

REA Date Stamp

USUHS FORM 3203
ASSURANCE SUPPLEMENT FORM
 (annual non-competing continuation protocols, modifications, and addendum)

Project Number: _____

Project Title: _____

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"/> AFRI <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.

 Principal Investigator

 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

 Date

If researchers from two departments are involved in this project, the second chair's signature is also required. If a third chair's signature is required, add another sheet.

 (Second) Department Chair

 Date

SECTION C: PROJECT INFORMATION

1. Application Due Date: _____

2. Project Type: Non-Competing Continuation Supplemental Modification

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

Performance Site (must not exceed 100%)	_____ % of Work
USUHS (on-campus space and/or rented off-campus space)	_____
Other off-site location(s): _____	_____
_____	_____
_____	_____

4. Have 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)

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

6. Is there scientific or budgetary overlap with other research projects under your direction? Yes No
If yes, for an intramural protocol please explain on the USUHS Form 3211.

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

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

SECTION D: ASSURANCE COMPLIANCE

Please check "Change" if work will deviate from work previously approved and attach appropriate assurance forms, "No Change" if work will not deviate from work previously approved, or "N/A" if the assurance is not applicable. If a change is indicated, please attach the appropriate assurance forms.

IRB

	Change	No Change	N/A
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).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does this project require immediate IRB review? (no funds required or needs approval to accompany application)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Does this project involve human research at a non-USUHS location(s), including AFFRI? If yes, list the location(s) below:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Location 1: _____			
Location 2: _____			
Location 3: _____			

IACUC

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

BIOSAFETY

Environmental Safety Certificate

		Change	No Change	N/A
9.	Does this project involve any of the following safety hazards? (Mark all that apply) (If your protocol involves the use of biohazards, control substances or dangerous materials please complete the USUHS Form 3203 – Appendix 1.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/> Dangerous Materials			
	<input type="checkbox"/> Class 3 or 4 Lasers			
	<input type="checkbox"/> Human Blood, Tissue, or Body Fluids			
	<input type="checkbox"/> Controlled Substances			
	<input type="checkbox"/> High Intensity (>85 decibels) Sound			
	<input type="checkbox"/> Other: _____			
	<input type="checkbox"/> Extremely Hazardous Chemicals <small>(If you checked this box please attach a list.)</small>			
10.	Have you discussed this requirement with the Pharmacy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Recombinant DNA or DNA

		Change	No Change	N/A
11.	Does this project involve the use of recombinant preparations and/or CDC select agents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Radioactive Materials

		Change	No Change	N/A
12.	Does this project involve the use of radioactive materials? (If your protocol involves the use of recombinant preparations and/or CDC select agents please complete the USUHS Form 3203 – Appendix 2.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Anatomic Material Use Committee

		Change	No Change	N/A
13.	Does your research involve the use of human cadaver material?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>