B. NON-FEDERALLY FUNDED UNMC/NHS IRB-APPROVED RESEARCH WHICH IS MINIMAL RISK OR GREATER CONDUCTED OFF-SITE WHICH INVOLVES PRIVATE PHYSICIANS AS PARTICIPATING INVESTIGATORS

1. Before such research can be initiated, a Non-Institutional Investigator Agreement (NIIA) must be in effect.

2. The UNMC PI assumes overall responsibility for research conducted at an external site by participating investigators. The UNMC PI must provide the participating investigator with a copy of the Belmont Report and a copy of the Federal Regulations (45 CFR 46). In addition, a copy of 21 CFR 50,56 must be provided for FDA-regulated IND/IDE studies.

3. The UNMC PI must obtain a copy of the consent form utilized by the private physician. The UNMC IRB will stamp these consents unless an external IRB has approved the consent.

4. The PI is responsible for obtaining information concerning AEs and any other problems concerning research subjects at the off-sites. This information should be reported to the UNMC IRB in a timely fashion.

5. The UNMC PI is responsible for advising the external participating investigators of IND safety reports, amendments and any other information pertinent to the research. If an adverse event or an amendment requires a change in the consent document. The UNMC PI should obtain a copy of the revised consent form approved, as necessary, by the external IRB. A copy of the consent form should be provided to the UNMC IRB.

6. The UNMC PI is responsible for obtaining all necessary information for continuing review as required by the UNMC IRB. Information pertinent to the research conducted at the off-site must be included in the UNMC IRB Application for Continuing Review.
NON-INSTITUTIONAL INVESTIGATOR AGREEMENT

IRB #: ______

TITLE OF PROPOSAL: _________________________________________________________________

A. ETHICAL PRINCIPLES

1. ______________________, hereinafter referred to as the "investigator", who is participating with the University of Nebraska Medical Center in the above-titled protocol, is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").

2. This investigator acknowledges that he/she has received and read a copy of the Belmont Report and a copy of the Federal Regulations (45 CFR 46) and 21 CFR 50,56 (if applicable).

3. This investigator understands and shall abide by the principles of respect for persons, minimization of risk, maximization of benefit, and fairness as stated in the Belmont Report; and shall apply such in compliance with Federal Regulations.

B. RESPONSIBILITIES OF INVESTIGATOR

1. This investigator acknowledges and accepts responsibility for protecting the rights and welfare of human research subjects in the above-cited research protocol and for complying with all applicable provisions of the UNMC OHRP approved assurance (FWA00002939) under which this agreement is authorized.

2. This investigator assures that before human subjects are involved in research, proper consideration will be given to:

   a. the risks to the subjects,
   b. the anticipated benefits to the subjects and others,
   c. the importance of the knowledge that may be reasonably expected to result,
   d. the informed consent process to be employed, and
   e. the need for additional safeguards if the human subjects are especially vulnerable.
3. This investigator accepts responsibility for their performance in the above-cited research protocol and will protect human subjects and satisfy the intent and procedures as specified in 45 CFR 46, as amended, 21 CFR 50,56 (for FDA regulated studies), and other Federal, state or local laws or regulations which may apply.

4. This investigator will comply with all other pertinent procedures, such as prior review by the UNMC IRB and/or other IRB named in the IIA and informed consent, that are designed to ensure effective application of protections for the rights and welfare of human subjects.

5. This investigator will abide by full board reviews of the UNMC IRB and/or other IRB named in the IIA and will accept the final authority and decisions of that IRB.

6. This investigator acknowledges and agrees to cooperate in the IRB’s responsibility for initial and continuing full board review, record keeping, reporting, and certification.

7. This investigator will report promptly to the UNMC IRB and other IRB named in the IIA:
   a. any proposed changes in the IRB-approved protocol and agrees not to initiate such changes without prior IRB review and approval except to eliminate apparent immediate hazards to subjects, and
   b. any injuries to subjects or unanticipated problems involving risks to subjects or others.

8. This investigator will not delegate to others the treatment of subjects under the above-cited research protocol without prior IRB notification.

C. ENDORSEMENTS

The parties signing below agree that all human subject research conducted by the investigator in the above-cited protocol will be conducted in accordance with DHHS regulations for the protection of human research subjects (45 CFR 46) and 21 CFR 50,56 (if applicable), with the provisions of this Agreement, and with the stipulations of the UNMC IRB.
This Agreement is not effective until signed by the Investigator and the IRB Chairperson cited below.

This signed Agreement will be retained by the institution cited below and will be made available to OHRP upon request. A copy of this agreement will be retained by the investigator.

1. **Signature of the Non-Institutional Investigator**

   I will abide by the provisions of this Agreement and by the stipulations of the designated IRB.

   _____________________________________________           ___________________
   Signature     Date

   Name: _____________________________________________
   Title: _____________________________________________
   Address: _____________________________________________
   _______________________________________________
   Telephone #: _____________________________________________

2. **Signature of UNMC/NHS IRB Chairperson**

   This institution and its IRB will abide by the provisions of this Agreement and the requirements of OHRP-approved Assurance FWA00002939.

   _____________________________________________           ___________________
   Signature     Date

   Ernest D. Prentice, Ph.D.
   IRB Chairperson
   Institutional Review Board
   987830 Nebraska Medical Center
   Omaha, NE   68198-7830
   402/559-6463