Human Subject Studies that Require IBC Approval:

Clinical study which involves the 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

UR and IBC regulations require all investigators who plan to administer genetically-engineered micro-organisms or infectious agents to human research subject to register with both the IBC and the IRB, and to obtain approval from both review committees (as well as from relevant extramural committees such as the NIH Recombinant Advisory Committee) prior to initiating their studies.

The first step in obtaining IBC approval is the completion of the Human Subjects Study Registration Form (Form HS):

- Human Subjects Study Registration Form in PDF format
- Human Subjects Study Registration Form in Word format

In addition, the following supporting documents must be provided for the IBC:

1. Investigator Brochure
2. Clinical Protocol
3. Scientific abstract of study
4. Non-technical (lay) abstract of the study
5. Copy of RAC review/comments, if applicable
6. Investigator's responses to Appendix M of the NIH Guidelines, if applicable
7. Publicly available adverse events
8. Expected adverse events based on pre-clinical information related to DNA molecule
9. IBC laboratory registration, if applicable

Additional information may be required at the request of the IBC Chair.

**NOTE:** One copy of all required documents in both electronic and paper formats must be submitted to Donna Douglass (ddouglass@safety.rochester.edu), IBC Program Coordinator, RC Box 278878.

Follow-up activities by the IBC, upon receipt of complete documentation, will include protocol review/evaluation, as well as, (1) a survey of the facility where the study agent is stored/dispensed/administered, and (2) a review of study personnel training relevant to OSHA compliance. If study participant samples are used in a UR research lab, a Biosafety inspection will be need to be completed unless one has been done within the last year.
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**Reporting Requirements (including Adverse Event Reporting)**

All investigators must report all serious adverse events that are reported to the Research Subjects Review Board.

For more information, please click on the following link:

*Guidelines for Reporting Adverse Events and Submitting Reports from Data and Safety Monitoring Boards to the IRB*