OCCUPATIONAL AND ENVIRONMENTAL HEALTH AND SAFETY
THE UNIVERSITY OF UTAH

FACT Sheet

How to Register with the Institutional Biosafety Committee (IBC)

All work with biological materials must be registered in BioRAFT, which can be accessed here. Non-exempt work must be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to the commencement of work.

PIs of work with biological materials will need to register their work with the IBC through BioRAFT.

The following categories require review and approval by the IBC.

- Non-exempt recombinant or synthetic nucleic acid molecules research.
- Studies using human or animals pathogens, including materials known to harbor pathogens (for example, blood from HBV-positive patients).
- Generation of de novo transgenic animals. The breeding of transgenic animals to generate additional transgenic offspring does not require IBC approval. Those transgenic animals that already exist or which have been purchased also do not require IBC approval.
- Work with Acute Biological Toxins.
- Human Subjects research involving the introduction of recombinant molecules or biohazards into human subjects: these studies must be approved by the IBC and by the IRB.
- Animal Subjects: All research involving the use of recombinant molecules or human or animal pathogens in whole animals requires both IBC and IACUC approval.

The following categories require administrative review and approval by the Biosafety Officer and/or IBC Chair.

- Materials potentially containing human pathogens (for example, unfixed human specimens, human blood).
- Work with human cell lines that are not well-characterized or require BSL 2 containment. This includes all cell and organ cultures of human origin (except well-established cell lines that have had comprehensive pathogen testing), human embryonic stem cells, and pluripotent cells and their derivatives.
- The administration of human or human primate cells (primary cultures and established cell lines) or tumors into whole animals requires both IBC and IACUC approval

1. For protocols that require IBC review and approval, PIs should initiate the protocol registration at least 2 months prior to the planned start date or expiration of approved protocols. After completing the General Laboratory Setup and Biological Registration Wizards in BioRAFT:
   a. For work with recombinant or synthetic nucleic acids, human or animal pathogens, materials that may harbor human pathogens, involve the generation of genetically modified animals, or work with acute Biological Toxins, PIs must complete the relevant surveys in BioRAFT.
   b. In addition, for work with biological toxins, the PI must submit a signed Toxin registration form for review, which can be found here. The completed forms must be attached to the Laboratory registration in BioRAFT.
   c. Laboratory-specific SOPs and Biosafety manuals must be provided for all work at BSL2 or higher. OEHS has developed a fact Sheet on writing a lab SOP that can be found here

2. Experiments involving deliberate transfer of rsNA into human subjects require the submission of the following.
    a. A completed and signed copy of the Human Gene Transfer registration form, found here.
    b. Training records for personnel involved in the study
    c. Vector Maps.
    d. Copies of the Informed Consent Documents.
    e. Copies of Caregiver Information Sheets (BSL2 protocols).
    f. One copy of any portions of FDA, IND correspondence that discussed safety issues and/or agent description information attached.
    g. Investigator's brochure.
3. Experiments involving deliberate transfer of pathogenic organisms into human subjects require the submission of the following.
    a. A completed and signed copy of the Biological materials in Human Subjects registration form, found here.
    b. Training records for personnel involved in the study
    c. Copies of the Informed Consent Documents.
    d. Copies of Caregiver Information Sheets (BSL2 protocols).
    e. One copy of any portions of FDA, IND correspondence that discussed safety issues and/or agent description information attached.
    f. Investigator's brochure.
4. Experiments involving the introduction of recombinant or synthetic nucleic acids or pathogens into animals must also be approved by the University of Utah *Institutional Animal Care and Use Committees* (IACUC). IACUC protocols will not receive final approval until IBC approval is obtained and OEHS staff will advise the IACUC staff of protocol status.
5. Experiments involving Select Agents (http://www.selectagents.gov/) must be registered by the CDC or USDA. These protocols must be submitted to the BSO or Associate BSO to begin the CDC/USDA registration process and for IBC approval.
5. Experiments that fall under the potential **Dual Use Research of Concern (DURC) guidelines** (http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern) must be registered with the IBC, and be reviewed by the University of Utah Institutional Review Entity (IRE) for risk assessment and mitigation, as necessary. The PI should contact the BSO or Associate BSO immediately experiments covered by these guidelines are considered.
6. After initial review of the protocols by the BSO, Associate BSO and designated members of the IBC, investigators may be asked to modify or correct protocols. A modified protocol should then be submitted for full IBC review. After full review additional changes may be requested. Failure to respond within 3 months of review will result in withdrawal of the protocol. Amendments to protocols after approval must be completed in BioRAFT: changes to Human gene transfer studies are made using the amendment form that can be found here.
7. Any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses must be reported to the Institutional Biosafety Committee (IBC), using the Incident Reporting template below.
8. If PIs are dis-continuing registered experiments or leaving the University, please submit the IBC Closure Notification Form found here, to the Biosafety Office.

Other Fact Sheets and Guidance

University of Utah Policy 3-300: University health and Safety Policy.

Principal Investigator Responsibilities

The University of Utah Biosafety Manual.

How to Conduct a Risk Assessment.

Biological Safety Cabinets.

Chemical Disinfectants