IRB Authorization Agreements (IAA)

An IAA is usually specific to a single study but is sometimes used by trial networks to cover their studies. Commonly, IAAs are also used for collaborators engaging in research on behalf of an institution with its own IRB.

Table of Contents

Policy Statement

The IRB Authorization Agreement Policy outlines the procedures and guidelines for establishing and maintaining authorization agreements between the University of the Incarnate Word's (UIW) Institutional Review Board (IRB) and external researchers affiliated with another institution's IRB engaged in human subjects research. This policy aims to ensure compliance with applicable ethical, legal, and regulatory requirements while facilitating the review and oversight of collaborative research projects involving multiple institutions.

Definitions

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.

IRB Authorization Agreement (IAA): Documentation of an institution's reliance on an External IRB's review of a research study. An IAA is signed by:

- The Institutional Official of UIW, or his/her designee; and
- The Institutional Official of the collaborating institution, or his/her designee.

Non-affiliated Investigators: Non-affiliated PI(s) and/or Researcher(s) conducting research in conjunction with UIW PI(s) and/or Researcher(s).

Reviewing 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.

Relying IRB: The entity that is relying on an external IRB's review of a research study. In many cases, the relying institution will have an FWA and an internal IRB (i.e., the relying IRB).

UIW Investigators: The individual(s) at UIW serving as a PI or Researcher.

IRB Authorization Agreements (IAA)

A. Criteria

1. Eligibility

Eligible IAA requests must meet the following criteria:

a. The study is in collaboration with UIW Investigator(s);

b. UIW investigator(s) do not have a potential financial Conflict of Interest (COI), as defined by UIW Policy, associated with the research;

c. The External IRB holds an active Federalwide Assurance (FWA) that is in good standing with OHRP/FDA;

d. When applicable, Commercial and Non-Commercial External IRBs are accredited by AAHRPP or determined as part of administrative review to meet UIW standards;

e. Studies that are not determined to be exempt. In some instances, exempt studies may execute an IAA; and

f. The External IRB/Institution is located within the U.S.

g. Ineligible studies include studies involving:
   i. human gene transfer (HGT);
   ii. xenotransplantation;
   iii. embryonic stem cell research; and
   iv. research sites at international institutions.

h. Common examples of IAAs include:
   i. industry-initiated research requiring the use of a central IRB;
   ii. industry-sponsored research requiring the use of a central IRB; and
   iii. federally sponsored research requiring the use of a central IRB.

2. Requesting and Executing

UIW Investigator(s), who are engaged in collaborative human subject research with Non-affiliated Investigators associated with an institution that holds an FWA, may request UIW Human Research Protection Program (HRPP)/IRB IAA review with the understanding that:

a. UIW Investigators who are interested in an IAA must consult with the HRPP staff by submitting a protocol application for UIW IRB review or External IRB application for Relying IRB review in the ERM system in which they identify the Non-affiliated Investigator(s) and/or the Relying IRB; and

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

B. When UIW is the Reviewing IRB

1. UIW IRB Review

The UIW IRB will provide IRB oversight in compliance with 45 CFR 46 and 21 CFR 50 and 56 for the research specified in the IAA.

a. All UIW IRB review requests must be submitted using the ERM system. If accepted, oversight of compliance includes:
   i. The initial review, continuing review, review of proposed changes in the research, reportable events, and protocol closure.
   ii. Project submission, review, approval, and communication of IRB determinations will take place according to UIW IRB Policy, which is publicly available on the UIW IRB website.
   iii. The UIW IRB will review requests for waivers or alterations of authorization under the HIPAA Privacy Rule (45 CFR 164.512) and authorization language included in the consent form. Upon the request of the relying institution, the UIW IRB will also review standalone authorization documents associated with the research.

b. If all conditions described in this policy have been adequately addressed, and the UIW Institutional Official or his/her designee has accepted the IAA request. The investigator, Non-affiliated Investigator(s), and the Relying IRB will be sent a written notification and an IAA for execution.

