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Section 2: Responsibilities

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 the University of Denver (DU) and those associated with it to adhere to the intent of the *NIH Guidelines* as well as the specifics. Good judgment is a key along with the assistance of the Office of Biotechnology Activities (OBA). The potential consequences of noncompliance with the *NIH Guidelines* consist of:

- Suspension, limitation or termination of NIH funds for recombinant or synthetic nucleic acid molecules research at DU.
- A requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecules projects at DU.

2.0 Institution Responsibilities

Each institution conducting or sponsoring recombinant or synthetic nucleic acid molecule research, which is covered by the NIH Guidelines, is 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 institution shall:

- Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecule research and that ensure compliance with the *NIH Guidelines* (Section IV-B-1)
- Establish an Institutional Biosafety Committee that meet the requirements set forth in Section IV-B-2-a (Section B-1-b)
- Appoint a Biological Safety Officer, when required by NIH regulations (Section IV-B-1-c)
- Assist and ensure compliance with the *NIH Guidelines* by Principal Investigators conducting research at the institution (Section IV-B-1-g)
- Ensure appropriate training for the IBC Chair and members, Biological Safety Officer, Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. (Section IV-B-1-h)
- Determine the necessity for health surveillance of personnel involved in connection with individual recombinant or synthetic nucleic acid molecule projects (Section IV-B-1-i)
- Report any significant problems, violations of the *NIH Guidelines*, or any

significant research-related accidents and illnesses to NIH/OBA within thirty days. (Section IV-B-1-j)
- File an annual report with NIH/OBA, which includes: (i) a roster of all Institutional Biosafety Committee members, and (ii) biographical sketches of all Institutional Biosafety Committee members. (Section IV-B-2-a-(3))
- Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies if required to make available to the public. (Section IV-B-2-a-(7))

2.1 Institutional Official (IO) Responsibilities

The responsibility for Biosafety Program at DU rests with the Vice Provost for Research, who is the IO. The IO:

- Appoints IBC members.
- Annually evaluates IBC membership with input from the IBC Chair and Research Integrity & Education Director
- Oversees the IBC and research personnel who obtain, possess or use recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins.
- Annually evaluates allocation of resources to the IBC and adjusts as necessary.

The IO has charged the IBC (See Section 1.2 in the “Introduction”) to review, approve and provide oversight and guidance to those research personnel who seek to use recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in experiments or teaching. Any possession and/or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins at DU must be conducted with appropriate safeguards and in accordance to with University policies and federal guidelines and regulations.

2.2 IBC Responsibilities

The institution shall establish an Institutional Biosafety Committee whose responsibilities need not be restricted to recombinant or synthetic nucleic acid molecule research. (Section IV-B-2)

The responsibilities of the IBC include, but are not limited to, the following:

- Review, approve and oversee research utilizing recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins research, conducted at or sponsored by DU, for adherence with the *NIH Guidelines*. This pertains to the initial and continuing reviews and modifications to the currently approved research.
- Notify the Principal Investigator of the results of the IBC's review, approval, or disapproval.
- Make final determination of physical and biological containment for recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins research and modify containment levels as necessary.

- Review research identified by the principal investigator or identified during the protocol review process as DURC to determine if it meets the criteria defining DURC.
- Assess the facilities, procedures, practices, training and expertise of personnel involved in research utilizing recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and toxins.
- Review and report any significant problems, violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the IO and to the NIH/OBA per the *NIH Guidelines*.
- Direct development of appropriate procedures as required by NIH/OBA regulations to oversee the possession and/or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins.
- Suspend or terminate protocol approval for the possession or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins, where the IBC finds noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community.
- Review the IBC policies and procedures at least every three years, and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.
- Review research protocols that include the possession and/or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins for compliance with *NIH Guidelines* and Select Agents and Toxins regulations. As part of the review process, the IBC will do the following:
    - Conduct an independent assessment of the containment levels (BSL-1 to BSL-3), as required by the *NIH Guidelines.*
    - Conduct an assessment of the facilities, procedures, practices, training, and expertise of personnel conducting research involving recombinant or synthetic nucleic acid molecules and ensure adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines* for recombinant or synthetic nucleic acid molecules research and the select agents and toxins regulations.
    - Required to submit member rosters (completed by Research Integrity & Education) including members' biographical sketches to NIH/OBA.
    - Obtain specific review, registration and/or approval from NIH/OBA for research that fall under Sections III-A, III-B, III-C and Appendix M.

