

The University of North Carolina at Chapel Hill

IRB AUTHORIZATION AGREEMENT

This Agreement is entered into by and between the institutions identified below.

Name of Institution Providing IRB Review ("Reviewing Institution/IRB"): The University of North Carolina at Chapel Hill
Federalwide Assurance ("FWA") #: FWA00004801
IRB Registration #: IRB00000538, IRB00000539, IRB00001648, IRB00001649, IRB00000540, IRB00009770

Name of Institution Relying on the Designated IRB ("Relying Institution"):
Federalwide Assurance ("FWA") #:

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

(X) The agreement is limited to the following specific protocol(s):

- Name of Research Project:
IRB Study # at Reviewing Institution/IRB:
Principal Investigator at Reviewing Institution/IRB:
IRB Study # at Relying Institution:
Principal Investigator at Relying Institution:

() The agreement applies to research that meets the following criteria:

Signature of Signatory Official (or authorized designee) at Reviewing Institution/IRB:

_____ Date: _____
Print Full Name:
Institutional Title:

Signature of Signatory Official (or authorized designee) at Relying Institution:

_____ Date: _____
Print Full Name:
Institutional Title:

Division of Responsibilities

1. **Reviewing Institution/IRB** agrees that for the research covered by this Agreement it will:
 - 1.1. Provide initial and continuing reviews of submitted research, reviews of amendments, reviews of unanticipated problems that may involve risks to subjects or others, reviews of noncompliance that may represent serious or continuing noncompliance, reviews of local context information provided by Relying Institution, and reviews of other documents, requests, or information related to the approval and continuing oversight of the research, as applicable. The review and oversight of the research by the Reviewing IRB will be performed in accordance with the human subjects protection requirements of the Relying Institution's FWA(s), any applicable federal human subjects research regulations and ethical principles referenced therein and any other applicable federal human subjects research regulations or policies.
 - 1.2. Suspend or terminate approval of all or part of the research that is not being conducted in accordance with the requirements of Reviewing Institution/IRB.
 - 1.3. Notify the Relying Institution in writing of its findings and actions.
 - 1.4. Ensure that an institutional mechanism exists by which complaints about the research can be made by local research participants or others to a contact at the Reviewing Institution/IRB.
 - 1.5. Provide researchers at the Relying Institution the informed consent document to use for the research where the Reviewing Institution/IRB has determined that a consent form is required. The Reviewing Institution/IRB will permit a Relying Institution to customize limited site-specific sections of the consent form, generally the sections on the availability of treatment and compensation for research-related injury, payment or reimbursement of research costs incurred by participants, and local contacts. Any such modifications will be subject to approval by the Reviewing Institution/IRB, which will then provide a final approved consent document to the Relying Institution.
 - 1.6. Report determinations of Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval to OHRP, FDA, or any other applicable agency, as required under applicable rules or regulations. Relying Institution shall be provided with a copy of any such report in advance of submission and provided with a reasonable amount of time to review and comment. Reviewing Institution/IRB shall take such comments into consideration in finalizing its report, however, Reviewing Institution/IRB will follow its Standard Operating Procedures regarding content and timing of these reports. Nothing in this section shall preclude the Relying Institution from making its own report to applicable agencies.
 - 1.7. Make available relevant minutes of IRB meetings and other relevant documentation to the Relying Institution upon request.
 - 1.8. Upon request, provide the Relying Institution with a copy of the Reviewing Institution's Human Research Protection Program (HRPP) Standard Operating Procedures.
 - 1.9. When appropriate, conduct on site or remote post-approval monitoring or directed audits.
 - 1.10. Obtain an assurance from Relying Institution of its conflict of interest ("COI") review of research study personnel at Relying Institution and that a COI determination has been made. Review any research study personnel COI or financial conflict of interest ("FCOI") management plans specific to the research study submitted by the Relying Institution and

decide whether the management plan is adequate to address the COI or FCOI identified by Relying Institution to permit the research to continue at the Relying Institution. Convey to Relying Institution any concerns Reviewing Institution may have regarding the management plan and work with Relying Institution to resolve those concerns.

2. **Relying Institution** agrees that for the research covered by this Agreement it will:

- 2.1. Comply with the terms of this Agreement and the terms of Relying Institution's OHRP-approved FWA.
- 2.2. Cooperate in the Reviewing Institution/IRB's initial and continuing review of the research, including, but not limited to, providing Reviewing Institution/IRB with any non-compliance or protocol deviations or Data Safety Monitoring reports, not otherwise provided to Reviewing Institution/IRB as required under this Agreement and/or Reviewing Institution's HRPP Standard Operating Procedures.
- 2.3. Ensure compliance of its employees and agents with the Reviewing Institution's HRPP Standard Operating Procedures and determinations regarding the research, including, but not limited to, directives to suspend or terminate designated research activities.
- 2.4. Not approve research if it has not been approved by the Reviewing Institution/IRB, however, this does not preclude Relying Institution from conducting further review and approval or disapproval of research that has been approved by Reviewing Institution/IRB.
- 2.5. Be responsible for safeguarding the rights and welfare of each research participant in performance of the research and acknowledges that the participant's rights and welfare take precedence over the goals and requirements of the research.
- 2.6. Provide the Reviewing Institution/IRB with any local context information applicable to the research.
- 2.7. Ensure that the PI at the Relying Institution will properly oversee the conduct of the study at its institution. This includes but is not limited to:
 - 2.7.1. Monitoring protocol compliance;
 - 2.7.2. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
 - 2.7.3. Promptly reporting to the Reviewing Institution/IRB any proposed changes in the research and not initiating changes in the research without prior review and approval of Reviewing Institution/IRB, except where necessary to eliminate apparent immediate hazards to the participants;
 - 2.7.4. Enrolling individuals in the research only after Reviewing Institution/IRB review and approval;
 - 2.7.5. Obtaining, documenting, and maintaining records of consent and HIPAA authorization, as applicable, for each participant or each participant's legally authorized representative as stipulated by the Reviewing Institution/IRB; and
 - 2.7.6. Promptly notifying Reviewing Institution/IRB of new safety information that may represent Unanticipated Problems Involving Risk to Subjects or Others, or Serious or

