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**GUIDELINES FOR BIOSAFETY NOTICE OF INTENT SUBMISSION**

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**PURPOSE**

The purpose of this guideline is to inform researchers of what research requires a Biosafety Notice of Intent (NOI).

**SCOPE**

This guideline applies to all Emory University researchers that work with materials requiring Biosafety NOI Submission.

**WORK REQUIRING BIOSAFETY NOI SUBMISSION**

A Biosafety NOI must be submitted by PIs who intend to work with any of the following in vitro or in vivo:

- Microorganisms or infectious material including:
  - Bacteria
  - Viruses
  - Prions
  - Parasites
  - Fungi
- Human or Non-Human Primate blood, body fluid, fixed and unfixed tissue or **Other Potentially Infectious Materials (OPIM)<sup>1</sup>**. **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)**
- Recombinant and Synthetic Nucleic Acid Molecule (rDNA) experiments, including:
  - rDNA or creating rDNA constructs (i.e., pcDNA, pBluescript, or any vector/insert manipulation).
  - Inserting rDNA constructs into cell lines, tissue cultures, whole animals, humans, plants, or arthropods e.g., using CaCl<sub>2</sub>, lipofectamine, Fugene Human gene transfer .
  - Non-replicative viral vectors (i.e., lentivirus, adenovirus, adeno-associated virus)
  - Work regulated by the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#).
- Arthropods
- Plants (creating transgenic plants, exposing plants to rDNA, transgenic arthropods, or transgenic microorganisms/infectious agents that require USDA Registration)
- Biological 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
- Any agent listed above to be manipulated in animals
- Certain work with live human subjects:

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<sup>1</sup> 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.

- Deliberate transfer of recombinant or synthetic nucleic acid molecules, or derived from recombinant or synthetic nucleic acid molecules, into one or more human subjects
- Utilizing live, recombinant, or attenuated microorganisms for the purposes of vaccination of one or more human subjects
- Using investigational vaccines containing rDNA in humans

### **WORK NOT REQUIRING BIOSAFETY NOI SUBMISSION**

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

- Experiments using licensed vaccine (FDA approved)
- Experiments involving standard medical procedures such as obtaining biologic samples (analyzed in clinical laboratory) or administering licensed medications
- Experiments involved in obtaining biologic samples, such as blood, that are being sent to an establishment outside of Emory University
- Experiments involving investigational drugs which are not described by above

### **PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES**

- Submit a [Biosafety NOI](#) for new protocols
- Submit a [Biosafety Protocol Annual Update, Amendment & Termination Form](#) when any of the following occur:
  - Personnel addition or deletion
  - Agent addition or deletion
  - Any procedural changes
  - Animal addition or deletion
  - Changes to recombinant DNA research activities
  - Title change, addition or deletion
  - Transferring the protocol to another PI or terminating the protocol.
- Conduct a formal update of their protocol annually by submitting a [Biosafety Protocol Annual Update, Amendment & Termination Form](#) every year
- Submit a new [Biosafety NOI](#) every three years
- All forms and documentation regarding the Biosafety Protocol are submitted to [biosafe@emory.edu](mailto:biosafe@emory.edu)

### **REQUISITES FOR PROTOCOL APPROVAL**

The following are requisites for protocol approval:

- 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
- [Lab Self-Inspection Corrective Action Plan Form](#) submitted to [linspec@emory.edu](mailto:linspec@emory.edu) for the calendar year

### **FREQUENCY OF PROTOCOL APPROVAL**

- Protocols are approved for **three** years and must be updated annually
- Protocols are updated annually using the [Biosafety Protocol Annual Update, Amendment & Termination Form](#)
- At the end of three years, a new [Biosafety NOI](#) must be submitted
- Depending on the nature of the work described, the protocol may require Institutional Biosafety Committee (IBC) or Research Health and Safety Committee (RHSC) review. 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.

### **REFERENCES:**

1. [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)  
*Contact the Biosafety Officer at 404-727-8863 or [biosafe@emory.edu](mailto:biosafe@emory.edu) with any questions.*