# 1.0 Introduction

## 1.1 Purpose

The purpose of this guideline is to inform researchers of when they need to register the use of biological agents or materials.

## 1.2 Scope

This guideline applies to all Emory University researchers who work with biological agents or materials.

## 1.3 Definitions

**Biological Agent.** Biological agents include bacteria, viruses, fungi, other microorganisms and their associated toxins. They have the ability to adversely affect human health in a variety of ways.

**Materials.** Specimens obtained from humans, non-human primates, cell lines, cells, tissues

**Recombinant Nucleic Acids.** In the context of the NIH Guidelines, recombinant and synthetic nucleic acids 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.

## 1.4 Responsibilities

***Principal Investigators (PIs)***

- Complete the laboratory hazard assessment, biological registration, chemical registration, and chemicals in animals form (if using chemicals in animals) using the electronic platform in BioRAFT.
- Contact the Biosafety Office (biosafe@emory.edu) when you need to update the list of personnel in your lab.
- Amendments to add biological agents should be done by going to the electronic registration page and completing the appropriate surveys or forms. ***Any changes in the biological registration must be certified by the PI in order to be reviewed by the Biosafety Office.*** The following are some examples:

| Item to Add | What to Complete in BioRAFT |
|---|---|
| Human Source Materials (e.g. human cell lines) | • Survey<br>• Add cell lines to table |
| Pathogen, Risk 2 Group and Above | • Amend or initiate **Microbes survey**<br>• Add pathogen to table<br>• Complete **Pathogen form** |
| Any Viral Vector (e.g. baculovirus) | • Complete **Viral Vector form** |

# 2.0 Work Requiring Review by the BioSafety Office

The completion of the biological registration in BioRAFT is required for investigators who

intend to work with any of the following materials, *in vitro or in vivo*:

- All Microorganisms or infectious materials:
  - Bacteria
  - Viruses
  - Prions
  - Parasites
  - Fungi
- Human or Non-Human Primate blood, body fluid, fixed and unfixed tissue or Other Potentially Infectious Materials (OPIM)[1]. This includes blood samples obtained from the hospital or clinic that are being brought to the research laboratories for further experimentation (e.g. FACS analysis, cell culture, etc)
- Human and animal cell lines
- Recombinant and Synthetic Nucleic Acid Molecules. Experiments may include:
  - Recombinant DNA, RNA, or creating recombinant constructs (i.e., pcDNA, pBluescript, or any vector/insert manipulation).
  - Inserting recombinant or synthetic constructs into cell lines, tissue cultures, whole animals, humans, plants, or arthropods e.g., using $CaCl_2$, lipofectamine, Fugene Human gene transfer .
  - Non-replicative viral vectors (i.e., lentivirus, adenovirus, adeno-associated virus)
  - Viral Vectors
  - RNAi, shRNA
  - Gene editing technologies, i.e. CRISP/Cas, Zinc Finger
  - Work regulated by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- Arthropods
- Plants
  - Creating transgenic plants
  - Exposing plants to recombinant nucleic acids, arthropods, or microorganisms
  - Exposing plants to materials that require USDA Registration
- Biological and chemical toxins
- Nanomaterials or nanoparticles
- Environmental samples, including:
  - Field caught animals
  - Field caught arthropods
  - Unusual soil and water samples (i.e., stagnant pond or drainage ditch water or any environmental sample from an international source) based on the Biosafety Officer's evaluation

[1] Other Potentially Infectious Materials means 1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; 2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and 3) HIV-containing cell or tissue cultures, organ cultures, and HIV-or HBV, HCV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

- Any agent listed above to be manipulated in animals
- Work with human subjects- Clinical trials or studies:
  - Deliberate transfer of recombinant or synthetic nucleic acid molecules, or derived from recombinant or synthetic nucleic acid molecules, into one or more human subjects, i.e. gene transfer.
  - Utilizing live, recombinant, or attenuated microorganisms for the purposes of immunization of one or more human subjects
  - Using investigational vaccines containing recombinant or synthetic nucleic acids in humans

## 3.0 Work NOT Requiring Review by the BioSafety Office Registration

The following types of experiments do not require Biosafety NOI Submission:

- Experiments using licensed drug or biological (FDA approved)
- Experiments involving standard medical procedures such as obtaining biologic samples (analyzed in clinical laboratory) or administering licensed medications

## 4.0 Requisites for Project Approval

The following are requisites for project approval:

- Completion and certification of the biological registration in BioRAFT, including pathogen forms, viral vector forms, or any other applicable survey.
- Applicable training to be completed by PI and all personnel listed on the protocol (i.e., Research Laboratory Safety Training, Bloodborne Pathogen Training, Biosafety Training).
- Required immunizations to be completed (i.e., Hepatitis B, Meningococcal)
- Biosafety cabinets, laminar flow hoods and chemical fume hoods to be certified within the past 12 months.
- Laboratory Self-Inspection and Corrective Action Plan form is uploaded to BioRAFT (Document tab).

## 5.0 Frequency of Project Approval

- Review and update your biological registration annually.
- A registration may be reviewed by the Institutional Biosafety Committee (Recombinant Nucleic Acids) or Research Health and Safety Committee (High consequence pathogens or experiments) every three years.
- Refer to the IBC & RHSC Meeting Schedule for submission deadlines and meeting dates.
- EHSO will send PIs email notifications regarding annual updates and 3-year renewals 90 days, 60 days, 30 days and 10 days prior to submission deadlines.

## 6.0 Reference

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules - https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html

***Contact the Biosafety Officer at 404-727-8863 or biosafe@emory.edu with any questions.***