**Institutional Review Board (IRB) Authorization Agreement**

**Name of Institution or Organization Providing IRB Review** (Institution A):

**The University of Arizona**

IRB Registration #: **IRB00000291**

Federalwide Assurance (FWA) #: **FWA00004218**

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

Federalwide Assurance (FWA) #:

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

[ ]  This agreement is limited to the following specific protocol(s):

Name of Research Project:

Name of Principal Investigator:

Sponsor or Funding Agency:  Award Number, if any:

This document must be kept on file by both parties and provided to OHRP upon request. Terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

**Signature of Signatory Official (The University of Arizona):**

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

Print Full Name: **Sangita Judge, PhD, MBA**

Institutional Title: **Vice President of Research Operations**

**Signature of Signatory Official (Institution B):**

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

Print Full Name:

Institutional Title:

 **Attachment to IRB Authorization Agreement:**

**Division of Responsibilities between U of A and Institution B when U of A is IRB of Record**

The following Division of Responsibilities is based on the premise that Institution A is providing IRB oversight for human subjects' research activity occurring at Institution B, and that Institution B's primary function is (a) to contribute local context to Institution A and (b) conduct oversight of local performance of these studies. As the IRB of record, Institution A will conduct reviews in accordance with 45 CFR 46, 21 CFR 50 and 56, and local policies for review of non-Federally Funded Research. When Institution A is the University of Arizona, the UA has implemented flexible policies for research that is not federally funding or supported, or FDA regulated.

**The responsibilities of the UA IRB are to:**

* Maintain an OHRP-approved Assurance for human subjects research;
* Maintain compliance with state, local, or institutional requirements related to the protection of human subjects;
* Maintain records of Institution A approved research as per institution policies, with relevant IRB records available upon request by the relying institution including minutes, approved documents, and other records that document the IRB determination;
* Review and manage individual and institutional conflicts of interest per Institution A policies and procedures for locally affiliated personnel only;
* Perform initial review of new studies, discuss any issues with the Principal Investigator, require necessary modifications to the study, and make a final decision of approval or disapproval of the study;
* Conduct continuing review of the research and review study amendments;
* Conduct review and make determination regarding serious, unexpected, and related adverse events; serious or continuing noncompliance and other unanticipated problems; including for determining whether each allegation has a basis in fact;
* Obtain additional approvals from DHHS, if applicable, for involvement of pregnant women, fetuses, neonates, children, and/or prisoners;
* Within a reasonable timeframe, request that research approved under this agreement be audited as the IRB may determine to protect the rights and welfare of subjects, and to ensure ongoing compliance with all human subjects rules and regulations;
* Either directly, or through the appropriate coordinating center, inform the Principal Investigator at Institution B in writing of Institution A’s determinations including contact information for questions/concerns, approvals and disapproval, required modifications, determinations related to unanticipated problems and noncompliance, and any changes in the study approval status;
* Either directly, or through the appropriate coordinating center, notify the Principal Investigator at Institution B of new materials that have been reviewed and any changes in the study approval status;
* Promptly notify the Principal Investigator at Institution A, the Principal Investigator at Institution B, and appropriate officials at Institution B of any Institution A determinations that require reporting to institutional officials and/or regulatory agencies. Institution A, through the UA Human Subjects Protection Program (HSPP), will submit required reports to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
* Make available to Institution B the roster of Institution A membership and Standard Operating Procedures (SOPs);
* Ensure that Institution A members receive orientation and continuing education on topics relevant to human subjects protection;
* Ensure that Institution A has adequate meeting space and sufficient staff to support review and recordkeeping duties;
* Notify Institution B immediately if there is a suspension or restriction of Institution A’s authorization to review a study;
* Notify Institution B of any changes in Institution A SOPs that might affect the institution's reliance on Institution A reviews or performance of the research at the local institution; and
* Should termination of the agreement occur, Institution A will continue to oversee the activities until closure or a mutually agreed upon transfer of the study occurs.

**The responsibilities of Institution B are to:**

* Maintain an OHRP-approved Assurance for human subjects research; and be responsible for ensuring the reviewing IRB is consistent with the requirements of the relying organization’s FWA and whether they apply the FWA to some or all research;
* Promptly notify Institution A if Institution B becomes aware of events that change the ability of the site to conduct the research (e.g., suspension of the institution's FWA);
* Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
* Maintain compliance with state, local, or institutional requirements related to the protection of human subjects;
* Maintain records of approved research by Institution A at Institution B as per institution policies;
* Ensure that research subject to this agreement may not be approved by Institution B if it has not been approved by Institution A;
* Ensure qualifications and training of research staff are commensurate with the research activity;
* Conduct scientific review;
* Review, manage and monitor individual and institutional conflicts of interest per Institution B’s policies and procedures and report any relevant information regarding such conflicts to Institution A for final determination on the relevance to the proposed human research;
* If Institution B is not a participating organization in the Federal Demonstration Partnership, Institution A will review, manage and monitor outside individual and institutional conflicts of interest per Institution A’s policies and procedures and report any relevant information regarding such conflicts to Institution B unless Institution A’s Conflict of Interest Office approves of Institution B’s conflict of interest policy;
* Ensure that local reviews relevant to the research, e.g. radiation, chemical, biological safety, are obtained prior to conducting research the Institution;
* Provide the names and addresses to Institution A of local contact persons who have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
* Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by Institution A, submit amendments prior to implementation unless to protect the immediate safety and welfare of subjects; submit timely renewals; monitor protocol compliance and report promptly per Guidance Reporting local information any protocol deviations, unanticipated problems or noncompliance); provide any monitoring reports; manage any major protocol violations and any serious adverse events occurring at the institution; promptly report any changes; conduct monitoring in coordination with Institution A; and providing a mechanism by which complaints about the research can be made by local study participants or others; and
* When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and release of medical records or donation of human specimens) to verify for Institution A that these documents comply with applicable federal, state or local laws, institutional requirements, Confidentiality requirements, or IRB policies of Institution B.

**Further Delineation by Topic**

Confidentiality Laws and Regulations:

Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, is considered a local institutional issue. Institution B remains responsible for how compliance with these confidentiality requirements is implemented at the institution.

Prisoners:

The UA adheres to 45 CFR 46 Subpart C and needs to re-review a protocol when it becomes aware that an investigator wants to conduct research on a prisoner. Institution B must notify the UA IRB before enrolling prisoners in research overseen by UA IRB.

Serious Adverse Events and Other Unanticipated Problems:

It is the responsibility of Institution B’s Principal Investigator to identify and report Serious Adverse Events and Other Unanticipated Problems in accordance with the UA IRB SOP-065 ‘Reportable Information Items that are Potentially Problematic’ and guidance ‘Reporting Local Information’. For events that must be reported to the UA IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the UA IRB, or to the appropriate coordinating center at UA which will report the event it to the UA IRB. The UA IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the UA IRB determines the event constitutes an Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of Institution B's Principal Investigator to identify and report Noncompliance in accordance with the UA IRB guidance ‘Reporting Local Information’. For events that must be reported to the UA IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the UA IRB, or to the appropriate coordinating center at UA which will report the event it to the UA IRB. The UA IRB accepts the responsibility to ensure report is given to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the UA IRB determines the event constitutes Serious or Continuing Noncompliance.