

Experiments Involving the Following Must be Registered with the IBC

- Pathogens affecting humans, animals or plants;
- Materials potentially containing human pathogens (e.g., unfixed human specimens, human blood; human tissue, tissue/fluids from experimental animals);
- Recombinant DNA molecules including virus vectors (for more information see Recombinant DNA Categories);
- Mammalian cells and cell lines (refer to Extended Help for Registering Mammalian Cells, Mammalian Cell Lines and Unfixed Tissue/Fluids);
- De novo generation of transgenic animals (using recombinant DNA technology to add foreign DNA or subtract a portion of the animal's genome)
 - Generation of de novo transgenic animals: Defined as the addition of foreign DNA or subtraction of a portion of the animal genome using recombinant DNA technology. Examples of recombinant DNA technology used to generate transgenic animals include (1) Direct microinjection of a chosen gene construct from another member of the same species or from a different species into a pronucleus of a fertilized ovum; (2) Insertion of the desired DNA sequence by homologous recombination into a culture of embryonic stem cells; (3) Use of a plasmid or virus to transfer genetic material into germ cells.
- Breeding or crossbreeding of animals which were originally created using recombinant DNA technology AND which are genetically different from each other;
- Backcrossing transgenic animals that were originally created using recombinant DNA with wild type animals;

NOTE: Animals are defined as belonging to the Kingdom Animalia and include more than animals approved under UCAR protocols.

- Introduction of recombinant DNA (plasmids) or gene transfer vectors (including viral vectors) into human subjects;
- 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);

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- The analysis of experimentation, with sera, blood products or other human specimens in UR research laboratories or those UR labs that are NOT accredited with the College of American Pathologists (CAP) or with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- Generation of transgenic plants. Contact the Biosafety Officer (<mailto:jives@safety.rochester.edu>).

All research involving the use of recombinant molecules or biohazards requires a minimum of Biosafety Level 1 containment.

Animal Subjects: All research involving the use of recombinant molecules or biohazards in whole animals requires both UCAR and IBC approval.

Human Subjects: Complete instructions for any research involving the introduction of recombinant molecules or biohazards into human subjects are available on the policies and procedures [involving human participants](#) page.

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