INTER-INSTITUTIONAL AGREEMENT (IIA)

A. UNMC/NHS IRB-APPROVED RESEARCH WHICH IS MINIMAL RISK OR GREATER CONDUCTED AT AN EXTERNAL HOSPITAL BY NON-UNMC/NHS PHYSICIANS

1. When a UNMC/NHS research project classified as minimal risk or greater is conducted in an external hospital, an Inter-Institutional Agreement (IIA) for the study must be in effect before the research can be initiated at that hospital. Every participating investigator must be listed by name in the agreement. When an investigator is added to a study, a revised agreement must be completed.

2. Before an external participating investigator is authorized to enroll patients in a study covered by the IIA they must also complete a Non-Institutional Investigator Agreement (NIIA) and be provided with a copy of 45 CFR 46, 21 CFR 50.56 (if the study is FDA-regulated) and the Belmont Report.

3. The UNMC PI assumes overall responsibility for research conducted at an external site by participating investigators. This means the UNMC PI or their designee at the external site must ensure that the research protocol is submitted and approved by the external IRB (if existent) and inform that IRB of all amendments, adverse events and any other information pertinent to the research.

4. The UNMC PI should obtain a letter of approval of the research from the external site and a copy of the approved consent form for use at that site. The UNMC PI is responsible for reviewing the externally approved consent form and ensuring that it meets the requirements of 45 CFR 46.116 and 21 CFR 50.20,25 (for FDA-regulated studies). A copy of these documents must be forwarded to the UNMC IRB.

5. The UNMC 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.

6. 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 PI should obtain a copy of the revised consent form approved by the external IRB or designated administrative official at the site. A copy of the consent form should be provided to the UNMC IRB.

7. 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.

8. The UNMC PI should obtain a copy of any external IRB’s yearly reapproval of the study along with a copy of the approved consent form at the time that continuing review is performed at the external site. A copy of these documents should be submitted to the UNMC IRB in a timely fashion.

9. The UNMC PI is responsible for reporting to the UNMC IRB non-compliance with 45 CFR46 and 21 CFR 50.56 (if applicable).
INTER-INSTITUTIONAL AGREEMENT
FOR THE PROTECTION OF HUMAN SUBJECTS

A. ETHICAL PRINCIPLES

1. The _____, hereinafter referred to as the "institution", and cooperating with the University of Nebraska Medical Center (UNMC) on research protocol #______ entitled "_______", 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. Accordingly, this institution acknowledges that the following investigators: __________ hereinafter referred to as "investigators" understand 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 (45 CFR 46) as amended and 21 CFR 50,56 (for FDA-regulated studies).

B. RESPONSIBILITIES OF INVESTIGATORS

1. The investigators acknowledge and accept responsibility for protecting the rights and welfare of human research subjects.

2. The investigators assure 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 and documentation of consent to be employed, and
   e. the need for additional safeguards if the human subjects are especially vulnerable.

3. The investigators accept responsibility for his/her performance in the previously cited research protocol, and will protect human research subjects and satisfy the intent and procedures as specified in 45 CFR 46, as amended, and other Federal, state, or local laws or regulations which may apply.

4. The investigators will comply with all requirements of the UNMC IRB and the institution's IRB which are designed to ensure effective application of protections of the rights and welfare of human subjects.

5. The investigators acknowledge and agree to cooperate in the UNMC IRB's and the institution IRB's responsibility for initial and continuing full board annual reviews, recordkeeping, and reporting.

6. The investigators specifically acknowledge the need to promptly report the following to the UNMC IRB and the institution's IRB:
   a. any proposed changes in IRB-approved protocols, and agree 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.

C. RESPONSIBILITIES OF THE INSTITUTION'S IRB

1. The institution and its IRB agree to abide by 45 CFR 46, 21 CFR 50,56 (for FDA-regulated studies) and this agreement.

2. The IRB shall perform continuing review of the previously cited research project at intervals appropriate to the degree of risk but not less than one per year.

D. INSTITUTIONAL CERTIFICATION

The Institution and its IRB agree to be cognizant of the contents of this agreement and to act in concert with all of its requirements.

______________________________
IRB Chairperson or Administrative Official at the Institution

______________________________
Date

Ernest D. Prentice, Ph.D.
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