Continuing Noncompliance in accordance with Reviewing Institution's HRP Standard Operating Procedures.

- 2.8. Assist and cooperate with Reviewing Institution/IRB in the preparation of any report to notify OHRP, FDA, or any other applicable agency of determinations of Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval concerning incidents or safety information related to research at the Relying Institution.
- 2.9. Cooperate with and provide reasonable assistance to the Reviewing Institution/IRB in conducting directed audits as applicable. Nothing in this Agreement shall preclude Relying Institution from conducting its own post-approval monitoring of the research.
- 2.10. Obtain disclosures of, and review and manage, in accordance with Relying Institution's conflict of interest policy(s) or as required by the funding or regulatory agency COI or FCOI determinations for research study personnel involved in the research at the Relying Institution. Provide Reviewing Institution/IRB with an assurance documenting training, review, and determinations for all research study personnel and provide details of any associated management plan specific to the research study. This assurance shall be provided at initial review, annual review and/or at any interim time point determined necessary by the Reviewing Institution/IRB. Relying Institution will expect its personnel to submit any changes in financial interests to the appropriate office at Relying Institution within 30 days and will provide updates to Reviewing Institution/IRB regarding any changes to research study personnel COI status as soon as possible thereafter.
- 2.11. Maintains responsibility for reporting any COI or FCOIs as required by applicable funding or regulatory agencies.
- 2.12. Notify the Reviewing Institution/IRB immediately if there is a suspension or restriction of the Relying Institution PI in the conduct of the research.
- 2.13. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.
- 2.14. Ensure that the Relying Institution's research personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of research subjects. This includes, but is not limited to, having any institutionally required professional staff appointments, credentialing, insurance, or other liability coverage, training in human subjects protections, and background checks for their assigned role in the research. A Relying Institution's selection of appropriate education/training requirements and other qualifications for its research personnel is at its discretion. A Relying Institution shall provide information or documentation regarding its research personnel's education, training, and qualifications in connection with a ceded review as requested by the Reviewing IRB.

3. **Both parties** agree to the following general provisions:

- 3.1. This Agreement will become effective upon full execution by the parties and will remain in effect for as long as IRB review for the above referenced research is required or until the Agreement is terminated pursuant item 3.2 below.
- 3.2. The Agreement will be terminated in its entirety in the event that:
 - 3.2.1. The Parties mutually agree to termination;

3.2.2. The Reviewing or the Relying Institution terminates its participation under this Agreement upon thirty (30) business days' prior written notice to the other party.

3.2.3. The Reviewing Institution terminates IRB approval for the research.

3.2.4. The Reviewing or the Relying Institution's FWA is suspended, restricted, terminated, or expires; or

3.2.5. The Reviewing IRB fails to remain registered with OHRP.

Upon termination under this Section 3.2, the Parties will work together to determine the effect of such termination on the research and will work together to ensure an orderly transition of the research to another IRB, as applicable.

3.3. Each institution will be responsible for its own negligence in connection with its performance of this Agreement and the research specified in this agreement.

3.4. As permitted by the HIPAA Privacy Rule, Reviewing Institution/IRB shall serve as the privacy board for consideration of a waiver or alteration of authorization. The Reviewing Institution/IRB make no representation about the compatibility of a waiver or alteration of authorization with a Relying Institution's privacy practices, implementation of HIPAA or obligations under state law. As an alternative, a Relying Institution, with the agreement of the Reviewing Institution/IRB, may retain responsibility for reviewing and approving waivers of or alterations of authorization for research ceded under this Agreement in accordance with the HIPAA Privacy Rule.

If a separate HIPAA authorization form will be used for the research, the Relying Institution will ensure the accuracy of the information within the form, the compliance of the form with the HIPAA Privacy Rule and that the form permits PHI to be used by and disclosed to the Reviewing Institution/IRB as necessary for conducting, reviewing and overseeing the research. In the case of a combined consent and HIPAA authorization, the Reviewing Institution/IRB shall be responsible for ensuring that the form complies with applicable requirements in the HIPAA Privacy Rule and the Relying Institution will work with the Reviewing Institution/IRB to provide, as requested, any language specific to the Relying Institution.

3.5. This agreement must be kept on file by both parties and provided to OHRP upon request.

Contact Information

IRB Contact at External Institution:

Name:

Title:

Phone:

Email:

IRB Contact at UNC:

Name: IRB Reliance Group

Phone: 919-966-3113

Email: IRBreliance@unc.edu