Frederick National Laboratory for
Cancer Research, Frederick, MD

BDP

Biopharmaceutical Development Program

Standard Operating Procedure

Title: Policies and Procedures for Registering Research with the NCI Frederick Institutional Biosafety Committee (IBC)

SOP Number: 26301

Revision Number: 04

Supersedes: Revision 03

Effective Date: MAY 07 2019

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 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:

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]

- 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.

2.0 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.

3.0 Authority and Responsibility

3.1 The Program and Technical Director, BDP, has the authority to define this procedure.

3.2 The BDP Safety Officer has the authority and responsibility to:

3.2.1 Implement this procedure and provide oversight.

3.2.2 Assist BDP Principal Investigator (PI)s in the generation of IBC registration information (as requested by the PI).

3.2.3 Review drafts of IBC registration documentation before they are submitted to the IBC, as needed.

3.2.4 Provide advice regarding laboratory safety procedures.

3.2.5 Ensure periodic inspections of laboratories or production facilities engaged in operations involving IBC registered research.

3.2.6 Issue “Stop Work” orders for BDP activities determined to be out of compliance with NIH or NCI Frederick requirements.

3.2.7 Act as liaison with the Biological Safety Officer (Environment, Health, and Safety-EHS).

3.3 BDP personnel are responsible for conforming to this procedure.

3.4 The BDP 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. See also Section 6.0.

3.5 BDP PIs sign 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.

3.6 Leidos EHS has an on-line registration process that houses the BDP (BiopharmaceuticalDevelopment Program) IBC applications. EHS provides copies of applications once they are approved and these copies are kept electronically in the BDP IBC database. BDP maintains its own IBC database that is maintained by the head of Technical Operations and the BDP Safety Officer.

4.0 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. See NIH Guidelines at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

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.

5.0 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.

6.0 Principal Investigator (PI) Responsibilities

BDP Management selects a BDP staff member to serve as the BDP PI 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.

7.0 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.

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

8.0 BDP Policies for Managing IBC Submission Records

The BDP uses the EHS on-line registration process for submission of the necessary IBC documents. IBC approved documents are placed in the BDP electronic database so that IBC information is easily accessed and is searchable for reference and oversight.

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://ncifrederick.cancer.gov/ehs/ibc/Login.aspx**. 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 contact 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 PI will receive a copy of the IBC submission and approval letter electronically from EHS.

8.7 The PI or BDP safety officer will make sure the IBC submission is added to the BDP electronic IBC database at [redacted].

8.8 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.

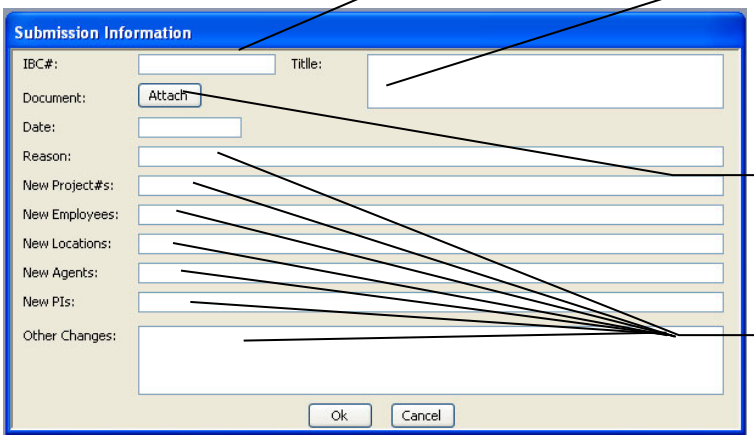
9.0 Directions for Saving IBC Registrations to the BDP IBC Database

9.1 Save the approved IBC submission (original or amendments) received from EHS with the approval memo in the BDP IBC database as indicated below:

Open the IBC database at [redacted]

