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

1. Clinical study which involves the introduction of Recombinant DNA (plasmids) or gene transfer vectors (including viral vectors) into human subjects with or without specimen analysis.

2. Clinical study which involves introduction of genetically engineered micro-organisms or infectious agents into human subjects (including live vaccines if they are experimental in nature and/or not FDA-approved for use in the specific study population) with or without specimen analysis.

Complete Form G INSTEAD of Form HS: If your clinical study will not involve the introduction of the above mentioned agents to human subjects, but sera, blood products or other specimens will be collected from the study participants which will be analyzed or experimented with in UR research labs.

http://www.safety.rochester.edu/ibc/doc/projectregform.doc

ADDITIONAL documentation supporting your study may be required. Please refer to the study type web page for the list of required supporting documents. http://www.safety.rochester.edu/ibc/ibchumanmenu#human

SUBMIT this form and supporting documentation in both electronic and paper formats to Donna Douglass (ddouglass@safety.rochester.edu), IBC Program Coordinator, RC Box 278878.

Useful references:
- UR Biosafety Requirements and Resources
- IBC web pages
- NIH Guidelines
- 5th edition of CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”

Bio-containment and safety questions can be referred to the Biosafety Officer jives@safety.rochester.edu

Revised: 11/26/14
University of Rochester Institutional Biosafety Committee
Human Subjects Studies Registration Form

Principal Investigator: Dept: Medicine Phone:
Co-Principal Investigator: Dept: Medicine Phone:
Study Coordinator or Alternate Contact: Phone:
RSRB or WIRB#: IBC Grant Registration #: GNT-
Study Title:
Study Sponsor:

➢ Declaration of Confidentiality:

Other than HIPAA restrictions, are any of the declared experiments subject to a confidentiality agreement with the sponsor? □ no □ yes

1. STUDY AGENT DESCRIPTION:

A. Briefly describe the study agent that you will be administering to the human subjects.

B. What is the biosafety level recommended by the sponsor or the federal government?
C. 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 |

D. Do you expect these molecules to functionally suppress expression of the cognate gene?

| YES | NO |

If yes, please describe which genes will be regulated and the expected outcome.

2. 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 |

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.
3. **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/ihlabhome.html](http://www.safety.rochester.edu/ih/ihlabhome.html)

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<th>UR Employee Name</th>
<th>Tasks</th>
<th>Date of SMH Annual In-Service</th>
<th>Date of EH&amp;S Lab Safety Training</th>
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4. **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?

| YES | NO |

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)?

| YES | NO |

If yes, please list the Principal Investigators or Laboratory Directors of those laboratories **AND PROVIDE A SUMMARY OF THE ACTIVITIES PERFORMED IN EACH LABORATORY.**
5. **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](http://www.safety.rochester.edu/ih/bbpindex.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.safety.rochester.edu/ibc/biosftyrequireresource.html) [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm](http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.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](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: 11/26/14 [IBC SOP-05-05_Appendix II]