FACT SHEET

Responsibilities of Principal Investigators Working with Biological Materials

This fact sheet provides a summary of the responsibilities of Principal investigators (PIs) working with biological materials. A more detailed description can be found in the University of Utah Biosafety Manual.

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.

Principal Investigators (PIs) must:

1. Complete the General Laboratory Setup and Biological Registration Wizards in BioRAFT.
2. Register non-exempt research with recombinant or synthetic nucleic acid molecules (r-sNA), or hazardous biological agents or materials with the Institutional Biosafety Committee (IBC) prior to beginning experiments with these agents. If the PI is uncertain if their work is exempt from the NIH Guidelines or under University of Utah regulations they should contact the University of Utah Biosafety Officer (BSO), Dr. Neil Bowles, or Associate BSO, Derek Hedquist, at (801) 581-6950 or biosafety@OEHS.utah.edu. The BSO will provide PIs with letters confirming the exempt status of protocols, if requested;
3. Create a laboratory Biosafety Manual, as described in the CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, which should include laboratory-specific Standard Operating Procedures (SOPs) for all experiments involving biological agents, risk assessments for the agent, descriptions of personal protective equipment, procedures for using and decontaminating equipment, spill procedures and post-exposure plans, waste disposal and emergency equipment and practices. OEHS has developed a Fact Sheet on writing a lab SOP that can be found here.
4. Laboratories working with human blood, tissues or cells must create a laboratory-specific exposure control plan. This can be part of a Biosafety manual or a standalone document.
5. Ensure all lab personnel are trained and proficient prior to beginning experiments. The IBC will require documentation of training prior to final protocol approval;
6. Ensure that personnel receive refresher training annually for laboratory-specific, bloodborne pathogen, biosafety level (BSL) 2 and/or animal biosafety level (ABSL) 2 training, as applicable. The IBC will require documentation of training prior to final protocol approval;

7. Avail their lab(s) to audits/inspections;
8. Review and respond to IBC review and audit questions and findings;
9. Submit amended protocols when there are changes in lab personnel, agents used, the location of experiments, and any changes that may alter the risk-assessment of the approved protocol. For human gene transfer experiments changes to the risk assessment and/or to the risk section of the informed consent document will need to be submitted as an amended protocol: all other revisions to the informed consent document should be provided to the IBC after the document has been approved by the University of Utah Institutional Review Board (IRB);
10. Conduct an annual review of laboratory-specific SOPs and IBC registrations.
11. Re-register every 3 years for continuing experiments, or at intervals determined by the IBC and/or OEHS; and
12. Enforce adherence to all health and safety procedures in the approved protocol(s) and SOPs.

NIH has produced a useful brochure that describes the Investigator Responsibilities under the NIH Guidelines, called "Investigator Responsibilities under the NIH Guidelines for Research Involving Recombinant DNA Molecules" (National Institutes of Health Office of Biotechnology Activities)

For more information regarding investigator responsibilities, please see the University of Utah's Research and Integrity guidelines

Other Fact Sheets and Guidance

- University of Utah Policy 3-300: University Health and Safety Policy.
- The University of Utah Biosafety Manual.
- The University of Utah Exposure Control Plan
- Templates for Laboratory-Specific Biosafety Manuals or Exposure Control Plans
- How to Conduct a Risk Assessment.
- Biological Safety Cabinets.
- Chemical Disinfectants

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