Rev 06/18/26 cbj

Institutional Review Board (IRB) Authorization Agreement (IAA)
between
National University of Natural Medicine
and

_____

Institution/Organization Providing IRB Review (Institution A): National University of Natural Medicine
Federal-wide Assurance (FWA) #: FWA00003419
IRB Registration #: IRB 00002896

Institution Relying on the Designated IRB (Institution B): _____

FWA # (if applicable) **:** _____

IRB Registration # (if applicable) **:**_____

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 applies to all human subject research covered by Institution B's FWA.**

◉ **This agreement is limited to the following specific protocol:**

Study Title:

Name of Principal Investigator:

IRB Protocol #:

Sponsor or Funding Agency:

Award Number:

◯ **Other (describe):**

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature/Date of Signatory Official (Institution A):

_____

Print Full Name: _____

Institutional Title: _____

Signature/Date of Signatory Official (Institution B):

_____

Print Full Name: _____

Institutional Title: _____

Rev 06/18/26 cbj

NUNM IRB Terms of Authorization

I. Compliance with Federal Laws and Regulations. Both parties agree to adhere to all pertinent Federal laws and regulations involving the protection of human subjects in research, including 45 CFR 46, 21 CFR 50 and 56, and others as applicable.

II. Federal-Wide Assurance (FWA). The relying institution will maintain an FWA as required for DHHS-supported research and will abide by its terms. The oversight provided by the NUNM IRB per this Agreement will satisfy the terms of the relying institution's FWA, if applicable. The NUNM IRB will not review research on behalf of institutions collaborating with the relying institution unless applicable FWA requirements are satisfied.

III. IRB Membership and Registration. The NUNM IRB is registered with OHRP in accordance with 45 CFR 46, Subpart E, and satisfies the criteria for membership designated in 45 CFR 46.107 and 21 CFR 56.107. Current and past member rosters and registration information are publicly available on the NUNM IRB website.

IV. IRB Review. The NUNM IRB will provide IRB oversight in compliance with 45 CFR 46 and 21 CFR 50 and 56 for the research specified on Page 1 of this Agreement.

- This includes initial review, continuing review at intervals not to exceed once per year, and review of proposed changes in the research.
- Project submission, review, approval, and communication of IRB determinations will take place according to NUNM IRB Policies and Procedures, which are publicly available on the NUNM IRB website.
- The NUNM IRB will review requests for waivers or alterations of authorization under the HIPAA Privacy Rule (45 CFR 164.512) as well as authorization language that is included in the consent form. Upon the request of the relying institution, the NUNM IRB will also review standalone authorization documents associated with the research.
- Minutes of relevant IRB meetings will be made available to the relying institution's Signatory Official, designated Local Contact Person, or other designee upon written request. Per NUNM IRB policy, minutes are considered confidential.

V. Reportable Events. The relying institution is responsible for reporting Unanticipated Problems, Protocol Deviations, complaints, and other non-compliance to the NUNM IRB as required by NUNM IRB Policies and Procedures.

- The NUNM IRB will review reported events in accordance with federal regulations and NUNM Policies and Procedures to determine corrective actions and whether the event requires further reporting.
- 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 next steps.
- When investigation into a particular incident or situation is warranted, the parties will work together to thoroughly evaluate the situation and determine next steps. The parties agree to provide each other with reasonable access to documents and information relevant to the investigation.
- The NUNM 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 NUNM and the relying institution. The relying institution may request to review and/or revise the report before submission and may choose to submit its own additional report.

VI. Responsibilities of Relying Institution:

- ***Institutional oversight of research activities.***
  - Ensure compliance with all determinations and requirements of the NUNM IRB.
  - Ensure safe and appropriate conduct of the research at the relying institution. This includes, but is not limited to, monitoring study compliance and reporting events as specified in this Agreement.
  - Perform any ancillary reviews required by the institution and provide the NUNM IRB with any requirements or results of such reviews that are relevant to the NUNM IRB's review of the research.
  - Require the PI at the relying institution to maintain appropriate documentation of IRB approvals and other NUNM IRB correspondence.
  - Ensure compliance with all applicable requirements of the HIPAA Privacy Rule pertaining to uses and disclosures of PHI by the relying institution.
  - Ensure that all personnel involved in conducting the research at the relying institution are appropriately qualified to conduct human subjects research, and provide evidence of such qualification in accordance with NUNM IRB Policies and Procedures.
  - Ensure that researcher conflicts of interest are disclosed and managed in a manner consistent with federal regulations and NUNM Policies and Procedures.
- ***Facilitating review by the NUNM IRB.***
  - Provide the NUNM 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 NUNM IRB will rely on this information in performing its review.
  - Provide NUNM 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 NUNM IRB's main contact person for all necessary communication with the relying institution.
  - Notify NUNM IRB staff immediately if there is a suspension or restriction of a Principal Investigator (PI) conducting the research, a change in the status of the relying institution's FWA, or any other change that affects the NUNM IRB's review of research under this Agreement.