2. UIW Investigator(s) Responsibilities

In addition to standard UIW PI responsibilities, when UIW is the Reviewing IRB, the UIW Investigator(s) is responsible for the items outlined below:

a. *Training:* The UIW Investigator(s) will ensure the appropriate training of all engaged UIW-affiliated personnel as put forth in the UIW IRB Policy.

b. *Protocol submission:* Ensure research activities to be conducted by Non-affiliated Investigator(s) are described in the research protocol submitted to and approved by UIW IRB prior to implementation.

c. *Compliance:* Complying with UIW IRB Policy, federal, and state regulations, and if applicable, complying with the relying institution's policies and procedures.

d. *Communication and Record Dissemination:* Communicating with all Non-affiliated Investigator(s) to ensure necessary and required coordination of any research activities, including disseminating the most recent approved version of the protocol, consent document(s), and study materials to Non-affiliated Investigator(s).

e. *Reporting:* Submitting reports of unanticipated problems involving risks to subjects or others, serious adverse events, deviations, and/or non-compliance to UIW HRPP on behalf of the Non-affiliated Investigator(s).

3. *Non-affiliated Investigator(s) Responsibilities*

The responsibilities of Non-affiliated Investigators, who are relying on UIW review, are outlined below.

a. *Training:* Follow UIW Education and Training requirements.

b. *Compliance:* The Non-affiliated Investigator(s) will comply with UIW IRB Policy, federal and state regulations, and if applicable, complying with the relying institution's policies and procedures.

c. *COI:* The Non-affiliated Investigator(s) must declare any potential COI associated with the research that may emerge for the duration of this Agreement. Any COI declaration must be accompanied with a management plan.

d. *Conducting Research:* The Non-affiliated Investigator(s) will conduct research according to the protocol approved by UIW IRB. The Non-affiliated Investigator(s) should not implement any revisions or changes to the protocol without prior approval from the UIW IRB, except where necessary to eliminate immediate hazard(s) to research subjects. Necessary changes to the research should be communicated to the UIW Investigator(s). The UIW Investigator(s) is responsible for handling the IRB amendment submission to the UIW IRB.

e. *Consent:* The Non-affiliated 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 and stipulated by the UIW IRB.

f. *IRB Authority:* The Non-affiliated Investigator(s) will abide by all determinations of the UIW IRB designated under FWA # 00009201 and 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 Investigator(s) will immediately cease all research and subject recruitment activities.

g. *Reporting:* The Non-affiliated Investigator(s) will report promptly to the UIW Investigator(s) any proposed changes in the research conducted under this Agreement. The Non-affiliated

Investigator(s) will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazard(s) to the subject. The Non-affiliated Investigator(s) will report immediately to the UIW Investigator(s) any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

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

4. Relying IRB Responsibilities

The responsibilities of the External IRB, when they are the Relying IRB, are outlined below:

a. *Compliance:*
   i. *Federal:* For studies conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Relying IRB will comply with the terms set forth in the Code of Federal Regulations at 45 CFR 46, unless the research is otherwise exempt from these requirements, or the department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.
   ii. *Clinical:* For clinical investigations regulated by the FDA, the Relying IRB will apply FDA human subject regulations. These regulations include but are not limited to, Protection of Human Subjects (21 CFR 50), Institutional Review Boards (21 CFR 56), Investigational Drugs (21 CFR 312), Investigational Devices (21 CFR 812), and Application for FDA Approval to Market a New Drug (21 CFR 314).
   iii. *All other research:* For all other research involving human participants the Relying IRB will be guided by the Code of Federal Regulations at 45 CFR 46 when providing equivalent protections.

b. *Records:* The Relying IRB will make available to the UIW IRB, upon request, relevant minutes of its meetings and any other documents related to the review, approval, and continuing oversight of the research study.

c. *Ancillary Support:* The Relying IRB will perform any ancillary reviews required by the UIW IRB and provide any requirements or results of such reviews that are relevant to the UIW IRB's review of the research.

d. *Review:* The Relying IRB will provide the UIW IRB with any relevant information regarding local context, including, but not limited to, state and local laws and regulations, local community information, and institutionally required consent form language. The UIW IRB will rely on this information in performing its review.

e. *Point of Contact:* The Relying IRB will provide the UIW IRB staff with the current name and contact information of at least one Local Contact Person who has the authority to communicate for the IRB at the relying institution. This individual will be the UIW IRB's primary contact person for all necessary communication with the relying institution.

f. *Reportable Events:*
   i. The Relying IRB will notify the UIW IRB staff immediately if there is a suspension or restriction of Non-affiliated Investigator(s) conducting the research, a change in the

status of the Relying IRB's FWA, or any other change that affects the UIW IRB's review of research under this Agreement.

