

Instructions for completing the UTHSC rDNA Registration Form

Each section of the rDNA registration form is color coded. Below is an explanation for the type of information that should be included in each section.

If you have general questions about completing the form, please contact the IBC Office (448-2871).

If you have specific questions regarding sections 7 and 8, contact the UTHSC Institutional Biosafety Officer, Francine Rogers (frogers@utmem.edu) in the Office of Research Compliance (448-3537).

Face Page

Principal Investigator / Co-Investigator: Self-explanatory

Institution: If UTHSC include the School i.e. School of Medicine, Dental School etc.

New: Registration is for new line of research – previously unregistered.

Amendment: Significant changes to an existing, approved registration. Changes result in a change in the experimental procedures, NIH experimental category or risk assessment.

Renewal: Every 3 years, previously registered work must be re-registered using this form.

Proposed dates: A project can be registered for 3 year intervals. After 3 years, if the research is still being conducted then the PI must complete a “renewal” registration (see above.) Be aware that NIH requires annual updates to be completed for the first and second years. You will receive a separate one-page form from the IBC office for annual updates. Failure to respond to the annual update will result in the termination of your approved research registration.

Project Title: The title should be descriptive of the project being registered. The title must be unique for each registration.

Supporting Agency: What agency is providing the funding for the research? If no support is available, indicate “None”.

Personnel: List *ALL* persons involved in the research. The alternative contact should be a person in the laboratory that knows the research that is being conducted within the lab (e.g. not an administrative assistant.).

Location of the Research: List all the locations including shared and departmental spaces. If animal work will be conducted within the animal facility, list the rooms in the Department of Comparative Medicine (DCM) where the research will be conducted.

Keywords:

An X should be placed in front of all the key words that correspond to components of the research.

Examples:

If you will be using *Escherichia coli*, place an X before the Prokaryote/Bacteriophage key word.

If you will be using HEK 293T cells, place an X before the human cells/tissues/blood.

If you are using rabies virus, place an X before the eukaryotic viruses.

Section 1:

The non-technical description of the proposed work should be a general description of the goals. Explain all acronyms or abbreviations since not all IBC members may be familiar with these terms.

Section 2:

2a - Sequence name: List the names of all the recombinant DNA or RNA sequences that will be used, including markers like green fluorescent protein etc.

Nature of the Sequence: Indicate the function of the gene or sequence (e.g. a kinase, reporter, cytoskeletal element, transporter, etc.).

2b. Will you be expressing a gene that is exogenous to the host? i.e. A human gene on a plasmid in *E. coli* or animal cells

2c. If yes, then discuss potential risks associated with the constructs in Section 7 and how those risks will be mitigated in Section 9.

Section 3: Prokaryotic

3a. List the bacteria and / or bacteriophage to be used. Provide strain designations (e.g. *E. coli* DH5 α).

3b. List the source (purchase or donation) where you obtained the organisms or phage. This should be a company (Invitrogen, Sigma) or an individual (J. Smith, UTHSC).

3c. Quantities over 10L are regulated by the NIH large-scale guidelines that may increase the biosafety containment depending on the material. Address the potential risks in Section 7 and mitigation in Section 8.

Section 4: Eukaryotic

4a. List all the eukaryotic organisms (non-animal) or cell lines used – use one line per entry i.e. *Candida albicans*, *Saccharomyces cerevisiae*, cell lines. Cell lines should include the name of the cell line followed by the species i.e. SF9 (insect), 293T (human)

4b. List the source (purchase or donation) where you obtained the organisms or cell lines. This should be a company (Invitrogen, Sigma) or an individual (J. Smith, UTHSC).

4c. List eukaryotic viruses

4d. List the source (purchase or donation) where you obtained the virus. This should be a company (Invitrogen, Sigma) or an individual (J. Smith, UTHSC).

4e. If you will be using viruses as vectors for rDNA procedures or if viruses will be studied, what fraction of the viral genome is present?

4f. List eukaryotic organisms used in multi-cellular form. List the species, strain and source.

