Individual Investigator Agreements

This policy is intended for investigators outside the UIW system who do not have an institutional review board and wish to collaboratively rely on UIW for review.

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Policy Statement

Requests to the University of the Incarnate Word (UIW) Institutional Review Board (IRB) for review of a study involving non-affiliated key personnel may be initiated when a UIW faculty member is engaged in the reviewed research. To receive UIW Human Research Protection Program/IRB (HRPP/IRB) review, either the UIW faculty or their non-affiliated collaborator must complete an IRB Application form using the UIW online submission system. Non-affiliated key personnel who do not have an institutional review board will be asked to execute an Independent Investigator Agreement (IIA).

Definitions

1. **Engagement:** an institution is considered engaged in a human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; (3) the informed consent of human subjects for the research; 4) whenever the institution receives a grant, contract, or cooperative agreement from a funding agency (e.g., National Institutes of Health, National Science Foundation, Department of Defense) to conduct human subjects research. In such instances, UIW will still be considered engaged in human subject research even if all activities involving human subjects are carried out by another entity (e.g., contractors, enumerators, collaborators), and that entity only provides de-identified data to the UIW researchers. See What Needs IRB Review – Determination of Human Subjects Research for additional information.

2. **Individual Investigator Agreement (IIA):** Documentation of the agreement that an external individual investigator is relying on HRPP/IRB review, when the investigator is engaged in human subject research in collaboration with a UIW (co-)Principal Investigator (PI)/Key Investigator. This individual investigator agreement is signed by:
   a. The Institutional Official of UIW, or his/her designee; and

b. The collaborating individual investigator.

3. **Individual Investigator:** An individual who is not otherwise an employee/agent of UIW (e.g., faculty, staff, or student) and is either:
   a. Not acting as an employee/agent of any institution with respect to his/her involvement in the research being conducted with UIW; or
   b. Is acting as an employee/agent of an institution that neither holds a Federalwide Assurance (FWA) nor operates an IRB.

4. **Non-affiliated PI:** The individual serving as the PI and subject to an IIA.

5. **Non-affiliated Investigators:** Key personnel who are working under the supervision of the Non-affiliated PI.

6. **UIW Institution/IRB:** The entity conducting the review of a research study on behalf of another entity. The term **IRB of Record** is deemed to be synonymous with reviewing IRB.

7. **UIW PI/Key Investigator:** The individual serving as the PI or Key Investigator at UIW. This individual must be a faculty member. A student/trainee **may not** serve as the UIW PI/Key Investigator for a project involving external agreements.

Individual Investigator Agreements (IIA)

A. Criteria for IIA

1. Eligibility

Eligible IIA requests must meet the following criteria:

a. The Non-affiliated key personnel are not employed by or affiliated with any institution with an IRB. They also must confirm that they are not required to obtain an exemption determination, reliance, or IRB approval for the proposed study or studies from another institution; and

b. The study is in collaboration with UIW PI/Key Investigator; and

c. The study involves research that presents no greater than minimal risk to subjects and is categorized as an exempt or expedited study. The UIW IRB will not review full board studies with an IIA; and

d. The **studies do not involve Federal funding** to either UIW or Non-affiliated researchers; and

e. Non-affiliated researchers do not have a potential Conflict of Interest (COI) associated with the research or will declare any COI(s) that may emerge for the duration of this Agreement. If the Non-affiliated researcher does not fall under a COI policy, they must declare COI as described in the UIW Individual Conflict of Interest

Policy. If they do fall under a COI policy, any managed COI must be submitted to UIW for inclusion in the IIA.

2. *Requesting and executing*

Requesting review of a study involving an IIA includes:

a. Consulting with the Office of Research and Graduate Studies HRPP staff and submitting a protocol application in the UIW IRB management system in which the non-affiliated key personnel are identified; and

b. IIA(s) are subject to the approval of the UIW Institutional Official and may be declined for any reason; and

c. If the request is declined, each entity shall seek separate IRB reviews for their respective involvement in human subject research.