ii. If a complaint from a subject or other person regarding the research or the IRB review process is received, the parties will communicate the concern and work together to determine the next steps. When an investigation into a particular incident or situation is warranted, the parties will work together to thoroughly evaluate the situation and determine the next steps. The parties agree to provide each other with reasonable access to documents and information relevant to the investigation.

iii. The UIW IRB will follow written procedures for reporting unanticipated problems involving risks to subjects or others, serious and/or continuing non-compliance, and suspension or termination of research to the appropriate federal officials, the sponsor or funding agency if applicable, and institutional officials at both UIW and the relying institution. The Relying IRB may request to review and/or revise the report before submission and may choose to submit its own additional report.

5. UIW IRB Responsibilities

The responsibilities of the UIW IRB, when acting as the Reviewing IRB, are outlined below:

a. *Compliance:* The UIW IRB will be guided by all federal regulations and guidance applicable to research involving human participants in its review of research conducted by relying sites.

b. *Records:* The UIW IRB will ensure that convened IRB minutes pertaining to the relevant research study be made available to relying sites upon request. The UIW IRB reserves the right to execute a Confidentiality Agreement with the relying site prior to providing minutes, as determined appropriate.

c. *Reporting:* The UIW IRB will be responsible for reporting serious or continuing noncompliance, unanticipated problems involving risks to subjects or others, and suspensions or terminations of IRB approval. However, as stated above, there may be cases in which the UIW IRB reaches out to the Relying IRB to report these items jointly.

d. If the UIW IRB becomes aware of additional regulatory requirements (for example, those of DoD) that the Relying IRB has failed to address, the UIW IRB will notify the Relying IRB.

C. When UIW is the Relying IRB

1. Administrative Review

The UIW IRB does not complete an additional IRB review; instead, the HRPP completes an administrative review of the application.

a. Administrative review of the IAA application includes the following:

i. Negotiate and execute an IRB reliance agreement (if necessary);

ii. Confirm that the necessary documentation from the Reviewing IRB is included;

iii. Confirm UIW Investigator(s) have completed required human subjects protection training;

iv. Verify that consent documents include any required local context; and

v. Identify necessary local ancillary reviews (e.g., conflict of interest, radiation safety).

b. The UIW HRPP/IRB reviewer will recommend to the Institutional Official or his/her designee to either:
   i. Accept the external IRB approval;
   ii. Accept the external IRB approval with minor modifications; or
   iii. Not accept the external IRB approval, in which case the investigator may either withdraw the study or have it referred to a convened UIW IRB for review.

c. If all conditions described in this policy have been adequately addressed, the investigator(s) will be sent a written notification (Notice of Administrative Review) by the UIW HRPP/IRB that the request for the IAA is affirmed.

2. UIW Investigator(s) Responsibilities

The responsibilities of UIW Investigator(s), when relying on an External IRB, are outlined below.

a. *Agreement:* The UIW Investigator(s) must seek UIW HRPP/IRB approval for all research that will rely on an External IRB. The UIW Investigator(s) will request an IAA using the External Agreement form in the ERM system.

b. *Protocol Status:* The UIW Investigator(s) with an approved IAA must provide the UIW IRB with a copy of the letter of approval from the Reviewing IRB, final approved protocol, and informed consent, and any status changes such as continuing review approval letter, approved modified or amended protocol, unanticipated problem, noncompliance, and closure report, or any other documentation as it pertains to the protocol, using the ERM system.

c. *Training:* The UIW Investigator(s) will ensure the appropriate training of all engaged UIW-affiliated personnel, as put forth in the UIW IRB Policy.

d. *Conducting Research:* The UIW Investigator(s) will conduct research according to the approved protocol and ensure that the planned research activities are approved by the reviewing IRB prior to implementation. The UIW Investigator(s) should not implement any revisions or changes to the protocol without prior approval from the Reviewing IRB, except where necessary to eliminate immediate hazard(s) to research subjects. Necessary changes should be reported to the Non-Affiliated Investigator of the Reviewing IRB. The Non-Affiliated Investigator is responsible for handling the IRB amendment submission to the Reviewing IRB.

e. *Compliance:* The UIW Investigator(s) will comply with UIW IRB Policy and, if applicable, comply with the Reviewing IRB's policies and procedures, in addition to federal, state, and local regulations

f. *Reporting:* The UIW Investigator(s) will report unanticipated problems involving risks to subjects or others, serious adverse events, deviations, non-compliance, and suspension/termination to the IRB of Record and, if applicable, the site Relying IRB.

g. *Other compliance-related reviews:* The UIW Investigator(s) will ensure other required compliance-related reviews and/or training at UIW (e.g., radiation safety, laser safety, biosafety) are completed.

