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Section 1: Introduction

1.0 Purpose

It is the responsibility of the University of Denver (DU) Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in all teaching, research, or testing activities conducted by University facilities or research personnel. The Institutional Biosafety Committee Policies and Procedures Manual (IBC Policies) provides a review of the relevant regulatory and local requirements. Since laboratory work can involve exposure not only to recombinant or synthetic nucleic acid molecules and biohazardous agents, materials and toxins, but also to chemical and radiological hazards, the IBC Policies should be used in conjunction with any other pertinent University policies and procedures.

1.1 Mission Statement

Ensure the University safeguards human health and the environment by maintaining an adherence with the ***NIH Guidelines*** for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) and the Biosafety in Microbiological and Biomedical Laboratories (BMBL), and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC).

Through a balance of outreach and support for research personnel, the IBC will:

- Ensure activities meet the ethical and legal requirements for the responsible use of recombinant or synthetic nucleic acid molecules, biohazardous agents, materials and toxins.
- Establish policies and make recommendations to the University regarding such activities.
- Minimize risks to the research personnel, community and the environment by educating the University community regarding the regulatory requirements for the use of recombinant or synthetic nucleic acid molecules, biohazardous agents, materials and toxins.

1.2 Charge and Authority of the IBC

The Institutional Official (IO) has charged the IBC with review, approval and oversight of research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in research and teaching activities. Responsibilities of the

IBC include assessment of facilities, procedures, practices and training of research personnel to assure compliance with NIH/OBA and other pertinent guidelines and regulations. To successfully carry out these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

The IBC has been charged in the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins. The IBC makes certain that research conducted at the University is in compliance with the NIH Guidelines, BMBL, and the HHS regulations, and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, drafts campus policies and procedures, and reviews individual research proposals using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins. Since the University receives NIH funding for research involving recombinant or synthetic nucleic acid molecules, all activities involving recombinant or synthetic nucleic acid molecules must follow the *NIH Guidelines*. Failure to adhere to these guidelines can result in suspension or termination of NIH funding, or to a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecules projects at the institution. The IBC is therefore responsible for establishing and implementing policies that provide for the safe conduct of research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins to ensure adherence with *NIH Guidelines*. IBC responsibilities with regards to activities involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins are specified in the *NIH Guidelines*. Also, as delineated in the IO's charge to the IBC, the committee is given authority to oversee all research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins including suspension or termination of research that does not comply with IBC Policies.

1.3 Committee Composition (Section IV-B-2-a-(1)
The Provost delegates the IO authority to appoint the chair, IBC members and alternates as needed. Members consist of faculty, research personnel, and the community. The term of the Chair is recommended for a minimum of 4 years. Members will be evaluated annually by the IO and Director of Research Integrity & Education. They will be evaluated on satisfactory attendance, their preparation for each meeting by reviewing the submitted research, and if they have effectively contributed.

Members who serve on the IBC and take a sabbatical during their term on the committee will have the following options:

- An alternate will be selected from their department to serve as voting member during the duration of the sabbatical.
- Resign from the committee and a new member from their department would be assigned as the new member, or
- Continue to serve as a voting member and participate in the committee deliberations via conference call or in person, if applicable.

Members will collectively have appropriate expertise and experience in the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents or

toxins. They must have expertise in assessment of risk to environment and public health along with knowledge of institutional commitments and policies, applicable law, professional standards, community and environment. The IBC will have no fewer than five members who will be composed of the following:

- At least one member with expertise in recombinant or synthetic nucleic acid molecules technology.
- At least one member with expertise in biological safety and physical containment.
- At least one member with expertise in select agents and toxins (use, storage, transfer, and disposal).
- At least one member with expertise in animal containment principles.
- An individual representing laboratory technical staff.
- The Biological Safety Officer (where needed).
- At least two members from the surrounding community, and not affiliated with the University, to represent the interests of the community in regards to health and protection of the environment. These will be chosen from:
    - Representatives of community interests with respect to health and protection of the environment, e.g., officials of state or local public health or environment authorities, local government bodies, persons with medical, occupational, or environmental expertise.
    - They can also be the individuals who represent community attitudes.

