The University of Tulsa Institutional Biosafety Committee – GENERAL POLICY

PURPOSE

The University of Tulsa's Institutional Biosafety Committee is responsible for reviewing and approving those research and teaching activities conducted by faculty, staff, students and/or visiting scientists on University of Tulsa property, and/or under the control of The University of Tulsa faculty, staff or students, that involve the use of recombinant DNA molecules or synthetic nucleic acid molecules.

***NIH Guidelines* (April 2019) states, "The purpose of the *NIH Guidelines* is to specify the practices for constructing and handling:**

1. recombinant nucleic acid molecules,
2. synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and
3. cells, organisms, and viruses containing such molecules"[1]

POLICY

It is the policy of the University of Tulsa that all research involving the use of recombinant DNA molecules or synthetic nucleic acid molecules be conducted safely and consistent with regulatory requirements. All such research must be submitted in advance to the University's Institutional Biosafety Committee for review and approval.

"As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the *NIH Guidelines*."[2]

Federal Guidelines established by the National Institute of Health, require that institutions conducting or sponsoring research, within the United States (U.S.) or its territories, using recombinant DNA molecules or synthetic nucleic acid molecules covered by the *NIH Guidelines*, be responsible for ensuring that the research is conducted in full conformity with the provisions of the *NIH Guidelines*. In order to fulfill this responsibility, The University of Tulsa has established an Institutional Biosafety Committee (IBC) charged with oversight responsibilities for all research related activities involving recombinant DNA molecules or synthetic nucleic acid molecules.

This policy shall be interpreted to be consistent with the *NIH Guidelines*. To the extent that this policy conflicts with the *NIH Guidelines*, including updated versions of the *Guidelines*, or other NIH guidance, that agency guidance shall govern except where this policy permissibly implements more stringent requirements.

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[1] Department of Health and Human Services, National Institutes of Health, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), April 2019), at 10.
[2] *Id.* at 11.

*Note: "The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant or synthetic nucleic acid molecules cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to the specifics."[3] The TU IBC (through the IBC Chair or chair designate) shall decide at its discretion, what items to bring in front of a convened meeting of the TU IBC.

DEFINITIONS

In the *NIH Guidelines for Research Involving Recombinant and synthetic Nucleic Acid Molecules*, recombinant and synthetic nucleic acid molecules are defined as:

1. molecules that a) are constructed by joining nucleic acid molecules, and b) that can replicate in a living cell (i.e. recombinant nucleic acids);
2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids); or
3. molecules that result from the replication of those described in (1) or (2) above.[4]

RISK GROUPS

Risk assessment is ultimately a subjective process. The investigator must make an initial risk assessment based on the Risk Group (RG) of an agent (see **Appendix B**, *Classification of Human Etiologic Agents on the Basis of Hazard*).[5]

Classification of agents in **Appendix B**, *Classification of Human Etiologic Agents on the Basis of Hazard*, is based on the potential effect of a biological agent on a healthy human adult and does not account for instances in which an individual may have increased susceptibility to such agents, e.g., preexisting diseases, medications, compromised immunity, pregnancy or breast feeding (which may increase exposure of infants to some agents).[6]

Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following criteria:[7]

[3] *Id.* at 26 (emphasis added).
[4] *Id.* at 10.
[5] *Id.* at 13.
[6] *Id.*
[7] *Id.*

Basis for the Classification of Biohazardous Agents by Risk Group[8]

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)

BIOSAFETY LEVELS

The same regulatory groups - Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH), have created Biosafety Levels (BSL) that define a set of laboratory practices, facilities and equipment that are appropriate to contain and safely work with the different Risk Groups. The determination of appropriate biosafety level for a project or for a laboratory is made by evaluating the agents in use and the specific procedures and experiments being performed with those agents. Unless specified by regulation, the determination of Biosafety Level for a project or laboratory is made by the University of Tulsa IBC in conjunction with the PI. In general, the Biosafety Level will be the same as the highest Risk Group for the agents involved.

The following table below gives an overview of Biosafety Levels. See the **CDC BMBL 5th Edition, 2009** link for a detailed description of Biosafety Levels: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

[8] *Id.* at 42 (Appendix B, Table 1)

Biosafety Level (BSL)

- Prescribe procedures and levels of containments for the particular agent used
- Four BSLs - **BSL-1 to BSL-4** based on risk assessment

Biosafety Level	Risk Group	Examples
BSL-1	Individual Risk: LOW Community Risk: LOW	*Escherichia coli*, K12 based strains Baculovirus
BSL-2	Individual Risk: MODERATE Community Risk: LOW	*Salmonella* *Staphylococcus* Hepatitis B And C Viruses Adenoviruses
BSL-3	Individual Risk: HIGH Community Risk: MODERATE	*Mycobacterium tuberculosis* Yellow fever virus
BSL-4	Individual Risk: HIGH Community Risk: HIGH	Ebola virus Herpes B or Monkey B virus

Containment refers to the safe work practices, equipment and facility design used to reduce or eliminate exposure to laboratory personnel, other persons, and the outside environment to potentially hazardous material. Four biosafety levels (BSL/BL) that describe increasing levels of containment are defined in both the Centers for Disease Control and Prevention's Biosafety in Microbiological and Biomedical Laboratories and the NIH Guidelines.

Dual Use Research of Concern is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. These should be considerations when determining procedures and Biosafety Levels (BSL),

TU IBC TRAINING REQUIREMENTS

Federal Guidelines established by the National Institute of Health, require that institutions conducting or sponsoring research using recombinant DNA molecules or synthetic nucleic acid molecules covered by the *NIH Guidelines*, be responsible for:[9]

1. Ensuring that the IBC has adequate expertise and training (using *ad hoc* consultants as necessary); and

[9] *See id.* at 26-27.