3. External IRB Responsibilities

The responsibilities of an External IRB, when acting as the Reviewing IRB, are outlined below:

a. *Compliance:*

i. *Federal:* For studies conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the External IRB will comply with the terms set forth in the Code of Federal Regulations at 45 CFR 46, unless the research is otherwise exempt from these requirements, or the department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

ii. *Clinical:* For clinical investigations regulated by the FDA, the Reviewing IRB will apply FDA human subject regulations. These regulations include but are not limited to, Protection of Human Subjects (21 CFR 50), Institutional Review Boards (21 CFR 56), Investigational Drugs (21 CFR 312), Investigational Devices (21 CFR 812), and Application for FDA Approval to Market a New Drug (21 CFR 314).

iii. *All other research:* The Reviewing IRB for all other research involving human participants will be guided by the Code of Federal Regulations at 45 CFR 46 when providing equivalent protections.

b. *Records and Review:* The Reviewing IRB will make available to the UIW IRB, upon request, relevant minutes of its meetings and any other documents related to the review, approval, and continuing oversight of the research study.

i. The UIW IRB may conduct for-cause audits or routine post-approval monitoring assessments of research ceded to the Reviewing IRB as part of routine-monitoring activities or as directed by the Reviewing IRB. Any consent and/or HIPAA authorization documents used at UIW will name the UIW HRPP as an entity that may access participants' data. The results of any for-cause audit or findings that could represent non-compliance will be shared with the Reviewing IRB.

c. *Reporting:* The Reviewing IRB will provide prompt notification of all actions, requirements, and determinations it makes related to the participation of UIW in the research study to the UIW IRB.

4. UIW IRB Responsibilities

The responsibilities of the UIW IRB, when acting as the relying institution, are outlined below:

a. The UIW HRPP will review the research protocol and the External IRB's decisions and determinations to ensure that:

i. *Training:* UIW Investigator(s) and researchers conducting the research are appropriately trained per UIW IRB Policy;

ii. *Compliance:* The study is consistent with UIW IRB Policy, including consent form requirements;

iii. *Approvals:* Those actions and determinations made by the Reviewing IRB meet UIW IRB standards for initial review, continuing IRB review, or review of amendments to previously approved research;

iv. *Local Laws:* The UIW IRB will review the protocol(s) for concerns about local context;

v. *Accreditation:* The Reviewing IRB is AAHRPP accredited or is determined as part of administrative review to meet UIW standards.

b. *Reporting:* Promptly report to the Reviewing IRB and, as applicable, to the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), study sponsor, and all other appropriate agencies and individuals:

i. Any unanticipated problems involving risks to subjects or others (UPIRTSO) declared by the UIW IRB to be related to the research reviewed by the Reviewing IRB;
ii. Any serious or continuing noncompliance with the determinations of the UIW IRB related to the research reviewed by the Reviewing IRB;
iii. Any suspension or termination of approval declared by UIW related to the research reviewed by the Reviewing IRB.

c. *Records:* The UIW IRB will make available to the Reviewing IRB relevant minutes of meetings and any other documents related to the UIW HRPP's monitoring or oversight of this research study, or the declaration by the UIW IRB of an unanticipated problem involving risks to subjects or others, serious or continuing noncompliance, or any suspension or termination.

d. If the UIW IRB becomes aware of some additional regulatory requirements (for example, those of DoD) that the Reviewing IRB has failed to address, UIW IRB will notify the UIW study team, and they will communicate with the Reviewing IRB.

Effective Date

6/14/2022

Revision History

7/10/2023

References

1. UIW Human Research Protections Program Policies and Procedures
2. UIW Individual Financial Conflict of Interest Policy
3. 21 CFR 50, 56, 312, 314, 812
4. 45 CFR 46