

Mentored Project IBC Registration Form

Form
MP

1. This form is to be used **only** for mentored awards for research already declared by the PI and approved by the Institutional Biosafety Committee.
2. Any deviations from the original IBC declarations must be noted below on this form.

<i>Name of Graduate Student:</i>	
<i>Name of Mentor (Principal Investigator)</i>	
<i>Department:</i>	
<i>Original Project Title: (PI's previous declaration – include GNT #)</i>	
<i>New Project Title:</i>	
<i>IBC Grant/Project Registration# (to be assigned by IBC)</i>	GNT-

Instructions:

1. Please review your mentor's original IBC documents while completing this form.
2. For YES/NO questions, please place an "X" in the box next to the correct answer.
3. Please submit all forms electronically as a Word or PDF attachment to Patty Bardeen and a signed copy by fax (274-0001) or by mail (RC Box 278878). **Signed copies must be maintained by the IBC per the National Institutes of Health.**
4. Questions? Contact Patty Bardeen, IBC Program Coordinator, at X52402

Please check applicable boxes.

1. Is there a UCAR associated with this protocol?

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
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If YES, what is the UCAR number? _____

2. *Please provide a summary outlining experiments done with each agent declared in Questions A-E. (i.e. cells, DNA, viruses, bacteria). This summary must outline the individual experiments proposed with each agent. You may paste it into this space or provide as a separate document.*

DO NOT cut and paste your grant abstract or your UCAR abstract, as it will not provide enough detail for the IBC review. Providing the specific aims of the project may be useful to provide perspective to the committee, however, submitting the aims without providing a summary of what you intend to do with each agent is no longer acceptable.

Failure to provide information detailing how each agent will be used will result in a SIGNIFICANT delay in your approval.

3. Has there been any changes or additions to the recombinant DNA constructs that differ from the original project?

YES		NO	
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If "YES", please describe in detail (i.e., for what purpose are they used and/or how they are administered to animals):

4. Has there been any changes or additions in the mammalian cells, cell lines, or mammalian unfixed tissues that differ from the original project? for what purpose they are used, or how they are administered to animals?

YES		NO	
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If "YES", please describe in detail (i.e., for what purpose are they used and/or how they are administered to animals):

5. Has there been any changes or additions in the pathogens that differ from the original project?

YES		NO	
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If "YES", please describe in detail (i.e., for what purpose are they used and/or how they are administered to animals):

6. Has there been any changes or additions in the mammalian viral vectors that differ from the original project?

YES		NO		N/A	
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If "YES", please describe in detail (i.e., inserts for this project, for what purpose are they used and/or how they are administered to animals) New vector systems must be registered using the Mammalian Virus Vector Registration Form (<http://www.safety.rochester.edu/ibc> under "Registration").

7. Does this project involve Select Agents? Please refer to <http://www.safety.rochester.edu/restricted/selectagent.html> for additional information.

YES		NO	
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8. Is there any new information or data available regarding the biohazardous agents or recombinant DNA used in this project which could affect biosafety considerations that differ from the original project? Please note that, as Principal Investigator you are required to share such information with the IBC immediately upon discovery.

YES		NO	
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9. Will your experiments involve flow cytometric sorting (**not analysis**) of viable cells?

YES		NO	
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Cell type with corresponding species of origin:

Potential contaminants (biologicals, radiologicals, hazardous chemicals) in preparation to be sorted:

Sorting equipment name and its location:

10. **Please list all names of laboratory personnel, including Principal Investigator. Reminder: All lab employees, including Principal Investigator, must complete laboratory safety training once per year.**

11. Criteria for review from the Fink Committee Report - The IBC will, as part of its protocol review process, consider whether experiments being proposed fall into any of the seven categories of experiments of concern. PIs are responsible for the initial assessment of their experiments in light of the Fink Report. For more information, please visit <http://www.nap.edu/books/0309089778/html>.

Please check the appropriate answer:

The Fink Committee identified seven classes of experiments that it believes illustrate the types of endeavors or discoveries that will require review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail.		
1. Would this experiment demonstrate how to render a vaccine ineffective? This would apply to both human and animal vaccines. Creation of a vaccine-resistant smallpox virus would fall into this class of experiments.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		
2. Would this experiment confer resistance to therapeutically useful antibiotics or antiviral agents? This would apply to therapeutic agents that are used to control disease agents in humans, animals, or crops. Introduction of ciprofloxacin resistance in Bacillus anthracis would fall in this class.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		
3. Would this experiment enhance the virulence of a pathogen or render a nonpathogen virulent? This would apply to plant, animal, and human pathogens. Introduction of cereolysin toxin gene into Bacillus anthracis would fall into this class.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		
4. Would this experiment increase transmissibility of a pathogen? This would include enhancing transmission within or between species. Altering vector competence to enhance disease transmission would also fall into this class.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		
5. Would this experiment alter the host range of a pathogen? This would include making nonzoonotics into zoonotic agents. Altering the tropism of viruses would fit into this class.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		
6. Would this experiment enable the evasion of diagnostic/detection modalities? This could include microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		
7. Would this experiment enable the weaponization of a biological agent or toxin? This would include the environmental stabilization of pathogens. Synthesis of smallpox virus would fall into this class of experiments.	<i>Yes</i>	
	<i>No</i>	
If Yes, please explain:		

If the any of the changes noted on this form require clarification, the IBC will contact you. The IBC reserves the right to request additional documentation.

Graduate Student/Mentor Affirmation:

By signing below, I certify that I have read the following statements and agree that my lab and I will abide by them.

1. All research involving rDNA performed in my laboratory will comply with the NIH Guidelines for Research Involving Recombinant DNA.
2. All research involving non-recombinant infectious agents performed in my laboratory will comply with the University’s adopted biosafety manual, the CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”.
3. All research performed in my laboratory involving materials that may contain bloodborne pathogens such as human blood will comply with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and with the University’s Exposure Control Plan.
4. All personnel have completed the University’s Laboratory Safety Training Program. **Required annually.**
5. All personnel have received training regarding your laboratory and agent specific guidelines **prior to working at the bench.** Annual refresher biosafety training that is research specific is required at least annually for lab personnel working at BSL-2 & higher. This training is documented including date of training, summary of training, signature of trainee, initials or signature of trainer. Safety information is available in the laboratory for referral or upon request by the Biosafety Officer.
6. All significant laboratory-related accidents and illnesses will be reported to the IBC immediately.
7. All employee injuries and/or exposures are reported to the University through the University’s Employee Incident Report Form.
8. The Principal Investigator is responsible for rapidly communicating new information or data to the IBC if that new information or data should reveal or strongly suggest that the anticipated safety or biohazard potential of the approved experiments or vector systems diverge significantly from what was originally anticipated. (For example, it may be determined that a replication-incompetent viral vector system in fact contains substantial levels of a replication-competent revertant virus, with the potential for human infection of transmission.)

Graduate Student Signature

Date

Mentor Signature (Principal Investigator)

Date

Revision Date: 6-22-07 [IBC SOP-03-03_Appendix XI]