and (7) research misconduct.

# Contacts.

* 1. Contact Information. The following individuals shall be available for contact at each institution during normal business hours.

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| Reviewing IRB | Relying Institution |
| Joseph M. SmithDirectorHuman Research Protection Program University of Maryland, College Park (301) 405-4212relianceagreements@umd.eduReviewing IRB: irb@umd.edu |  |

1. **Entire Agreement.**

This IRB Reliance Agreement constitutes the entire agreement and understanding by and among the Parties on the subject matter presented herein and supersedes any and all prior agreements, understandings, or commitments, written or oral, between the Parties. There are no representations, warranties, agreements, or understandings, express or implied, written or oral, between the Parties relating to this subject matter that are not fully expressed herein.