

## ***IBC Training Policy***

*Approved by IBC 1/4/2013*

It is the policy of the University of Chicago Institutional Biosafety Committee (IBC) that all investigators, technicians and students involved with research activities described on a given IBC Protocol be appropriately trained to mitigate research-associated risks as well as to ensure compliance with applicable local, State and Federal regulations and guidelines. This training will include IBC-mandated training elements, developed and provided by the Office of Research Safety (ORS) as well as lab-specific training, provided by the Principal Investigator (PI) for each of his/her IBC research protocols.

As part of the UC IBC risk management process, it is the responsibility of the PI to assess research-associated risks; this risk assessment process is facilitated and documented through completion of the UC AURA-IBC system. The PI must also ensure that all lab personnel named as staff member on the IBC protocol are sufficiently trained to safely work with the biohazardous materials and that each staff member is aware of what to do in the event of spills or exposures to potentially infectious materials. Accordingly the PI is responsible for the following:

- Ensure that each staff member is aware of the specific risks associated with the work to be conducted, as described in each IBC protocol.
- Ensure that each staff member has been trained and has demonstrated that they can safely perform the procedures as described in that protocol.
- Ensuring that each staff member listed on the PI's IBC protocols have completed the training required by the IBC as outlined in this Policy.
- Ensuring that each staff member has completed any additional training identified by the IBC during its risk assessment of the research project.

**ORS staff is available to assist the PIs in the training of their staff.**

---

### **Rationale for the Training Policy:**

Laboratory safety begins with a comprehensive assessment of risks posed by research reagents and associated lab activities as well as an assessment of compliance issues associated with research conducted within that lab. An important component of this risk assessment process is the identification of laboratory safety issues that can only be mitigated through appropriate training. The responsibility to perform this assessment is a shared responsibility, beginning with the principal investigator and augmented by the risk assessment performed by the IBC during the protocol review process. This process is concluded with implementation within the lab of the risk mitigation requirements (including required training) and recommendations articulated by the IBC as part of the IBC Protocol approval process.

It is obvious that educating UC student, investigator scientists, and research staff about the risks associated with their research activities, as well as how to mitigate these risks, is a responsibility and an ethical obligation. However, training activities are also required by Federal and State laws and Guidelines [e.g. OSHA Laboratory Standard (29CFR1910.1450), OSHA Bloodborne Pathogens Standard (29CFR1910.1030), CDC Select Agent Regulation (42CFR73.10(c)), CDC *Biosafety in Microbiological and Biomedical Laboratories*-5<sup>th</sup> edition, *NIH Guidelines* (IV-B-1-h), DOT Shipping Infectious Substances (49CFR172.704(a),49CFR173.134, 49CFR173.199(e)].

**Failure to comply with these training requirements places the UC at risk for the imposition of monetary fines, the potential loss of research funding and even criminal penalty.**

A comprehensive laboratory safety training program involves specialized training elements (Biosafety Courses offered by the ORS) as well as lab or project-specific training elements provided by each PI. The final determination of which of the available Biosafety Courses (listed below) is/are required for staff associated with a given protocol is made by the IBC during their review of the IBC Protocol submission. The training programs currently offered by the ORS and when they are required are described below.

### **COURSES AVAILABLE from CHALK and from the OFFICE OF RESEARCH SAFETY**

**Recombinant DNA at BSL-1 Course:** This training module is required for all personnel listed on an IBC protocol that describes work managed at BSL-1 utilizing recombinant or synthetic nucleic acids (as defined in the *NIH Guidelines*). Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

**Recombinant DNA at BSL-2 Course:** This training module is required for all personnel listed on an IBC protocol that describes work managed at BSL-2 with or without the usage of recombinant or synthetic nucleic acids. This includes work with transactive or infectious proteins and biological toxins regulated by the IBC. If a protocol includes both BSL-1 and BSL-2 work, this course will satisfy both requirements. Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

**Viral Vectors Course:** This training module is required for all personnel listed on an IBC protocol that describes work utilizing viral vectors (both replication-competent and replication-defective) regardless of the biosafety level used to manage them. Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

**Biological Toxins Course:** This training module is required for all personnel listed on an IBC protocol that describes work with any of the toxins regulated by the IBC. Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

**Review of the Human Gene Transfer Trial NIH Review Process and the other resources available for Human Gene Therapy research:** This material, found on the IBC website (<http://researchadmin.uchicago.edu/ibc/>), must be reviewed by all personnel listed on an IBC protocol describing the use of human subjects for a gene transfer study.

**OSHA Blood Borne Pathogen Training:** This training is required for all personnel listed on an IBC protocol that describes work with human (or non-human primate) cells, blood or tissues. Each individual shall complete this course annually as stated in the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030).

**DOT/IATA Shipping of Infectious Substances:** This training is required when shipping infectious substances categorized as Class 6.2 dangerous goods by the Department of Transportation (DOT) and the International Air Transport Association (IATA). Anyone shipping Category A, Category B or Exempt samples will be required to receive this training module ([http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Transporting\\_Infectious\\_Substances\\_brochure.pdf](http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Transporting_Infectious_Substances_brochure.pdf)). The PI may choose to designate only a subset of individuals listed on the IBC protocol to fulfill this role for the entire laboratory. These individuals must be trained and certified to package and ship infectious substances and will be the only ones allowed to perform this role for the laboratory. Each individual responsible for shipping infectious substances shall complete this course every two (2) years as required by the IATA Dangerous Goods Regulations.