



**USUHS FORM 3208**  
**ASSURANCE SUPPLEMENT FORM**  
**(new or competing continuation protocols)**

REA Date Stamp

Project Number (REA will assign): \_\_\_\_\_

**PRINCIPAL INVESTIGATOR INFORMATION**

Name (Last, First, MI): \_\_\_\_\_

Degree(s): \_\_\_\_\_

Percent Effort on this project: \_\_\_\_\_ % (Effort on awarded projects and other activities may not exceed 100%)

Academic Title: \_\_\_\_\_

USUHS Department: \_\_\_\_\_

USUHS Building and \_\_\_\_\_

Room Number: \_\_\_\_\_

Off-Site Address: \_\_\_\_\_

Billet Organization: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_ E-mail: \_\_\_\_\_

**PROJECT INFORMATION**

1. Project Title: For NIH submissions do not exceed 56 characters.  
 \_\_\_\_\_

2. Purpose:      \_\_\_ New Protocol              \_\_\_ Competing Continuation              \_\_\_ Supplemental

3. Anticipated Period of Performance:              \_\_\_\_\_ Project Start              \_\_\_\_\_ Project End

4. Assurance Committees: (check applicable assurances)

- \_\_\_ None              No assurances required
- \_\_\_ BCD              Biohazards, Controlled Substances, and Dangerous Materials Committee
- \_\_\_ BIC              Biomedical Instrumentation Center
  
- \_\_\_ IRB              Institutional Review Board (including research using human subjects; human cell lines; pathological specimens; any human tissue including blood, sera, excreta, saliva, placenta, etc.; physiological measurements; exposure to X-ray, microwave or other radiations; recordings via MRI, ECG, ERG, PET, ultrasound; drugs; medical devices; voice, video, digital, image recordings; survey, interview, focus group procedures; human performance/behavior evaluation; medical records or data)
  
- \_\_\_ External IRB      IRB at non-USU locations                              Location(s): \_\_\_\_\_
- \_\_\_ IACUC              Institutional Animal Care and Use Committee              Animal Protocol # \_\_\_\_\_
- \_\_\_ External IACUC    IACUC at non-USU locations                              Location(s): \_\_\_\_\_
- \_\_\_ RSC              Radiation Safety Committee                              \_\_\_\_\_

5. Select a single category that best describes your project:

**Behavioral and Neuroscience**

- Behavioral (1a)
- Neurosciences - Basic Sciences (1b1)
- Neurosciences – Pathology (1b2)

**Combat Casualty Care**

- Biological, Chemical, Nuclear and Medical Defenses (4f)
- Blood and Blood Substitutes (4c)
- Gulf War (4h)
- Inflammation (4d)
- Other (4g)
- Shock, Ischemia, and Cryopreservation (4b)
- Wound Healing, Trauma, and Resuscitation (4a)

**Genetics/Cell Biology**

- Cancer (Neoplasia) (3c)
- Cell Mechanisms of Disease, Cell Injury and Repair (3b)
- Genetics (3d)
- Normal Biology not Fitting in Other Topics (3a)

**Health Maintenance and Disease Prevention**

- Accident Prevention and Safety (5e)
- Epidemiology (5f)
- Health Promotions (5d)
- Health Services Research (5a)
- Smoking (5b)
- Substance Abuse (5c)

**Infectious Disease**

- Basic Biology of Bacterial, Viral, or Parasite Diseases (2c)
- Immunology, Host Defenses (2e)
- Other (2f)
- Population Biology (2d)
- Toxins, Diagnostics, and Therapies (2b)
- Vaccines (2a)

**Nursing**

- Anesthesia (9a)
- Education (9c)
- Family Nursing (9b)
- Other (9d)

**Operational Medicine/Military Readiness (8b)**

**Other Diseases**

- Cardiovascular (7b)
- Clinical Pharmacology/Drugs (7g)
- Endocrine (7f)
- Gastrointestinal (7c)
- Renal (7a)
- Reproductive (7d)
- Respiratory (7e)

**Student Research**


GSN Student Research (10a)

Medical Student Research (10b)

Other Student Research (10c)

**Teaching/Education (6)**

**Telemedicine (8a)**

**Other (8):** Describe: \_\_\_\_\_

6. List performance sites and indicate percentage of the work being performed at each site:

Performance Site	% of Work
USUHS (on-campus space and/or rented off-campus space)	_____
Other off-site location(s): _____	_____
_____	_____

7. What is the funding source?

USUHS  
 Extramural DoD (specify): \_\_\_\_\_  
 Extramural Non-DoD (specify): \_\_\_\_\_

8. Is there scientific or budgetary overlap with other research projects under your direction? If yes, explain on separate page.

Yes  No

9. Additional resources required for the conduct of this project have been identified and made available by the Chairperson. (Check those resources that apply)

Space  Personnel  Equipment

10. Does this project involve any classified information? (Please contact the USUHS security office for clarification)

Yes  No

*I certify that I will undertake the attached protocol if awarded and that assurance(s) will be obtained from the responsible individual(s) at the performance site(s) indicated before any work begins.*

\_\_\_\_\_  
Principal Investigator (signature)

\_\_\_\_\_  
Date

*I have reviewed this protocol, **approve the content**, and certify that adequate resources and facilities are available to support this research effort.*

\_\_\_\_\_  
Department Chair (signature)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Department Chair (signature)  
(Second chair's signature is required if two departments are involved.)

\_\_\_\_\_  
Date

---

Department Chair (signature) \_\_\_\_\_ Date \_\_\_\_\_  
(Third chair's signature is required if three departments are involved.)

## **ROLES AND RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS FOR RESEARCH PROJECTS**

When undertaking a research project, the Principal Investigator assumes numerous important responsibilities that include the preparation of the proposal, the compliance with appropriate assurance processes, the conduct and integrity of the scientific project and its close-out processes, and the subsequent dissemination of the research results.

### **The Principal Investigator is responsible for:**

#### **-the scientific soundness, accuracy, and completeness of the research proposal including**

Preparation of the technical research proposals or research fellowship applications;  
Submission of these proposals through REA with the proper scientific, statistical, and departmental review and the verification of the adequacy of the resources to conduct the research; and  
Coordinating proper review of any off-site research activity.

#### **-the scientific, ethical, and technical aspects of any resulting research project including**

Oversight of all activities in the laboratory and each study site involved;  
Training and education of all individuals working on the research project in such areas as laboratory safety, scientific rigor, data collection and management, and scientific integrity including, but not limited to, issues such as authorship, conflict of interest and commitment, and humans and animal subjects issues; and  
Understanding that research conducted at USUHS must satisfy not only the needs of the investigators but of the institution, society, and the funding agency.

#### **-the proper budgetary management of awarded funds including**

Authorizing the allocation and verifying the appropriateness of research costs as legitimate, allowable, and correct;  
Financial monitoring of accelerated expenditures, large unobligated balances, and over expenditures;  
Initiation and coordination of personnel actions for the research personnel;  
Re-budgeting in a timely and accurate way; and  
Ensuring that program income (if any) is returned to the research project.

#### **-compliance with the specific terms of the award and statues including**

Obtaining, maintaining, and adhering to all research assurances such as human subjects, animal care and welfare, radiation safety, hazardous chemicals, recombinant DNA, and biological substances;  
Compliance with terms including prior written approval for change in scope, foreign travel, equipment purchases and disposition, hiring, contracting, and re-budgeting; and  
Submitting interim and final scientific reports and other required reports to REA for submission to the funding organization.

#### **-protecting the University from legal liability related to the research project**

#### **-following other Federal regulations**

Such as those concerning proscriptions against lobbying, financial discussions with industry funding sponsors, and as specified in the USUHS Grant Terms and Conditions.

**Principal Investigator Signature:** \_\_\_\_\_

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