



**University of Rochester  
Institutional Biosafety Committee (IBC)**

**Human Subjects Study Registration Form**

**This document is to be used for IBC registration of the following study types involving human subjects.**

1. Introduction of Recombinant DNA (plasmids) or gene transfer vectors (including virus vectors) into human subjects;
2. Introduction of genetically engineered micro-organisms into human subjects;
3. Infectious agents, deliberately introduced into human subjects (including live vaccines if they are experimental in nature and/or not FDA-approved for use in the specific study population)
4. The analysis of, or experimentation, with sera, blood products, or other specimens derived from humans in UR research laboratories or in those UR labs that are NOT accredited with the College of American Pathologists (CAP) or with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).  
**Note:** SMH and Highland Clinical Labs are CAP accredited. Therefore, if your clinical study ONLY involves using these labs (or a lab not associated with the University) for specimen analysis or experimentation, then you do NOT have to register with the IBC.

**ADDITIONAL documentation supporting your study may be required.** Please refer to the study type web page for the list of required supporting documents.

**SUBMIT** this form and supporting documentation in both electronic and paper formats to Patty Bardeen ([pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu)), IBC Program Coordinator, RC Box 278878.

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Principal Investigator: Dept: Phone:

Co-Principal Investigator: Dept: Phone:

Study Coordinator or Alternate Contact: Phone:

RSRB or WIRB#: IBC Grant Registration #: GNT-

Study Title:

Study Sponsor:

**1. Please check the applicable box indicating the type of study for which you are seeking IBC approval:**

	Introduction of Recombinant DNA (plasmids) or gene transfer vectors (including virus vectors) into human subjects
	Introduction of genetically engineered micro-organisms into human subjects
	Infectious agents, deliberately introduced into human subjects (including live vaccines if they are experimental in nature and/or not FDA-approved for use in the specific study population)
	This study DOES NOT involve the administration of a biological requiring IBC approval (listed above), but does involve the analysis of, or experimentation, with sera, blood products, or other specimens derived from humans in UR research laboratories or those UR labs that are NOT accredited with the College of American Pathologists (CAP) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). <b>Please skip to OSHA Training and complete form from that point to the end.</b>

**2. STUDY AGENT DESCRIPTION:**

A. Briefly describe the study agent that you will be administering to the human subjects and the biosafety level recommended by the sponsor or the federal government.

B. Does this study agent contain small informational polymers based on DNA, RNA (including antisense, RNAi/siRNA), or mimetics of DNA or RNA (PNA, LNA, etc)?

YES		NO	
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C. Do you expect these molecules to functionally suppress expression of the cognate gene?

YES		NO	
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If yes, please describe which genes will be regulated and the expected outcome.

For information related to potential long-term effects of siRNAs and related molecules, please see:

*Noma K., et al. Nature Genetics 36:1174, 2004.*

*Verdel A., et al. Science 303: 672, 2004.*

*Kawasaki, H. et al. Nature 431:211, 2004.*

*Morris, K.V., et al. Science 305:1289, 2004.*

D. Is the study agent a risk group 2 or 3 virus or bacterial vector?

YES		NO	
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If yes, please complete and submit the Mammalian Virus Vector Registration Form.

[www.safety.rochester.edu/ibc/ibcvirus.htm](http://www.safety.rochester.edu/ibc/ibcvirus.htm)

**3. AGENT ADMINISTRATION:**

A. Who is the Study Pharmacist?

B. Will anyone other than the Pharmacist and his/ her staff be involved in preparing the study material for administration?

YES		NO	
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If yes, please list their names.

C. Where will the study agent be administered? Provide the room number where the study agent will be administered.

D. How will the study agent be administered to the study participants? Describe the route of exposure.

**4. OSHA TRAINING:**

Complete the following table with the names of UR staff involved in this study correlated with their tasks (e.g. diluting or preparing study material, administering study material, collecting specimens for analysis) and their last date of safety training. Feel free to add lines to the table below.

**NOTE:** In many cases physicians and nursing staff may only have to provide their last date of completion for the SMH Annual In-Service. However, those individuals who centrifuge or manipulate blood (EXCLUDING phlebotomy), and physicians who also supervise laboratory staff must complete the Lab Safety Training as provided by Environmental Health and Safety.

Link to Environmental Health and Safety Lab Safety Training page: <http://www.safety.rochester.edu/ih/ihtmlabhome.html>

UR Employee Name	Tasks	Date of SMH Annual In-Service	Date of EH&S Lab Safety Training

**5. LABORATORY ANALYSIS or EXPERIMENTATION with STUDY PARTICIPANT SPECIMENS**

- A. What specimens will be collected from the study participants?
  
- B. Describe briefly the types of analysis or experiments that will be completed with each specimen derived from humans. Include the aims of the experiments/analysis.

- C. Will the proposed analysis or experiments involve infectious agents, human pathogens, mammalian virus vectors, genetically modified organisms, or recombinant DNA?

<b>YES</b>		<b>NO</b>	
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**If yes,** describe the agent and for what purpose it is being used. **NOTE:** the IBC reserves the right to request additional information or documentation regarding the biologicals declared under this section.

- D. Will UR laboratories be utilized for specimen analysis or any other laboratory aspect of the study (i.e. centrifugation, shipping)?

<b>YES</b>		<b>NO</b>	
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**If yes,** please list the Principal Investigators or Laboratory Directors of those laboratories.

**6. Principal Investigator Affirmation:**

By signing below, I certify that I have read the following statements and agree that my staff and I will abide by them. I understand that a site visit is part of the approval process. If there are any changes to the protocol, I understand that it is my responsibility to notify the Institutional Biosafety Committee in writing.

1. Studies involving human subjects will comply with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and with the University's Exposure Control Plan. <http://www.safety.rochester.edu/ih/bbpindex.html>
2. Studies involving recombinant DNA will comply with the NIH Guidelines for Research Involving Recombinant DNA and with the University's requirements for the applicable biosafety level. <http://www.safety.rochester.edu/ibc/biosftyrequireresource.html>  
<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>
3. Studies involving non-recombinant infectious agents will comply with the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" and with the University's requirements for the applicable biosafety level. <http://www.safety.rochester.edu/ibc/biosftyrequireresource.html>  
<http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>
4. All personnel have completed the SMH Annual In-Service and/or the University's Laboratory Safety Training (AS APPLICABLE). **Required annually.** <http://www.safety.rochester.edu/ih/ihlabhome.html>
5. All personnel have received training regarding the specific study agent. This training is documented including date of training, summary of training, signature of trainee, initials or signature of trainer.
6. All significant or potential exposures to the study agent 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. All Serious Adverse Events (SAE) as submitted to the Research Subjects Review Board (RSRB or WIRB) or NIH Office of Biotechnology Activities are also submitted to the IBC.
9. 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.)

Principal Investigator: \_\_\_\_\_

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

**If applicable:**

Co- Principal Investigator: \_\_\_\_\_

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

Revision date: 05-09-08 [IBC SOP-05-02\_Appendix II]