B. Description

1. *UIW PI/Key Investigator Responsibilities*

In addition to standard UIW PI/Key Investigator responsibilities when UIW is the reviewing IRB, the UIW PI/Key Investigator is responsible for the items outlined below.

a. *Compliance:* In addition to the UIW PI/Key Investigator's responsibilities associated with human subject research delineated in UIW Policy, the UIW PI/Key Investigator will be engaged in the research activities described in the protocol(s) referenced in the IIA and performed by the Non-affiliated PI and Investigators.

b. *Training:* The UIW PI/Key Investigator will ensure the appropriate training of all UIW engaged personnel and the Non-Affiliated PI, as put forth in the UIW Policy.

c. *Coordination and dissemination of study materials:* The UIW PI/Key Investigator will ensure the Non-affiliated PI has access to the necessary protocol(s) via the UIW IRB management system. This includes, but is not limited to, disseminating the most recent approved version of the protocol, consent document(s), and study materials to Non-affiliated PI and Investigator(s).

d. *Reporting:* The UIW PI/Key Investigator is responsible for ensuring reports of unanticipated problems involving risks to subjects or others, serious adverse events, deviations, and/or non-compliance to the UIW IRB are submitted.

2. *Non-UIW-Affiliated Investigator Responsibilities*

Responsibilities of Non-UIW Researchers (i.e., Non-affiliated PI and Non-affiliated Investigators), who are relying on UIW HRPP/IRB review, are outlined below.

a. *Assurance:* The Non-affiliated PI will affirm that they are not employed by or affiliated with any institution with an IRB. They will confirm that they are not

required to obtain an exemption determination, reliance, or IRB approval for this listed protocol(s) from another institution.

b. *Compliance:* The Non-affiliated PI and Investigator(s) will review The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46, the UIW Human Research Protections Program Policies and Procedures and will comply with all applicable federal, international, state, and local laws, regulations, and institutional policies that may provide protection for human subjects participating in research conducted under the IIA agreement.

c. *COI:* Non-UIW researchers must declare potential Conflict of Interest (COI) associated with the research that may emerge for the duration of this Agreement. If the Non-affiliated PI does not fall under a COI policy, they must declare COI as described in the UIW Individual Conflict of Interest Policy. If they do fall under a COI policy, the COI management plan must be declared to UIW.

d. *Training:* The Non-affiliated PI will ensure appropriate human subjects research training, such as that provided by CITI, is completed by all Non-affiliated key personnel. Training must be validated at least annually, renewed every 3 years, and kept in current standing for the duration of this Agreement. Only the non-affiliated PI must provide UIW HRPP/IRB with evidence of completion.

e. *Insurance:* The Non-affiliated PI will maintain professional liability insurance that is applicable to the protocol(s) they are performing for the duration of this agreement.

f. *IRB Authority:* The Non-affiliated PI and Investigator(s) will abide by all determinations of the UIW IRB designated under FWA # 00009201 and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities. In the event of protocol expiration, suspension or termination the Non-affiliated PI and Investigators will immediately cease all research and subject recruitment activities.

g. *Records and Review:* The Non-affiliated PI and Investigator(s) will cooperate in the UIW IRBs' responsibilities for initial and continuing review, evidence of human subject research training, record keeping, reporting, and certification. The Non-affiliated PI will provide all information requested by the HRPP/IRB in a timely manner.

h. *Consent:* The Non-affiliated PI and Investigator(s), when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural

standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

i. *Recruitment:* The Non-affiliated PI and Investigator(s) will not begin research under an IIA, including recruitment and enrollment of subjects or performance of any protocol-specific procedures, prior to receiving notification of formal confirmation of exemption or final IRB approval of an expedited, non-federally funded study.

j. *Reporting:* The Non-affiliated PI will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The Non-affiliated PI will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. The Non-affiliated PI will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

k. *Emergency:* Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

l. The Non-affiliated PI will adhere to all other additional responsibilities articulated in the IIA.

Effective Date

August 11, 2022

Revision History

May 20, 2022; June 9, 2022; August 11, 2022

References

1. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
2. UIW Human Research Protections Program Policies and Procedures
3. UIW Individual Financial Conflict of Interest Policy
4. 45 CFR 46