Consultants may be invited to meetings for their expert advice when necessary but will not be allowed to vote on any protocol.

1.4 Scope

The IBC policies apply to all research personnel engaged in activities and/or research involving recombinant or synthetic nucleic acid molecules, biohazardous agents, materials and toxins that are:

- Sponsored by the University.
- Conducted by University research personnel.
- Conducted using the University's property and facilities.
- Received, stored, used, transferred or disposed of at the University facility.
- Research at other institutions conducted on behalf of the University.

1.5 Federal Registrations

The purpose of registration and annual membership updates are:

- Provide assurance of local review of biosafety risks to the Office of Biotechnology Activities (OBA).
- Indicates University point of contact.
- Provides census of the field: where recombinant or synthetic nucleic acid molecules research is being conducted.

The IBC is registered with OBA for purposes of recombinant or synthetic nucleic acid

molecules research. For more information visit https://osp.od.nih.gov/biotechnology/nih-guidelines/. An annual report is filed with OBA, which includes an updated list of IBC members indicating the role of each member and biosketches for each member. The OBA is notified of any changes in IBC membership when they occur. Such notice shall include a revised list of members, contact information and a biosketch for each new member. The Research Integrity & Education Department, through the Office of Research & Sponsored Programs, notifies OBA of changes in IBC membership and submits an annual report on behalf of the University.

Should a Principal Investigator request use, possession, or transfer of a biological material listed as a Select Agent and/or Select Agent Toxin, and not listed as an exempt strain or quantity, the University will initiate a Laboratory Registration for Select Agents and Toxins with the National Select Agent Registry. Laboratory registrations for Select Agents and Toxins will be maintained by the Office of Environmental Health and Safety (EHS). For additional information visit **http://www.selectagents.gov/**

1.6 Regulations and Guidelines

The IBC Policies are based upon the following regulations and guidelines:

- ***NIH Guidelines*** This document specifies practices and provides guidelines for constructing and handling recombinant or synthetic nucleic acid molecules and organisms containing recombinant or synthetic nucleic acid molecules. Institutions conducting or sponsoring recombinant or synthetic nucleic acid molecules research covered by NIH Guidelines are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the NIH Guidelines and are available online https://osp.od.nih.gov/biotechnology/nih-guidelines/.

- **BMBL** is published by Centers for Disease Control and Prevention (CDC) and the NIH – This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered the standard for biosafety. The BMBL is available online **http://www.cdc.gov/biosafety/publications/bmbl5/index.htm**

- **Select Agents and Select Agent Toxins** – The Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC) regulations, 42 CFR Part 73, and the United States Department of Agriculture (USDA) regulations, 9 CFR Part 121, establish requirements regarding the possession, use, receipt, and transfer of listed select agents and select agent toxins. The

  regulations set forth the requirements for registration of listed select agents and select agent toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. For more information visit **http://www.selectagents.gov/**

- **United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC) -** IODURC is a US Government (USG) policy established with the purpose of instituting regular review of USG funded or conducted research with certain high-consequence pathogens and

toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. IODURC addresses the institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. For more information visit **http://www.phe.gov/s3/dualuse/Pages/default.aspx**

1.7 Definitions

Biohazardous Materials, Agents and Toxins: Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human and nonhuman primate blood, blood products, tissues, and certain body fluids (use of human blood and body fluid for clinical diagnostic and treatment purposes is excluded).
- Cultured cells and potentially infectious agents these cells may contain.
- Infected animals and animal tissues.

Recombinant or Synthetic Nucleic Acid Molecules: In the context of the NIH Guidelines recombinant and synthetic nucleic acid molecules are defined as (1) recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and 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. Synthetic nucleic acid molecule segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

Dual Use Research of Concern (DURC): DURC 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. "Life sciences" pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules.