

INSTRUCTIONS - FORM D -
Protocol for Use of
Recombinant DNA in Research-
Human Gene Transfer
Version 1.0

Office of Animal Care and Institutional Biosafety
(OACIB)

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I. Instructions

*Important: Form A - Protocol for Use of Recombinant DNA (rDNA) in Research Form A must be completed by the investigators for **ALL** work that involves the use of rDNA at UIC with the exception of human gene transfer. Complete Form D if human gene transfer will be conducted . NO WORK WITH rDNA IS EXEMPT AT UIC.*

A. General

The NIH Guidelines for Research Involving Recombinant DNA Molecules (*NIH Guidelines*) require the IBC to 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 inserted DNA (e.g., species)
- 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. Investigators are encouraged to submit separate protocols for work under each category so as to not delay approval of work in lower categories. Protocols cannot be partially approved.
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 D

1. Experiments involving rDNA that correspond to this category require IBC approval and additional approvals in order to be initiated.

- i. The deliberate transfer of rDNA, or DNA or RNA derived from rDNA into one or more human subjects. This includes both in vivo and ex vivo (transfer to cells in culture that are then transferred to a human subject).

Unless exempt under Appendix M-VI-A of the *NIH Guidelines*, a completed Appendix M must be completed and submitted to OBA for determination of RAC review.

If UIC is the initial performance site submitting to OBA, the following additional documentation must be submitted to the IBC with the IBC protocol prior to submission to OBA.

- Human Gene Transfer Appendix M
- Lay Summary (Same as submitted to IRB)
- Scientific Summary (Same as submitted to IRB)
- Detailed Clinical Protocol (Same as submitted to IRB)
- Clinical Investigator's Brochure, if available from sponsor. (Same as submitted to IRB)
- Specific Study Consent Document Template (Same as submitted to IRB)
- UIC Specific Study Consent Document (Same as submitted to IRB)

Final IBC approval will not be granted until review by OBA/RAC review and all correspondence from RAC has been submitted to the IBC for review.

If UIC is not the initial performance site, the following additional documentation must be submitted with the IBC protocol.

- Human Gene Transfer Appendix M
- All documentation/correspondence related to submission of Appendix M to OBA and RAC response (see comment below)
- Lay Summary (Same as submitted to IRB)
- Scientific Summary (Same as submitted to IRB)
- Detailed Clinical Protocol (Same as submitted to IRB)
- Clinical Investigator's Brochure, if available from sponsor. (Same as submitted to IRB)
- UIC Specific Study Consent Document (Same as submitted to IRB)

In addition to IBC approval, approval by UIC IRB will also be required. Protocols will not be scheduled for review by the IRB until documentation of submission to the IBC is provided. Final IRB approval will not be granted until the IBC has approved the study.

2. **Section II- Study Details-** Provide details related to study phase and RAC submission and review.
3. **Section III- Purpose and Scientific Background-** Attach Lay and Scientific Summaries. These should be the same documents submitted to the IRB.
4. **Section IV- Human Gene Transfer Agent (if applicable)-** Provide complete a description of the construct to be administered (gene, source, function, promoter, other elements); vector (any attenuation of vector, packaging), route of administration, vehicle, concentration(s)/volume(s), frequency of administration, number of doses, duration of experiment, adverse effects, and monitoring for shedding.
5. **Section V- Infectious Agent (if applicable)-** Provide complete a description of the agent to be administered, any attenuation of agent, route of administration, vehicle, concentration(s)/volume(s), frequency of administration, number of doses, duration of experiment, adverse effects, and monitoring for shedding.
6. **Section VI- Locations, BSL, Storage, and Shipping**
 - a. Section VIa- List all locations in which rDNA and/or infectious agents work will occur.
 - b. Section VIb- List all locations in which rDNA and/or infectious agents will be stored.
 - c. Section VIc- List highest BSL at which work will be conducted. 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.
 - d. Section VI d- 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.
7. **Section VII-** Provide a description of the biosafety procedures implemented as specified by the NIH guidelines, the UIC Biosafety Program Manual, and the Biosafety in Microbiological and Biomedical Laboratories, 5^h Edition from the CDC and NIH for preparation and administration of the agent.
8. **Section VIII- Funding-** List all funding support for this protocol.
9. **Section IX- 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.***
10. **Section X- Assurances-** All investigators must sign all assurances.