University of Rochester

Form

HS

**Institutional Biosafety Committee (IBC)**

Human Subjects Study Registration Form (Form HS)

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

1. [Clinical study that involves the introduction of infectious agents or genetically engineered micro-organisms 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](http://www.safety.rochester.edu/ibc/ibchuman2.html)
2. Clinical study that involves the introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.), or cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects with or without specimen analysis.

See Section III-C-1 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules for a complete list, e.g. synthetic nucleic acid molecules that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

Please note:

If UR is the initial study site, IBC review and approval may take significant time for studies that involve:

1. A new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk;
2. The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or
3. The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for the IBC or RSRB to evaluate the protocol rigorously.

* Effective April 26, 2019, per the NIH Guidelines, the deliberate transfer of recombinant or synthetic nucleic acids into one human research participant, conducted under an FDA regulated individual patient expanded access IND or protocol, including for emergency use, does not need to be submitted to an IBC for review and approval.

**When to complete Form G instead of Form HS:**

* Yourclinical study will not introduce the above-mentioned agents to human subjects
* Blood, body fluids or other specimens will be collected from study participants and then analyzed by or used in experiments within UR research labs by non-clinical personnel. [www.safety.rochester.edu/ibc/doc/projectregform.doc](http://www.safety.rochester.edu/ibc/doc/projectregform.doc)

**SUBMIT** this form and supporting documentation (Study Protocol, Investigator’s Brochure, Informed Consent Form, etc.) in electronic format to Donna Douglass, IBC Program Coordinator (ddouglass@safety.rochester.edu).

Useful references:

* + - * [UR Biosafety Requirements and Resources](http://www.safety.rochester.edu/labbiosafe/biosftyrequireresource.html)
      * [IBC web pages](http://www.safety.rochester.edu/homepages/ibchome.html)
      * [NIH Guidelines](https://osp.od.nih.gov/biotechnology/nih-guidelines/)
      * [5th edition of CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)

Bio-containment and safety questions can be referred to the Biosafety Officer [srosen22@safety.rochester.edu](mailto:srosen22@safety.rochester.edu)

Revised: 9/9/2019

University of Rochester Institutional Biosafety Committee

Form

### HS

# *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#:

Study Title:

Study Sponsor: IBC Project Registration #: HS-(to be assigned by the IBC)

* Declaration of Confidentiality:

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

The Institutional Biosafety Committee’s meeting minutes may be made public upon request. Answering this question helps protect proprietary information.

1. **STUDY AGENT DESCRIPTION:**
2. Briefly describe the study agent that you will be administering to the human subjects.
3. What is the biosafety level recommended by the sponsor or the federal government?
4. 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 |  |

1. 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?

1. 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. NIH, OSHA, AND SHIPPING TRAINING:**

The Institutional Biosafety Committee is required to verify personnel have received appropriate training for recombinant or synthetic nucleic acids. For research lab personnel, that includes EHS Laboratory Safety Training ‘Chemical and Biological’ in MyPath.

Alternatives will be provided in the approval letter for this study – generally, this includes:

|  |  |
| --- | --- |
| Staff | Training |
| All | Read the Informed Consent Form and IBC Approval letter for this study |
| Clinical | SMH Annual In-Service (in MyPath) – not tracked by the IBC |
| Laboratory | EHS Laboratory Safety Training – Standard Chemical (includes OSHA’s Bloodborne Pathogens) (in MyPath) |
| Staff shipping human samples  - Category B infectious substances, or  - dry ice | EHS Shipping Biologicals and Dry Ice (in MyPath) or acceptable alternative |

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, shipping samples) and their last date of training. Feel free to add lines to the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| **UR Employee Name** | **Tasks** | **Date of EH&S Lab Safety Training** | **Date of Shipping Biologicals Training** |
|  |  |  |  |
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|  |  |  |  |

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

A. What specimens will be collected from the study participants?

B. 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.** **Note:** For screening/safety lab testing by UR clinical labs, it’s sufficient to say “screening/safety lab testing will be performed by UR clinical labs.”

1. Will the proposed analysis or laboratory experiments involve infectious agents, human pathogens, mammalian virus vectors, genetically modified organisms, or recombinant DNA? (note: this question does not refer to the study product)

|  |  |  |  |
| --- | --- | --- | --- |
| 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.

**5. Human Gene Transfer Protocols:**

* 1. Will the proposed experiments involve the transfer of recombinant or synthetic nucleic acid molecules, gene transfer vectors (including viral vectors), or cells that have been treated with nucleic acids or gene transfer vectors into one or more human research participants?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| YES |  | NO |  | Skip to Principal Investigator Affirmation if:   * you answered ‘no’ or * this is a vaccine study meeting previous NIH Guidelines M-III-A “human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected.” |

* 1. Will UR be the initial site for the study?

|  |  |  |  |
| --- | --- | --- | --- |
| YES |  | NO |  |

|  |  |
| --- | --- |
| **Information required** | **How Supplied** |
| 1. Clinical Study Protocol |  |
| 1. Investigator’s Brochure, including description of the product:    1. Derivation of the delivery vector system including the source (e.g., viral, bacterial, or plasmid vector); and modifications (e.g., deletions to attenuate or self-inactivate, encapsulation in any synthetic complex, changes to tropisms, etc.).  Please reference any previous clinical experience with this vector or similar vectors.    2. Genetic content of the transgene or nucleic acid delivered including the species source of the sequence and whether any modifications have been made (e.g. mutations, deletions, and truncations). What are the regulatory elements contained in the construct?    3. Description of any other material to be used in preparation of the agent (vector and transgene) that will be administered to the human research subject (e.g., helper virus, packaging cell line, carrier particles)    4. Methods for replication-competent virus testing, if applicable    5. Intended *ex vivo* or *in vivo* target cells and transduction efficiency    6. Gene transfer agent delivery method |  |
| 1. Adverse Event information    1. Publicly available Adverse Event Reports relating to the recombinant or synthetic nucleic acid molecule    2. Expected Adverse Events, based on pre-clinical information related to the recombinant or synthetic nucleic acid molecule (include whether or not this is a new preclinical model system) |  |
| 1. IBC laboratory registration, if applicable (L: form is required for all research laboratory spaces) |  |

**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 will comply with the University’s requirements for the applicable biosafety level. [www.safety.rochester.edu/ibc/biosftyrequireresource.html](http://www.safety.rochester.edu/ibc/biosftyrequireresource.html)
2. Studies will comply with OSHA’s Bloodborne Pathogens Standard (29 CFR 1910.1030) and UR’s Exposure Control Plan. [www.safety.rochester.edu/ih/bbpindex.html](http://www.safety.rochester.edu/ih/bbpindex.html)
3. Studies involving recombinant or synthetic nucleic acid molecules will comply with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). <https://osp.od.nih.gov/biotechnology/nih-guidelines/>
4. Studies involving non-recombinant infectious agents will comply with the CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”. [www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm](http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm)
5. All personnel have completed the SMH Annual In-Service and/or the University’s Laboratory Safety Training (AS APPLICABLE). **Required annually.** [www.safety.rochester.edu/ih/ihlabhome.html](http://www.safety.rochester.edu/ih/ihlabhome.html)
6. 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.
7. All significant or potential exposures to the study agent will be reported to the IBC immediately. All employee injuries and/or exposures are reported using UR’s Incident Report Form. [www.safety.rochester.edu/SMH115.html](http://www.safety.rochester.edu/SMH115.html)
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, a replication-incompetent viral vector system instead generates a replication-competent revertant virus.)

Principal Investigator: / Date:

**Signature Print**

**If applicable:**

Secondary PI: / Date:

**Signature Print**

**Please submit this form electronically as a Word e-mail attachment to the IBC Program Coordinator** [**ddouglass@safety.rochester.edu**](mailto:ddouglass@safety.rochester.edu)**. Also submit a copy of the signature page (last page) by fax (274-0001), e-mail, or mail (RC Box 278878).**

Revision date: 1/27/2021 [IBC SOP 05-Studies Involving Human Research Subjects]