Frederick National Laboratory for Cancer Research

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title:	**Policies and Procedures for Registering Research with the NCI Frederick Institutional Biosafety Committee (IBC)**
SOP Number:	**26301**
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1. PURPOSE

The purpose of this SOP is to define Biopharmaceutical Development Program (BDP) policy and requirements for basic and clinical research involving any of the following materials:

- Recombinant (r) DNA/RNA
- Synthetic nucleic acid molecules
- RNAi
- Pathogens
- Oncogenes
- Biological Toxins
- Human Material
- Other Potentially Infectious Material (OPIM)
- Genetically engineered animals
- Nanomaterial
- Material with Dual Use potential

Requirements are presented in NIH Guidelines and are overseen by NCI-Frederick Institutional Biosafety Committee (IBC). This SOP outlines the procedures for providing an application to the IBC for approval to conduct basic or clinical research.

2. SCOPE

This policy is applicable to BDP personnel working with rDNA/RNA, RNAi, pathogens (viruses or immunocytokines), oncogenes, human materials, biological toxins, transgenic and/or knock-out/in animals, synthetic biology, nanotechnology, dual use materials, and other potentially infectious material (OPIM) that is being used at the BDP.

Recombinant or synthetic nucleic acid molecules are defined as:

i. Molecules that a) are constructed by joining nucleic acid molecules, and b) can replicate in a living cell (i.e., recombinant nucleic acids)

ii. 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 molecules (i.e., synthetic nucleic acids); and cells, organism, and viruses containing such molecules, or

iii. Molecules that result from the replication of those described in (i) or (ii) above.

3. RESPONSIBILITIES

3.1 The Program and Technical Director, BDP

- Defines the procedure.

3.2 The Project Scientists

- Implements this procedure and provide oversight.
- Generates the IBC registration information (as requested by the BDP Program Director).
- Provides advice regarding laboratory safety procedures.
- Requests updates to job codes in the eDMS.

3.3 The BDP Safety Officer

- Ensures periodic inspections of laboratories or production facilities engaged in operations involving IBC registered research.
- Notifies BDP Directors of any activities determined to be out of compliance with NIH or NCI Frederick requirements.

3.4 IBC PIs/Project Scientists

- Provides personnel information regarding the IBC applications and ensure all required names are listed if they are working on a project (development, production, QA, and QC) and ensures room locations for work are listed properly.
- Ultimately responsible for all aspects of the research conducted including personnel safety and full compliance with the appropriate NIH Guidelines in the conduct of this research. See also Section 6.0.
- Signs a Commitment Statement to acknowledge their responsibilities for compliance with NCI-Frederick and NIH Requirements for the management of basic and clinical research involving recombinant DNA/RNA, including the creating and use of organisms and viruses containing recombinant DNA/RNA in the IBC registration application.

3.5 BDP personnel

- Complies to the procedure.

3.6 Leidos EHS has an on-line registration process that houses the BDP (Biopharmaceutical Development Program) IBC applications.

4. NIH GUIDELINES

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic Nucleic Acid Molecules DNA, including the creation and use of organisms and viruses containing recombinant DNA/RNA. Links are provided in the modules to the NIH guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf).

The guidelines provide information and requirements on the policy, scope, safety considerations, experiments covered by the guidelines, roles, and responsibilities (of the institution, of the Institutional Biosafety Committee, of the PI, or the NIH, etc.).

Institutions must follow the NIH Guidelines when conducting or sponsoring any recombinant or synthetic nucleic acid molecule DNA/RNA research that is funded by the NIH. Compliance with the NIH Guidelines is mandatory as a condition of receiving NIH funding. Institutions that fail to comply risk suspension, limitation, or termination of NIH funding for the non-compliant NIH project and for other NIH-supported recombinant or synthetic nucleic acid molecule research at the institution.

5. IBC SUBMISSIONS/RESEARCH REGISTRATION PROGRAM

IBCs were established under the NIH Guidelines to provide local review and oversight of nearly all forms of research utilizing recombinant DNA/RNA. The NCI-Frederick Institutional Biosafety Committee implements policies and procedures to assure that people and the environment are protected during work involving human pathogens, oncogenes, biological toxins, blood and blood components, human cell lines, other potentially infectious material, rDNA & rRNA molecules and experiments involving whole animals or plants, including the generation/use of transgenic animals or genetically engineered plants, select agents and large-scale work. These molecules are hereafter referred to as infectious/biohazardous agents (see EHS/IBC Biological Safety procedures at https://ncifrederick.cancer.gov/Ehs/Procedures/Default.aspx for Biological Research Registration Program and Biological Research Registration Procedure.).