2. Providing appropriate training for the IBC Chair and members, principal investigators (PI), and laboratory staff (faculty, staff and students).

3. The Institutional Biosafety Committee Chair is responsible for ensuring that IBC members are appropriately trained.

4. The Institutional Biosafety Committee is responsible for ensuring that the Principal Investigator has sufficient biosafety training,

5. The Principal Investigator is responsible for ensuring that their laboratory staff are appropriately trained.

6. Under certain circumstances, additional training may be required (e.g. Responsible Conduct in Research (RCR) training for research studies funded by the National Science Foundation (NSF)).

7. All investigators, staff and students working on projects involving recombinant DNA molecules or synthetic nucleic acid molecules must successfully complete the following CITI Program Biosafety courses:
   - "Basic Biosafety Training for Investigators, Staff & Students" and
   - "NIH rDNA Guidelines"

   CITI IBC training completion certificates should be submitted at the time of protocol submission or emailed to the Research Compliance Coordinator for confirmation at carmen-schaar-walden@utulsa.edu .

For IBC training see:

www.citiprogram.org

https://utulsa.edu/research/office-research/research-compliance/research-compliance-training/ibc-training/

THE IBC

The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing **Appendix L**, *Physical and Biological Containment for Recombinant or Synthetic*

Nucleic Acid Molecule Research Involving Plants, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing **Appendix M**, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*, require Institutional Biosafety Committee prior approval.

No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

The IBC is authorized to create specific procedures that relate to the operation of the program. The IBC's authority is granted by the Institutional Official, the Vice President for Research. The IBC has the authority to act independently to bind all activities falling under its purview.

THE BIOLOGICAL SAFETY OFFICER (BSO)

When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or at a Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (For further information, see *NIH Guidelines* **Section IV-B-3**, *Biological Safety Officer*).

Currently The University of Tulsa does not conduct research activities that meet the criteria needed to appoint a Biological Safety Officer (BSO).

IBC RESPONSIBILITIES AND FUNCTIONS per NIH GUIDELINES:

1. Reviewing and approving those research and teaching activities conducted by faculty, staff, students and/or visiting scientists on University of Tulsa property, and/or under the control of The University of Tulsa faculty, staff or students, that involve the use of recombinant DNA molecules or synthetic nucleic acid molecules.

2. Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.

3. Lowering containment levels for certain experiments as specified in *NIH Guidelines* **Section III-D-2-a**, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.*

4. Setting containment levels as specified in *NIH Guidelines* **Sections III-D-4-b** , *Experiments Involving Whole Animals*, and **III-D-5**, *Experiments Involving Whole Plants.*

5. Periodically reviewing recombinant or synthetic nucleic acid molecule research conducted at the institution to ensure compliance with the *NIH Guidelines.*

6. Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research.

7. Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator.

8. The Institutional Biosafety Committee may not authorize initiation of experiments, which are not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the RAC when required) establishes the containment requirement.

9. Performing such other functions as may be delegated to the Institutional Biosafety Committee under **Section IV-B-2**, *Institutional Biosafety Committee*.

SUBMISSIONS BY THE PRINCIPAL INVESTIGATOR (PI) TO THE IBC per NIH GUIDELINES:

1. Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;

2. Select appropriate microbiological practices and laboratory techniques to be used for the research;

3. Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under *NIH Guidelines* **Sections III-A, III-B, III-C, III-D** or **III-E** (*Experiments Covered by the NIH Guidelines*), to the Institutional Biosafety Committee for review and approval or disapproval; and

4. Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project (e.g. submissions of Annual Progress Reports, modification requests, incident reports, or any other type of project correspondence as needed).

5. The principal Investigator shall:
    - Initiate or modify **no** recombinant or synthetic nucleic acid molecule research which requires IBC approval prior to initiation until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the *NIH Guidelines*;
    - Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
    - Ensure that laboratory staff have completed the required general IBC training courses on CITIProgram.org ("Basic Biosafety Training for Investigators, Staff & Students" and "NIH rDNA Guidelines") and forward their completion reports to the Research Compliance Coordinator for confirmation. See TU IBC training requirements.
    - Investigate and promptly report any significant problems pertaining to the operation and implementation of containment practices and procedures, including violations of the *NIH Guidelines* or any significant research-related accidents and

illnesses, in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH OSP, and other appropriate authorities.

- Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials.
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).
- Comply with reporting requirements for human gene transfer experiments conducted in compliance with the *NIH Guidelines* (see *NIH Guidelines* **Appendix M-I-C**, *Reporting Requirements*).
- Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination.
- Comply with shipping requirements for recombinant or synthetic nucleic acid molecules (see *NIH Guidelines* **Appendix H**).

NONCOMPLIANCE

Strict adherence to current biosafety policies and practices ensures the safety of workers and compliance with government regulations and guidelines. Noncompliance may jeopardize the ability of the institution to obtain federal funding or result in suspension of work of all federally funded research. Grantees and contractors must be prepared to demonstrate that proper practices and procedures are in place.

REVIEW OF THIS POLICY

The TU IBC will review this policy every four years or when circumstances require immediate review.

Approved by: Estelle Levetin Date Approved: 10-1-19
TU IBC Chair

https://utulsa.edu/research/office-research/research-compliance/research-compliance-training/institutional-biosafety-committee/

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf