**IRB Authorization Agreement**

**Name of Institution or Organization Providing IRB Review (Institution A):** University of Chicago BSD-IRB

**IRB Registration #:** BSD-IRB Committee A: IRB00000331; BSD-IRB Committee B: IRB00000735; BSD-IRB Committee C: IRB00002169

**Federalwide Assurance (FWA) #:** FWA00005565

**Name of Institution Relying on the Designated IRB (Institution B)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OHRP Federalwide Assurance (FWA) for Institution B#:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Please note: If the FWA lists the Institution A (University of Chicago BSD-IRB) IRB Registration #, Institution B must remove themselves from the OHRP website when the specific protocol(s) listed below have ended in order to disassociate from Institution A’s FWA.*

**The Officials signing below agree that Institution B may rely on the designated IRB for review and continuing oversight of its human subject research described below:**

This agreement is limited to the following specific protocol(s) and only the following protocol(s):

**Name of Research Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of University of Chicago Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**UC BSD-IRB Study Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
UC BSD-IRB Amendment Number (if applicable):\_\_\_\_\_\_**

**Sponsor or Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Award Number, if any: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**The University of Chicago BSD-IRB agrees to the following in regard to the above listed research protocol or activities:**

1. Provide initial and continuing review in accordance with 45 CFR 46 and its FWA.
2. Arrange for prompt reporting to the Relying Institution’s IRB of any of the following, as defined and determined by the Reviewing Institution’s IRB:
	1. Any unanticipated events or problems involving risks to subjects or others.
	2. Any serious or continuing non-compliance.
	3. Any suspension or termination of IRB approval.
3. Comply with all applicable Federal, State and Local laws and regulations.
4. IRB meeting minutes will be made available to the Relying Institution’s IRB upon request.
5. Copy the Relying Institution on all correspondence to regulatory agencies if reporting of an event is required.

**The Relying Institution remains responsible for the following:**

1. Ensuring research activities at its site are in compliance with the IRB’s determinations and with the terms of its OHRP-approved Assurance.
2. Adhering to its institutional conflict of interest policies and procedures and providing the Reviewing Institution with any applicable COI management plan related to the study.
3. Ensuring principal investigators and other research personnel involved in the research are appropriately qualified and meet its institutional standards for eligibility to conduct research, including, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.
4. In relation to HIPAA, will provide when authorization of use or disclosure of protected health information may be waived.
5. Ensuring the Local Site Context form remains up to date regarding the research being conducted at the relying site, including any changes to regulatory, institutional or ancillary review requirements.
6. Maintaining and updating the Relying Site Master Personnel List document each time personnel amendments are submitted.

This document must be kept on file at both institutions and provided to OHRP upon request. This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution.

Signature of Signatory Official (University of Chicago):

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

Print Full Name: **Jennifer A. Ponting, JD**

Institutional Title: **Associate Vice-President for Research, Director University Research Administration**

Signature of Signatory Official (Institution B):

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Print Full Name:

Institutional Title: