

USUHS FORM 3208A
ASSURANCE SUPPLEMENT FORM

(Special Programs)

REA Stamp

Project Number: _____
(REA will assign)

Project Title: _____
(Do not exceed 56 characters)

SECTION A: PRINCIPAL INVESTIGATOR INFORMATION

1. Name (Last, First, MI):			
2. Degree(s):			
3. Academic Title/ Military Rank			
4. Percent Effort on this project:	% (Effort on awarded projects and other activities may not exceed 100%)		
5. USUHS Department:			
6. Telephone:	Office:	Fax:	E-mail:
7. USUHS Building/ Room No.			
8. Off-Site Address:			
9. PI's Source of Salary:	<input type="checkbox"/> USUHS <input type="checkbox"/> AFRRRI <input type="checkbox"/> Henry M. Jackson Foundation (HJF) <input type="checkbox"/> Other Foundation (name): _____ <input type="checkbox"/> Other Federal/ Military (name): _____		
Billet No./Organization: (if known) _____			

SECTION B: SIGNATURES

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. As the Principal Investigator, I assume full responsibility for: 1) the scientific soundness, accuracy, and completeness of the research proposal, 2) the scientific, ethical, and technical aspects of any resulting research project, 3) the proper budgetary management of awarded funds, 3) complying with specific Sponsor terms and conditions and USUHS policies and 4) protecting the University from legal liability related to the research project as outlined in Appendix 1.

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.

USUHS Department Chair (signature)

Date

USUHS Department Chair (signature)

Date

(Second chair's signature is required if two departments are involved. If additional chair's signature is required, add additional sheet)

For REA use only

I have reviewed this protocol and approve the content..

USUHS Vice President for Research

Date

SECTION C: PROJECT INFORMATION

1. **Application Due Date:** _____
2. **Project Type:** New Competing Continuation Non-Competing Continuation Revision
3. **Is this a revised application?** Yes No **If yes, list the previous project number:** _____
4. **Anticipated Period of Performance:** Project Start: _____ Project End: _____

5. **List performance sites and indicate percentage of the work being performed at each site:**
- | | |
|--|-----------|
| Performance Site (Should not exceed 100%) | % of Work |
| USUHS (on-campus space and/or rented off-campus space) | _____ |
| Other off-site location(s): _____ | _____ |
| _____ | _____ |
| _____ | _____ |

6. **Funding source?**
Program Name: _____

7. **Does the Sponsor allow for indirect cost?** Yes No

8. **If yes what is the allowable rate?** **Percent (%)**

9. **Review Appendix 1 of the USUHS Form 3208 Guidelines, Project Description List. Choose a single category that best describes your project and enter the code and corresponding category below.**

- a. Code (number and letters, ie. 1a) _____
- b. Category (description, ie. Behavioral) _____
- c. Other (if your research does not fall into any of the categories listed) _____

10. **Select a single category that describes the science of this project:**
 Basic Science Clinical Science
 Other (Describe): _____

11. **Has additional resources (personnel, space, equipment), not covered by the funding of this research, required for the conduct of this project been identified and made available by the chairperson?** Yes No
(If yes, submit a letter from your chair outlining the resources)

12. **Does this project include USUHS paid employees?**
If yes, list the employees (Do not list yourself here) (Use an additional sheet if needed): Yes No
- | | | |
|-------|-------|-------|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

13. **Is there scientific or budgetary overlap with other research projects under your direction? If yes, explain on a separate sheet.** Yes No

14. **Does this project involve any classified information? (Contact the USUHS Security Office for guidance)** Yes No

15. **Does this project involve research with foreign entities? (Contact the Clinical Affairs Office for guidance)** Yes No

SECTION D: ASSURANCE COMPLIANCE

IRB

1. Does this project involve human research? *(including human cells, tissues or fluids, surveys or database use or development)* (Submit the USUHS Form 3204: *Research Involving Human Subjects (new or modification/addendum)* with the application to REA, Room A1032). Yes No
2. Does this project require immediate IRB review? *(no funds required or needs approval to accompany application)* Yes No
3. Does this project involve human research at a non-USUHS location(s), including AFRRRI? If yes, list the location(s) below: Yes No
- Location 1: _____
- Location 2: _____
- Location 3: _____

IACUC

4. Does this project involve animal research at USUHS? Yes No
5. Have you submitted the proper animal protocol form to DLAM? If yes, provide the Animal Protocol Title and number. Yes No
- Animal Protocol Title: _____
- Animal Protocol Number: _____
6. Check the applicable box and submit the form to DLAM.
- USUHS Form 3206 Animal Study Proposal Form
 - USUHS Form 3206A Animal Study Protocol *(annual review)*
 - USUHS Form 3206B Animal Study Protocol *(modification/addendum)*
 - USUHS Form 3206C Conveyance with Standard Animal Use Procedure
7. Does this project involve animal research at a Non-USUHS location, including AFFRI? Yes No
- If yes, list the location(s) below:
- Location 1: _____
- Location 2: _____
- Location 3: _____

BIOSAFETY

8. Do you require a Certificate of Environmental Safety to accompany this proposal submission? If yes, list labs to be used: Yes No
9. Do you require a Recombinant DNA approval to accompany this proposal submission? Yes No
10. Do you require a Radiation Safety approval to accompany this proposal submission? Yes No

Environmental Safety Certificate

11. Does this project involve any of the following safety hazards? (Mark all that apply) Yes No
- Biohazardous Chemicals
 - Class 3 or 4 Lasers
 - Human Blood, Tissue, or Body Fluids
 - Controlled Substances
 - High Intensity (>85 decibels) Sound
 - Other: _____
 - Dangerous Materials
12. Have you discussed this requirement with the Pharmacy? Yes No

Recombinant DNA or DNA

13. Does this project involve the use of recombinant preparations and/or CDC select agents? Yes No

Radioactive Materials

14. Does this project involve the use of radioactive materials? Yes No

Anatomic Materials Use Committee

15. Does your research involve the use of human cadaver material? Yes No

**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 statutes 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.