Rev 06/16/26 cbj

Individual Investigator Agreement (IIA)
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

Study Short Name:

NUNM PI:

NUNM IRB Number:

Full Study Title:

Non-NUNM – Individual Investigator

Name + credentials/degrees:

Title:

Address:

Phone:

Email:

Definitions of Collaborating Individual Investigators

Independent collaborating investigator:

- Not otherwise an employee or agent of NUNM
- Conducting collaborative research activities outside the facilities of NUNM; and
- Not acting as an employee of **any** institution with respect to their involvement in the research being conducted at NUNM

Institutional collaborating investigator:

- Not otherwise an employee or agent of NUNM;
- Conducting collaborative research activities outside the facilities of NUNM;
- Acting as an employee or agent of a non-assured institution with respect to their involvement in the research being conducted by NUNM; and
- Employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

OHRP will permit an assured institution to extend its FWA to cover a collaborating independent or institutional individual investigator provided all of the following conditions are satisfied:

1. The above-named Individual Investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internally recognized equivalent; see section B.1 of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under the Agreement.
3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
4. The Investigator will abide by all determinations of the NUNM Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
8. The Investigator, 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.
9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.
10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
12. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
13. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Individual Investigator Signature _____ _____
Full Name Date

NUNM FWA Institutional Official or
Designee Signature _____ _____
Full Name Date

Institutional Title