4g-h. Are the organisms transgenic? If so, where did you obtain (e.g. the source) the transgenic?

Section 5: Vectors and Plasmids

All plasmids and vectors that will be used must be listed. The source of the vector is either the company where you purchased the material or the person and institution that gave you the material. The host for propagation should list all organisms or cells that will be used to propagate the plasmid or vector.

5a. Provide justification why a viral vector is necessary for the experiment versus using a non-infectious plasmid transfection system.

5b. List what genetic modifications have been made to the viral vector system to limit its infectivity, and explain why the deletions are significant to reduce infectivity or replication competency. For example – Adenoviral vectors have had the E1A and E3 gene deleted.

5c. List the tests that will be completed to assay for replication competent viral vectors. Will you be using any positive and negative controls containing wild-type virus? Please describe these as well. You must include a statement indicating that viral stocks will not be used until the vector preparation has been tested and shown to be free of replication competent virus.

Section 6: Experimental procedures in detail

This section is probably the longest section of the registration. This section should outline the proposed experiments. You do not need to include information on how to perform common molecular biological techniques but you must provide a general outline of the proposed studies (e.g. cDNA will be subcloned into plasmid X; the plasmid will be purified and transfected into cell line Y...). Writing “we will perform molecular biological techniques” is not sufficient. Also indicate what analysis will be performed on the samples? What manipulations will the samples undergo? Will any steps result in exposure of personnel to aerosols containing plasmids, viral vectors, etc? Will animal work be performed? Animal experiments should be outlined in this section.

Section 7: Risk Assessment

This section will also require time to write. You should perform a risk assessment of the materials and the techniques that will be used in the laboratory. What are the risks to laboratory workers? Simply writing “these experiments are low risk” is not sufficient. Realistically assess what activities could result in exposure of lab personnel to materials containing recombinant DNA or other materials used in the studies. The exposure does not have to cause death, or illness to be potentially hazardous.

Contact the UTHSC Biosafety Officer , Francine Rogers (frogers@utmem.edu; 448-3537) for help with this section. More information on conducting a risk assessment can be found in the

NIH Guidelines for rDNA Section II-A

(http://www4.od.nih.gov/oba/RAC/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261554)

and Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition Section II

<http://www.cdc.gov/OD/ohs/biosfty/bml5/bml5toc.htm>

Section 8: Biosafety practices and containment

Check off the appropriate containment levels for the proposed experiments. Be aware that human materials (including well characterized cell lines such as HeLa cells) must be handled with BL2 practices and containment per the OSHA Bloodborne Pathogen Standard.

This section is designed for you to describe the laboratory space and the procedures that will be followed to minimize exposure risks to personnel, the lab and the environment. Information on spill kits and signage are available under the Standard Operating Procedures on the Research Compliance web page (www.utm.edu/research/compliance). The NIH rDNA Guidelines and BMBL also have information that can be helpful in completing this section. Do not cut and paste this information directly but provide a lab and experimental specific description.

If samples will be transported between locations (e.g. between a lab and the animal facilities or between different buildings), provide a description of how the samples will be properly packaged and transported. Contact the UTHSC Biosafety Officer, Francine Rogers (fr Rogers@utm.edu; 448-3537) for shipping training.

Section 9: Occupational Health

9a. Use of human materials (this includes well characterized cell lines) requires enrollment with Occupational Health within 10 days of a job with the potential for exposure to these materials per OSHA. N-95 respirators are required in the adenovirus spill procedure approved by the IBC. Therefore, laboratories using adenovirus must enroll in Occupational Health and be medically cleared, trained and fit-tested for these respirators.

9b. Based on the Principal Investigator's risk assessment, is there a need for additional health surveillance such as vaccinations?

9c. Explain yes answers for 9b.

9d. Will serum from investigators or lab personnel be collected prior to experiments being conducted?

Signatures:

Initial submission for pre-review does not require signatures, but the PI and the Department Chair must sign the registration form prior to submittal to the Institutional Biosafety Committee for full review.

After full committee review, the project class and the approved biosafety levels are assigned by the IBC.