1. Select “Open”

2. Select “Amendment Submission” for all submissions to be added (including initial submission).



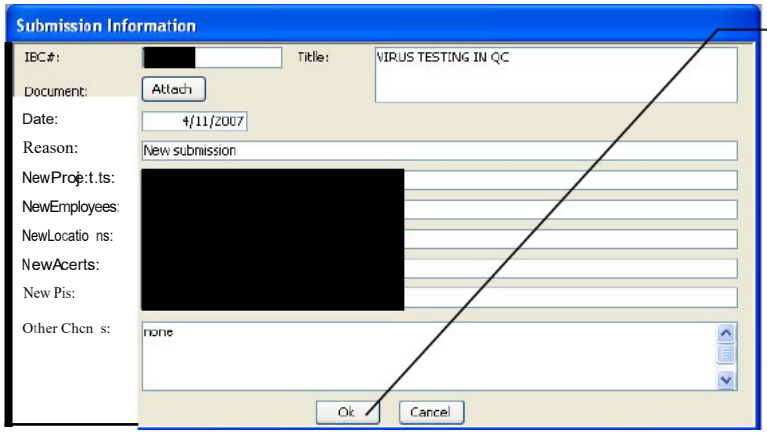
3. Input the IBC registration number.

4. Input the title of the IBC registration. Note: Titles for IBC numbers already in the database will automatically display the title.

5. Select “Attach” and browse to the location of the electronic file for the IBC submission.

6. Input remaining information. If no entry is applicable, input “none” or N/A.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]



7. When all inputs have been completed, select "OK".

8. Select "Yes".

10.0 References and Related Documents

10.1 **SOP 10001** *Project Acceptance and Completion of Projects for Clinical Use*

10.2 **SOP 17109** *Procedures for Safe Handling, Decontamination, and Spill Cleanup or Potentially Infectious Materials*

10.3 **SOP 26101** *Labeling, Transport, Submission, Storage and Handling of Biohazardous Materials within the BDP*

11.0 Attachments

11.1 **Attachment 1** Form 26301-01, BDP Project Scientist Responsibilities for Compliance to Institutional Biosafety Committee (IBC) Requirements

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]

Attachment 1
Form 26301-01, BDP Project Scientist Responsibilities for Compliance to Institutional Biosafety Committee (IBC) Requirements

FNLCR, BDP
Form No.: 26301-01
SOP No.: 26301
Revision 04: MAY 07 2019

NIH GUIDELINES

The NIH Guidelines detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creating and use of organisms and viruses containing recombinant DNA/RNA. (See NIH Guidelines at https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf)

Institutions must follow the NIH Guidelines when conducting or sponsoring any recombinant or synthetic nucleic acid molecule 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 DNA research at the institution.

IBC SUBMISSIONS / RESEARCH REGISTRATION PROGRAM

Institutional Biosafety Committees (IBCs) were established under the NIH Guidelines to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. The NCI at 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, and rDNA/RNA experiments involving whole animals or plants, including the generation/use of transgenic animals or genetically engineered plants, select agents and large scale work; see Environment, Health, and Safety (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 procedures state that this type of work be registered and approved by the NCI at Frederick IBC to ensure that an adequate risk assessment and risk abatement plan are in place prior to initiating any work involving recombinant or synthetic nucleic acid molecule research and/or a potential pathogen. The Principal Investigator is the BDP's point of contact with the IBC.

PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES

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. (See NCI at Frederick's Research Registration Program at https://ncifrederick.cancer.gov/Ehs/Ibc/.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 1 (Continued)
Form 26301-01, BDP Project Scientist Responsibilities for Compliance to Institutional Biosafety Committee (IBC) Requirements

FNLCR, BDP
Form No.: 26301-01
SOP No.: 26301
Revision 04: MAY 07 2019

BOP POLICIES FOR MANAGING IBC SUBMISSIONS

The BOP follom the EHS on-line registration process for submissionof the necessary IBC documents. IBC approved documents are placed in the BOP electronic database so that IBC information is easily accessed and is searchable for reference and oversight.

1. The Principal Investigator(s) for a project will oversee the origination of an IBC 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://ncifrederick.cancer.gov/ehs/ibc/Login.aspx.

2. The Program's Safety Officer (or designee), should review IBC applications before they are submitted to the IBC committee as needed

3. The PI or Safety officer will ensure approved IBC submissions are added to the BDP electronic IBC database at [redacted]

PRINCIPAL INVESTIGATOR COMMITMENT TO COMPLIANCE

Principal Investigators have significant responsbility to assure compliance to NCI at Frederick and NIH requirements. Signing this block indicates that you are aware of your responsibilities and will perform them to the best of your abilities.

Principal Investigator Signature	Printed Name	Date

This procedure is made available throughfederal funds from the National Cancer Institute, NIH, under contract [redacted]