

Protocol Modification Request Form

Oklahoma State University
Center for Health Sciences
1111 W. 17th Street

This form is to be used to request approval for modification(s) of previously approved IBC Protocols.

Changes in location of research facilities, personnel, as well as any significant modification to methods or biological materials subsequent to initial approval of a protocol must be reported to the IBC. The IBC will review the proposed changes to an investigator's previously submitted protocol to determine whether the changes alter the risk and/or biosafety level assessment.

FOR OFFICE USE ONLY

Date received: _____

IBC Protocol #: _____

☐ Approved

☐ Disapproved

Date Approved: _____

SECTION 1 – Administrative Information

- 1.1. Protocol #:
- 1.2. Principal Investigator (PI) name:
College/department: _____ Campus address: _____
Phone: _____ Fax: _____ E-mail: _____
- 1.3. Project title:
- 1.4. Date of original protocol approval: _____ Date of current protocol expiration: _____
- 1.5. Current approved biosafety level: ☐ BSL1 ☐ BSL2

SECTION 2 – Modification(s): Fill in ONLY where proposed changes apply.

- 2.1. **Renewal:** A renewal may be requested for an expiring protocol using this form PROVIDED the changes to the protocol are minor and can be documented in the following sections. Please justify below why a renewal is being requested.

2.1.1 Select Agent Protocols: If you are using this to meet the annual reporting requirements, indicate that below:

2.2. Biological:

Action	Classification	Specifics of Biomaterial
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	rDNA Hosts	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	rDNA Vector	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	rDNA Genes	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	rDNA Gene Sources	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	Infectious Agents	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	Toxins	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	Human/Primate blood/tissue/cell lines	
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify	Use of Animals	

2.3. Location of Facilities:

Action	Building	Room
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify		
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify		

<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify		
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2.4. **Equipment:** (autoclave, biosafety cabinet, etc.)

Action	Type/Specifications/Serial Number/Certification Date	Building/Room
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify		
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify		
<input type="checkbox"/> Add <input type="checkbox"/> Delete <input type="checkbox"/> Modify		

2.5. **Personnel:**

Action	Name	Address, Phone, E-Mail	Project Responsibilities
<input type="checkbox"/> Add <input type="checkbox"/> Delete			
<input type="checkbox"/> Add <input type="checkbox"/> Delete			
<input type="checkbox"/> Add <input type="checkbox"/> Delete			
<input type="checkbox"/> Add <input type="checkbox"/> Delete			

SECTION 3 – Experience:

- 3.1. If adding personnel, describe in narrative form their qualifications by documenting the relevant experience and training each individual has. Include the number of years of experience and the capacity in which this experience was gained. The PI should include a statement that he/she will bear direct responsibility for the training of all personnel and will ensure that every safety guideline is followed.

Each new individual must initial in Section 2.5. by their name to indicate they have read and understand the nature of the experiment(s) and the pertinent governing guidelines (including the USA Patriot Act—see Appendix F of the IBC Protocol Review/Approval Form.)

SECTION 4 – Scope of Work:

- 4.1. Summarize the work statement of the protocol and explain how the requested modification(s) will affect the scope of work.

SECTION 5 – Review of Risk Level and Biosafety Level:

- 5.1. Address whether or not the modification(s) described herein alter the risk level or the biosafety level of the protocol. Explain how the biosafety level will change and what precautions, decontamination, and disposal methods will be employed, as relevant.

SECTION 6 – PI Assurance and Signature

I attest that the information contained in this protocol modification request form is accurate and complete. I agree to comply with all requirements pertaining to the use, handling, storage, and disposal of biohazardous agents and recombinant DNA molecules as outlined in my approved IBC protocol and this modification request.

Principal Investigator Signature

Date