2.3 IBC Reviewer Responsibilities

All submissions that are complete will be reviewed by designated reviewers. Designated reviewers will consist of one or more IBC members, and if needed, to the BSO or EHS alternate, and can include faculty members from multiple areas of expertise as necessary to efficiently review the submissions. Protocols are generally grouped into three subject areas and are assigned to reviewers with the appropriate expertise.

- Animals: transgenic animals and animal hosts (including insects).

- Biochemistry/Plant: basic cloning, sequencing, structure, and function, transgenic plants, and containment.
- Microbiology and Toxins: pathogens and infectious agents, viral vectors, virulence factors.

The designated reviewer(s) will review protocols prior to a convened IBC meeting. They will be responsible for:

- Reviewing research submittal for completeness.
- Determining overall risk assessment.
- Setting appropriate containment levels.
- Determining exempt status, if applicable.
- Requesting clarifications or changes.
- Recommending additional conditions.
- Submission of approval/non-approval recommendation to the IBC.
- Review of amendments with non-significant changes and continuing reviews with no changes or non-significant changes for administrative approval (see Sections 3.3, 3.5, and 4.1.2).

2.4 IBC Chair Responsibilities
The IBC Chair responsibilities include:

- Serve as a contact for all regulatory agencies (in addition to IO who may delegate this function).
- Act as liaison between the research personnel and IBC.
- Assigns subcommittees as needed to review an issue prior to official committee decisions made at the convened meeting.
- Approve the agenda for the convened meeting of the IBC.
- Calls the meeting and directs the meeting deliberations, requests motions and seconds, and closes the meeting once it has concluded business.

2.5 Biosafety Officer Responsibilities (the requirements for this position are outlined in Section IV-B-3 of the NIH Guidelines)

The BSO (when required by virtue of the NIH regulations) shall be a member of the IBC. The BSO responsibilities include:

- Performing periodic inspections of laboratories conducting research using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins to ensure that laboratory standards are rigorously followed.
- Report to the IBC and University any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses.
- Performing and reviewing the required risk assessment to determine appropriate Biosafety level for handling an organism.
- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins.
- Providing advice on laboratory security to the IBC research personnel.
- Providing technical advice to research personnel and the IBC on research

safety procedures.

The principal function of the BSO should be to advise the research personnel, the IBC and the laboratory worker concerning the most appropriate safety practices that will assure the safe conduct of research with recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins.

2.6 Principal Investigator Responsibilities

On behalf of DU, the Principal Investigator is responsible to follow the *NIH Guidelines* and IBC Policies when using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins. Along with this understanding, the Principal Investigator will also have the following responsibilities:

- Make the initial risk assessment and determination of required levels of physical and biological containment in accordance with the *NIH Guidelines (Section IV-B-7-c-(1))*
- Be adequately trained in good microbiological practices and laboratory techniques. (Section IV-B-7-c-(2))
- Provide laboratory research personnel with protocols describing potential biohazards and necessary precautions.(Section IV-B-7-d-(3))
- Instruct, train and supervise research personnel in (1) the practices and techniques required to ensure safety, and (2) the procedures for dealing with spills or potential exposures to the agents described in the research.(Section IV-B-7-d-(2))
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) and correct procedures or conditions that might result in release of or exposure to recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents or toxins. (Section IV-B-7-e-(4))
- Develop and obtain IBC approval of and adhere to biosafety plans (refer to the IRBNet IBC site: www.irbnet.org), and to the EH&S Department for handling accidental spills and personnel contamination.
- Inform the research personnel of the Occupational Health & Safety Program and provisions for any precautionary medical practices advised or requested, e.g., vaccinations. (See Section 8)
- Ensure all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety. (See Section 7)
- List all personnel that will be performing the work described in the protocol. Individuals that must be added to the protocol include:

    1. A graduate or undergraduate student with a formal agreement to join the PI's lab.
    2. An individual who is being paid by the PI, by the university through a "work study" program, or by the Undergraduate Research Center.
    3. An individual that will be exposed to working with BSL-2 hazards.
    4. An individual responsible for training other lab members.
    5. Summer students working in a lab without enrolling in courses.

*Graduate or undergraduate students enrolled in a course for research credits, and students enrolled in a rotational program through the academic departments do not need to be added to the list of personnel in the protocol (unless they fall into category 1-5 listed above). The PI will however be responsible for confirming and maintaining all required online CITI and laboratory trainings.

- Obtain IBC approval prior to initiating or modifying any research involving use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and toxins. (Section IV-B-7-c-(3))
- Maintain IBC approval for use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins through timely submission of annual updates.
- Immediately report any significant problems or any research-related accidents and/or illnesses to EHS and any other university committees (Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee (IBC)) that have reviewed and approved the research activity.
- Identify any research falling within the scope of DURC to the IBC. The criteria for assessing DURC can be found at: **http://www.phe.gov/s3/dualuse/Pages/default.aspx**.
- Conduct DURC in accordance with the provisions in the risk mitigation plan.
- Be knowledgeable about and comply with all institutional policies and requirements for oversight of DURC.
- Ensure all laboratory personnel conducting life sciences research with one or more of the high consequences pathogens or toxins have received education and training on DURC.
- Communicate DURC in a responsible manner and in compliance with the approved risk mitigation plan.
- Comply with permit and shipping requirements for biohazardous materials.
- Although federal regulations allow exemptions for some types of recombinant or synthetic nucleic acid molecules use, the Principal Investigator must submit an application for all projects using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins so the IBC can verify that they are exempt.

2.7 Office of Biotechnology Activities Responsibilities

OBA serves as the focal point for information on recombinant or synthetic nucleic acid molecules activities and provides advice to all within and outside NIH/OBA. OBA's responsibilities include, but are not limited to, the following:

- Serving as the focal point for all aspects of gene transfer experiments.
- Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes for toxin molecules that are lethal for vertebrates at an LD50 of less than or equal to 100 ng/kg body weight in organisms other than Escherichia coli K-12.
- Publish proposed changes to rules or guidelines in the Federal Register.

- Reviewing and approving the membership of an Institution's Biosafety Committee, and where it finds the IBC composition to meet the requirements set forth in the *NIH Guidelines*, giving approval for the IBC membership.

2.8 Office of Research Integrity & Education / IBC Administrator Responsibilities

The Office of Research Integrity & Education, through the IBC Administrator, will provide overall administrative support, and will coordinate IBC reviews and meetings with the IBC Chair. Their responsibilities include, but are not limited to, the following:

- Provide the necessary liaison between the research personnel, the IBC, and federal and regulatory agencies.
- Conduct preliminary review of all IBC submissions for completeness, assist IBC Chair in assigning designated reviewers and maintain IBC database.
- Serve as the office of record for documentation involving the IBC.
- Provide all necessary documentation, forms, regulatory guidelines and regulations, to Principal Investigators.
- Maintain IBC protocol application forms and records.
- Assist the IO in filing annual updates and other reports to the NIH/OBA.
- Communicating with IRB or IACUC when protocols involve human subjects or animals.
- Assist in initial review of allegations of non-compliance with *NIH Guidelines*, and preparing reports for the IBC.
- Monitor Federal and state regulations, draft revised policies and procedures to remain in compliance with those regulations.
- Provide administrative support for the IBC by scheduling meetings, arranging for meeting space, taking meeting minutes, and distributing draft minutes for members' comments and reviews.