

INSTRUCTIONS - FORM B -
Protocol for Use of
Recombinant DNA in Research
Version 4.0

Office of Animal Care and Institutional Biosafety
(OACIB)
Institutional Biosafety Committee
1737 West Polk Street (MC 672)
206 Administrative Office Building
Chicago, IL 60612
Phone: 312.996.1972 Fax: 312.996.9088
www.research.uic.edu

I. Instructions

Important: Important: Form B - Protocol for Use of Infectious Agents/Toxins in Research Form B must be completed by the investigator for all work that involves the use of an infectious agent without rDNA if project involves rDNA or rDNA transfected organisms then Form A - Protocol for Use of Recombinant DNA (rDNA) in Research Form A should be completed rather than Form B. Complete Form D if human gene transfer will be conducted. NO WORK WITH rDNA IS EXEMPT AT UIC.

A. General

The IBC must conduct a comprehensive risk assessment of the project in order to determine the appropriate containment level for the project and the appropriate practices and procedures that should be used in handling the agents. The risk assessment must take into account the following:

- Agent characteristics (e.g., virulence, pathogenicity, environmental stability)
- Types of manipulations planned
- Source(s) of the organism(e.g., species/strain)
- Nature of the inserted DNA sequences (e.g., structural DNA, oncogenes)
- Host(s) and vector(s) used
- Whether a foreign gene will be expressed and if so, the protein that will be produced
- Containment conditions to be implemented
- Applicable sections of NIH Guidelines

In order to aid the IBC in its assessment and avoid delays in approval, please follow these general rules for each protocol application and the specific instructions for each applicable section.

1. Please read each question and answer all items requested.
2. Be specific and complete in your answers. Vague, incomplete answers may result in additional information being required before protocol can be forwarded onto the committee for review and/or deferral following review.
3. Although all work in a laboratory that has a related purpose can be submitted on one protocol, note that protocols cannot be partially approved and review of higher category research could delay start of the protocol.
4. All Forms must be typed; failure to do so will result in return of the forms
5. All investigators that submit a protocol to the IBC must complete Appendix 1, Personnel and Qualifications.
6. Send the original completed form(s) for review and approval to: Office of Animal Care and Institutional Biosafety (OACIB) at the address listed above.
7. Investigators with questions regarding the completion of forms are encouraged to contact the OACIB.

B. Instructions for Form B

1. **Section I- Agent, Location, BSL, Shipping**
 - a. Indicate the name of the infectious agent/toxin and strain (if using more than one agent)

please complete a separate section I for each agent.

- b. Indicate the source of the infectious agent/toxin (e.g., ATCC Cultures, Dr. John Doe from University of XYZ).
- c. Indicate the amount and concentration or total volume of infectious agent being used.
- d. Indicate the LD50 (in humans) or infectious dose (in humans) if known.
- e. Indicate whether the infectious agent/toxin is a risk group (1-4) human pathogen, animal pathogen or plant pathogen.
- f. Indicate the pathogenicity or attenuation of each organism used if applicable.
- g. Indicate the location of **ALL** lab(s)/rooms in which the work will take place.
- h. Indicate in which animal facility animal work will take place and type of housing in which animals will be maintained.
- i. Indicate the location of **ALL** lab(s)/rooms in which the infectious agents will be stored.
- j. Indicate if the agent is a select agent. If so, contact the Environmental Health and Safety Office at 996-7411 for select agent registration.
- k. Indicate the highest biosafety level at which this agent will be used. If using more than one agent and they will be used at different biosafety levels, this must be indicated clearly on the form. Note that * refers to conducting project in facilities at the BSL indicated, but incorporating some or all procedures and practices from the next highest BSL.
- l. Indicate if any potentially infectious material will be shipped off campus, indicate so on the form, indicate where it will be shipped, and who is responsible for shipping.

2. **Section II- Purpose and Background-** This section must be completed for all protocols. Investigators should describe the purpose of their work in lay language. This is important, as the IBC is required to have two non-affiliated members on the Committee who are often non-scientists.

A LABORATORY-SPECIFIC BIOSAFETY MANUAL MUST BE COMPLETED AND SUBMITTED WITH ALL PROTOCOLS. For work conducted at BSL1 or BSL2, complete the appropriate biosafety manual template provided on IBC website. For BSL3, contact IBC office to discuss biosafety manual requirements. **FAILURE TO SUBMIT A MANUAL WITH THE PROTOCOL WILL RESULT IN PROTOCOL BEING REVIEWED.**

3. **Section III- Procedures-** Describe ALL procedures (**in vitro and in vivo**) that involve manipulation of the infectious agents. For animal work, indicate the agent to be administered, amount administered, the route of administration, where the work will be conducted, where the animals will be housed post-administration, the duration of experiment, and the biosafety level for this portion of the project.
4. **Section IV- Funding-** List all funding support for this protocol.
5. **Section V- Conflict of Interest-** List all potential financial conflicts of interest. *“Investigators” include the principal investigator, co-investigators, and any other person who is responsible for the design, conduct, or reporting of research. For conflict of interest guidance and information, please email COI@uic.edu or call 312/996-4070.*
6. **Section VI- Assurances-** All investigators must sign all assurances