United Educators

Human Subjects Research (HSR)

Supplemental Application

INSTRUCTIONS

Instructions for the educational institution (applicant):

- Please complete all portions of this application completely, truthfully, and accurately.
- Complete this application electronically using the fillable fields. To save a partially completed application and send it to someone else, save the document as a .pdf file to your computer and then attach it to an email, or use the "send" function in Adobe Reader. Include any additional attachments.
- Print the .pdf file and sign the application. Scan the completed form and save it to your computer.
- Email the completed and signed application to your broker, along with all necessary attachments.
- If you do not understand a question, have your broker contact United Educators (UE) for clarification.

Submitting Broker

Please complete the broker information below. Confirm that all application questions are answered and that the application is signed before submitting it to UE.

Submitting Broker Must Complete		
Person to Contact:		
Address 1:		
Address 2:		
City:	State:	Zip:
Phone Number:		
Email:		
License Number:		

Send completed application to:

applications@ue.org
OR
Fax: 301-907-8620

United Educators
7700 Wisconsin Avenue
Suite 500
Bethesda, MD 20814
Phone: 301-907-4908

APPLICATION

Full Legal Name and Address of the Educational Institution		
Institution Name:		
Address 1:		
Address 2:		
City:	State:	Zip:

The undersigned is an authorized representative of the educational institution and all persons or concerns applying for Human Subjects Research (HSR) coverage. The undersigned declares that all information provided is complete, truthful, and accurate.

Signature: _____ Date: _____

Name: _____

Title: _____

Educational Institution: _____

The signing and submission of this application does not bind UE to issue, or the educational institution to purchase, any specific policy or coverage. Information provided in this application is for underwriting purposes only and does not constitute notice to UE of a claim or potential claim under any policy.

QUESTIONS

1. As defined in the accompanying endorsement, please estimate the number of active and/or planned Human Subjects Research (HSR) studies in the next 12 months: _____

2. Do any HSR studies specifically target any of the following populations?
   a. Pregnant Women* ☐ Yes ☐ No
   b. Minors ☐ Yes ☐ No
   c. Cognitively Impaired ☐ Yes ☐ No

   If yes, please describe and provide a copy of the submission to the Institutional Review Board (IRB), whether approved or pending approval.

3. Have any of your IRBs, investigators, or clinical sites received a warning letter or been the subject of an adverse Food & Drug Administration (FDA) action?
   ☐ Yes ☐ No

   If yes, please explain:

4. Have any trials been discontinued or suspended for a safety reason, whether by you, the FDA, or another authority?
   ☐ Yes ☐ No

   If yes, please explain:

5. Have any subjects suffered from an adverse event, as defined by the FDA?
   ☐ Yes ☐ No

   If yes, please explain:

**For application purposes, "Pregnant Women" includes any human subject within a six-week postpartum period.*

LIMITED HUMAN SUBJECTS RESEARCH COVERAGE

In consideration of the premium charged and subject to all other provisions of this Policy, **we** agree with the **Educational Organization** that:

DEFINITIONS

1. The following Definitions are added to this Policy:

   Human Subjects Research means an experimental study or research on humans in which an **Insured**:
   a. collects, analyzes or studies health, biometric, biomedical or behavioral data without any intervention or treatment of a disease or medical condition; or
   b. uses, causes to be used, contributes to, or furnishes any diagnostic, therapeutic or behavioral intervention designed or intended by a researcher to prevent, change or measure any change in the course of a human disease or medical condition.

   Solely with respect to a. and b. above, **Human Subjects Research** does not include studies or research involving any:
   i. **Invasive Procedure** of a human body,
   ii. testing involving the effectiveness, usefulness, success, or safety of any drug or pharmaceutical including; any potential secondary or side effects that may result from such drugs or pharmaceuticals; or
   iii. medical device other than a Class I medical device as classified by the U.S. Food and Drug Administration.

   Invasive Procedure means:
   a. the injection or infusion of any substance; or
   b. the use of radiation, in any form; or
   c. any controlled infection of a human subject with any virus, bacteria, or disease; or
   d. any medical procedure that by design or intention:
      i. penetrates or pierces the skin or mucous membranes of the body; or
      ii. enters any internal body cavity beyond a natural or artificial body orifice;

   Invasive Procedure does not include any:
   (1) simple venipuncture for blood sampling or the collection, analysis or study of surplus body fluids or tissues by an **Insured** after an **Invasive Procedure** has taken place;
   (2) fine-needle muscle biopsies performed as part of **Human Subjects Research**; or
   (3) X-ray, Computed Tomography Scan (CT), Magnetic Resonance Imaging (MRI), sonogram, or any other external imaging, whether or not contrast or dye is used.

2. The Definition of **Professional Services** is amended to read:

   Professional Service means:
   a. any **Healthcare Services**;
   b. any engineering, architecture, veterinary, law; or social work services;
   c. any activity designated in the Schedule of **Internship Programs** and **Professional Services** of this Policy; or
   d. **Human Subjects Research**,

   but only if the **Professional Service** is performed by an employee, faculty member, student, uncompensated volunteer, or independent contractor of an **Included Entity**, and only while acting within the scope of his or her duties assigned by an **Included Entity**.

   Professional Service does not include any activity for which an individual is compensated by any party other than an **Included Entity**.

EXCLUSIONS

3. The following Exclusion is added:

   This Endorsement does not apply to any liability related to or arising out of **Human Subjects Research** occurring before [XX/XX/XXXX].

4. Exclusion 5.g. of this Policy is amended to read:

   g. any surgery or biopsy;
   Exception: This Exclusion does not apply to:
   (1) suturing, stitching, or incising of superficial wounds, or lacerations to the skin; or
   (2) fine-needle muscle biopsies performed as part of **Human Subjects Research**;

5. Exclusion 5.s. of this Policy is amended to read:

   s. any:
   i. human clinical trial as defined by the National Institutes of Health; or
   ii. use, administration or prescription of any drug, pharmaceutical or medical device for treatment of human beings that has not been approved for distribution or sale by the U.S. Food and Drug Administration;
   Exception: Exclusion s.(i.) does not apply to **Human Subjects Research**;

All other Policy provisions remain the same.