**Institutional Review Board Authorization Agreement**

A. This Agreement is entered into by and between the institutions identified below (each a “party” and collectively the “parties”).

**Institution or Organization Providing IRB Review (“Reviewing Institution/IRB”):**

Federalwide Assurance (“FWA”) #:

IRB Registration #:

**Institution or Organization Relying on the Designated IRB (“Relying Institution”):**

Appalachian State University

Federalwide Assurance (“FWA”) #: FWA00027456

IRB Registration #: 00001458

B. The Officials signing below agree that the Relying Institution may rely on the Reviewing Institution/IRB for review and continuing oversight of the human subject research in the following protocol:

**Name of Research Project:**

**IRB Study # at Reviewing Institution/IRB:**

**IRB Study # at Relying Institution/IRB:**

**Principal Investigator at Reviewing Institution/IRB:**

**Principal Investigator at Relying Institution:**

**Sponsor or Funding Agency:**

**Award Number (if any):**

C. **Reviewing Institution/IRB** agrees that it will:

* + 1. Provide initial and continuing review for the research protocol specified in Section B pursuant to 45 CFR 46, its FWA as well as the requirements of federal, state and local laws. For research involving FDA regulated products, the Reviewing Institution**/**IRB is in compliance with the requirements defined in 21 CFR Parts 50, 56, 312 and 812 and ICH (International Conference on Harmonization) guidance related to GCPs (Good Clinical Practices).
    2. Follow written procedures for reporting its findings and actions to appropriate official(s) at the Relying Institution via the principal investigator at the Relying Institution specified in Section B.
    3. Make relevant minutes of IRB meetings and other relevant documentation available to the Relying Institution upon request.

D. **Relying Institution** agrees that it will:

1. Be responsible for the timely compliance of its employees, students, and agents with the Reviewing Institution/IRB’spolicies, procedures, and determinations regarding the research protocol(s) specified in Section B and with the terms of this Agreement and the terms of Relying Institution’s OHRP-approved FWA.
2. Accept the final authority and decisions of the Reviewing Institution/IRB, including but not limited to directives to suspend or terminate designated research activities.
3. Be responsible for safeguarding the rights and welfare of each research subject in performance of the research protocol(s) specified in Section B by its own employees, students, and agents in accord with the determinations of the Reviewing Institution/ IRB and the terms of the Relying Institution’s OHRP-approved FWA.
4. Not use, or authorize others to use, the name, symbols, or marks of the Reviewing Institution/IRBin any advertising or publicity material or make any form of representation or statement in relation to the research protocol(s) specified in Section B which would constitute an expressed or implied endorsement by the Reviewing Institution/IRB, except for factual representations of the Reviewing Institution/IRB’s performance of research pursuant to this Agreement.

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

1. The term of this Agreement shall begin upon full execution by the parties and shall continue in effect until expiration or termination of the Reviewing Institution/IRB’s approval of the research protocol(s) specified in Section B.
2. Each party will be responsible for its own negligence in connection with its performance of this Agreement and the research protocol(s) specified in Section B.
3. Upon the occurrence of events or incidents that require reporting to external regulatory agencies or other organizations, including without limitation the reporting of unanticipated problems or instances of non-compliance to OHRP or the agency sponsoring the research protocol(s) specified in Section B, the parties will make all reasonable efforts to determine which party has primary responsibility for making the required reports; provided, however, that both parties shall have a reasonable opportunity to review and comment on such reports. Both parties further agree to make all reasonable efforts to assist and cooperate in the preparation of any required reports relating to the research protocol(s) specified in Section B.
4. This document must be kept on file by both parties and provided to OHRP upon request.
5. Correspondence regarding the occurrence of events or incidents that require reporting to external regulatory agencies or other organizations, including without limitation the reporting of unanticipated problems or instances of non-compliance to OHRP or the agency sponsoring the research protocol(s) specified in Section B, shall be sent to the signatory officials listed below.

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

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

Name:

Institutional Title:

Address:

Email:

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

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

Name: Christine Ogilvie Hendren, PhD

Institutional Title: Vice Provost for Research and Innovation

Address: John E. Thomas Hall, 287 Rivers Street, Boone, NC 28608

Email: hendrenco@appstate.edu