

Using recombinant DNA (rDNA) or Hazardous Materials with Animals. 11/2006

The UCHC is required, as a condition of both Institutional and individual PIs' funding, to comply with the [NIH Guidelines for Research Involving Recombinant DNA Molecules](#) (a.k.a. *NIH Guidelines*, *NIH rDNA Guidelines*, *nihG*). Use of rDNA must be either registered with the Institutional Biosafety Committee (IBC) or exempted to the *NIH rDNA Guidelines*. The contact person for doing this is the IBC Coordinator, Ron Wallace (rwallace@adp.uchc.edu, x3781), who can also tell you if your experiment is exempt or not. Sometimes people look at experiments and because they see they are safe, they reason that they are exempt to the NIH rDNA Guidelines. This is not always the case. Sometimes safe experiments are not exempt.

Your ACC Protocol (ACCprot) will be reviewed for human occupational health, safety and compliance issues by the IBC Coordinator, who is also the Biological Safety Officer (BSO). Those ACCprot that have human occupational health, safety and/or compliance issues must be approved by the BSO before the ACC will grant approval. These issues will mainly be for *in vivo* experiments, which are the purview of the ACC. Occasionally, *in vivo* issues transfer into the lab for *in vitro* analysis. Those *in vitro* issues that originate *in vivo* will also be addressed by the BSO. You will be notified by the ACC after the Committee meeting if such issues exist in your ACCprot and asked to contact the BSO with information, clarifications, to fill out an application for the IBC, or to fill out an ACC Safety Protocol (ACC SP). Please note that the IBC is a separate committee from the ACC. It is possible that you will be asked to fill out both forms for the ACC SP and for IBC registration. There has been confusion, because the BSO collaborates with PIs or designees on both documents, that after the BSO was encountered once, all of the requirements had been met. Please see that all of the requirements listed by the ACC in their review are addressed by their respective committees. Because funding can be linked to an actual ACC approval letter and is usually unlinked to an approval letter from the IBC, ACC approval is sometimes granted without prior IBC approval. However, in order to be in compliance, research must not start without both approvals.

The following is a partial list of experiments typical to ACCprot and modifications and their exempt or non-exempt status in the *NIH rDNA Guidelines*. Even if you know that your experiment is exempt, please document how this is true in your ACCprot to avoid being contacted by the BSO for verification and documentation.

Description of Experiment or Procedure	Needs IBC Registration	nihG Ex-empt	Notes for ACC Protocol
Transgenic (Tg) or Gene Targeted (GT) rodents will be constructed for you in the GTTF at UCHC.	X		Please make a table of all of your Tg/GT strains and indicate where they were constructed or from where acquired.
Tg or GT rodents will be acquired from a <i>domestic</i> institution or vendor.		X	Please make a table of all of your Tg/GT strains and indicate where they were constructed or from where acquired.
Tg or GT rodents will be imported from outside the US.	X		Please make a table of all of your Tg/GT strains and indicate where they were constructed or from where acquired.
You will construct your own Tg or GT rodent strains.	X		Please make a table of all of your Tg/GT strains and indicate where they were constructed or from where acquired.
You will cross Tg or GT rodent strains with other strains. *Not exempt, but in most cases your description in the ACC protocol/modification will become the IBC registration.	X*		Please make <i>another</i> table of all of your Tg/GT strain crosses. Please indicate if each parent was constructed using plasmids or viral vectors or if this is unknown. Please indicate if potentially hazardous sequences are incorporated into either parent.
You will transfer non-infected, non-transfected, non-Tg/GT eukaryotic cells into animals. If cells are human, see table below.		X	Please state in your ACCprot that the transferred cells are not recombinant or infectious unless they are human.
You will introduce rDNA into animals either directly or using viral vectors.	X		Please indicate this in your ACCprot.
You will transfer recombinant cells (transfected by any means) or that come from a Tg/GT animal into other animals.	X		Please indicate this in your ACCprot.
You will infect animals with recombinant, infectious organisms or viruses.	X		Please indicate this in your ACCprot.
You will transfer untransfected hESC into animals. (see table below)		X	Please indicate this in your ACCprot. ESCRO committee approval is required.
You will transfer recombinant hESC (transfected by any means) into animals. (see table below)	X		Please indicate this in your ACCprot. ESCRO committee approval is required.

Exemptions for Tg/GT animals are in Section III-E-3 and Appendix C-VI in the nihG. Most of the transfer of recombinant materials into animals experiments fall under Section III-D-4 of the nihG. The requirement for registering crosses of Tg/GT animals comes from a letter of clarification from NIH/OBA.

The following is a partial list of experiments typical to ACCprot that need safety documentation: either a sentence in the ACCprot, or an ACC SP (independent of an IBC registration).

Description of Experiment or Procedure	Needs ACC Safety Protocol?	Notes for ACC Protocol
Use of Ethyl Chloride spray (carcinogen). Check 'yes' for hazardous chemicals in Section 7 of the ACCprot.	No	State that you will use this in a chemical fume hood. If you cannot, please consult the BSO.
Use of paraformaldehyde or formalin in perfusion or fixation (carcinogen, sensitizer). Check 'yes' for hazardous chemicals in Section 7 of the ACCprot.	No	State that you will use this in a chemical fume hood. If you cannot, please consult the BSO.
Use of anesthetic gases (e.g., isoflurane [carcinogen]) with a chamber or other than with a vaporizer and scavenger. Check 'yes' for hazardous chemicals in Section 7 of the ACCprot.	No	State that you will use this in a chemical fume hood. If you cannot, please consult the BSO.
Use of toxicologically hazardous or <i>uncharacterized</i> chemical compounds and toxins. Check 'yes' for hazardous chemicals in Section 7 of the ACCprot.	Yes	Please define chemical acronyms using the full chemical name, the CAS# and/or supply the MSDS.
Use of ionizing and non-ionizing radiation producing instruments and/or radioactive materials	Not Typically	Please indicate whether or not you are in contact with the Office of Radiation Safety regarding this use.
Use of human or non-human primate tissues, blood or body fluids, including cultured human cell lines (e.g. hESC, HeLa, HEK 293, etc.) for transfer into animals or any other purpose.	Yes	Under the OSHA Bloodborne Pathogen Standard, Universal Precautions and/or BSL-2 containment must be used with animals that contact these materials.
Use with animals of organisms or viruses pathogenic for humans, animals or plants. This includes recombinant organisms and viruses, select agents and most viral vectors even if replication incompetent.	Yes	Please indicate the name(s) and strain(s) of the organism(s) or virus(es) and the time course of infection and clearing. You may also be required to register your lab with the CT Department of Public Health.
Use of disease carrying vectors (arthropods, etc.)	Yes	Please specify species/strain of vector and containment conditions.

A positive answer in both tables generally means that both requirements will need to be fulfilled. Because the IBC meets every two months (<http://ors.uchc.edu/bio/ibc/ibc.html>) it may be more efficient to prepare the IBC registration in advance or in parallel with the ACC protocol and ACC Safety Protocol. Please consult the biosafety web site or contact the BSO for details and answers to questions about this. In addition, if hESC are involved, please allow time for consideration by the ESCRO committee.