These documents present the requirements for the communication of information, responsibilities of various groups and personnel (including NCI-Frederick, the NCI Frederick IBC Committee, Environmental Health and Safety, a project's PI, and Employees), and procedures for registration of work, renewal of registrations, required documentation, and accident reporting. Refer to the OSHA Bloodborne Pathogen Exposure Control Plan (https://ncifrederick.cancer.gov/Ehs/Procedures/EHS_BIO_1_OSHABloodbornePathogenExposureControlPlan.aspx) for information on blood-borne pathogen training.

The PI is the BDP's primary point of contact with the IBC.

6. PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES

BDP Management selects a BDP staff member to serve as the BDP PI/Project Scientist for specific projects. "PI" is the term used to define the BDP staff member responsible for the IBC submission and will be referred to throughout this SOP as "PI". The PI is ultimately responsible for all aspects of the research conducted including personnel safety and full compliance with the appropriate NIH Guidelines in the conduct of this research.

PIs have significant responsibilities defined by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (as referenced above).

6.1 PI Commitment to Compliance

PIs have significant responsibility to assure compliance to NCI Frederick and NIH requirements. Failure to comply risks suspension, limitation, or termination of NIH funding for the non-compliant NIH project and for other NIH supported recombinant or synthetic nucleic acid molecule research at the institution.

BDP policies require that PIs document their understanding and commitment to these policies by signing Form 26301-01. The completed form will be provided to the BDP audit manager for filing in the employees training file in Document Control.

7. BDP REQUIREMENTS FOR REGISTERING INFECTIOUS/BIOHAZARDOUS AGENTS WITH THE IBC

7.1 Projects are reviewed according to **SOP 10001 - Project Acceptance and Completion of Projects for Clinical Use**, to evaluate safety considerations and determine the need for an IBC submission.

7.2 Scope changes to projects are also evaluated for safety consideration and the need to submit or update an IBC submission.

7.3 PIs are responsible for meeting all PI responsibilities defined in the NIH Guidelines.

7.4 Work with infectious/biohazardous agents is restricted to employees included on appropriate current IBC registrations. Employees must be trained in and comply with the SOPs referenced in the specific IBC submission. The Project Scientist / Supervisor is responsible for requesting updates to job codes in the eDMS that would be required.

7.5 Questions/concerns should be brought to the attention of your supervisor, the project's PI and/or the BDP Safety Officer.

8. BDP POLICIES FOR MANAGING IBC SUBMISSION RECORDS

The BDP uses the EHS on-line registration process using Topez Elements for submission of the necessary IBC documents.

IBC meetings take place monthly and submission due dates are posted on the IBC website: https://ncifrederick.cancer.gov/ehs/ibc/ The IBC submissions are due at least one month prior to the meeting date.

8.1 The PI(s) for a project will oversee the origination of a IBC Research Registration (IBC Submission) to the IBC before lab work is started for a project. The on-line submission form/information can be found at https://elements.nih.gov/Elements/app/login/login.html?ReturnUrl=%2FElements%2F The login username and password are the same as the NIH/NCI login to your computer. Once logged in you will be prompted to answer a series of questions depending on the type of product and research you are registering.

8.2 The BDP Safety Officer should be added as a co-investigator in the on-line submission under Project Contacts. Once the PI for the project has completed the online form they should notify the BDP Safety Officer to review the submission.

NOTE: When a person is listed as a Contact on the IBC submission they will be included in correspondence to the PI and they may view the submission at any time.

8.3 Once the online submission is ready for committee review, the PI will submit it online. A draft of the document may be printed before submission.

8.4 Questions may be received from the IBC reviewers before the meeting. The PI should address all IBC reviewer comments and provide a response back to the committee and BDP contacts as quickly as possible prior to the meeting.

8.5 The PI may be asked to be present at the IBC meeting to address any issues raised by IBC committee members.

8.6 Once the IBC meets to review the application and it has been approved, the application (called “Protocols” in Topaz) are available in Topaz.

8.7 Amendments to the IBC registration must be made if information on the submission changes, or additional personnel or tasks are added. The same online procedure is followed.

9. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
10001	Project Acceptance and Completion of Projects for Clinical Use
17109	Procedures for Safe Handling, Decontamination, and Spill Cleanup or Potentially Infectious Materials
26101	Labeling, Transport, Submission, Storage and Handling of Biohazardous Materials within the BDP
26301-01	BDP Project Scientist Responsibilities for Compliance to Institutional Biosafety Committee (IBC) Requirements