Institutional Biosafety Committee (IBC)
Biosafety Protocol Application & Review Process

Institutional Biosafety Committee (IBC) review and approval is required prior to bringing biological materials to Augusta University or initiating research involving their use. Please refer to this document for training and occupational health requirements and for instructions for completing a biosafety protocol (BSP) application. A checklist is provided to guide you through the IBC review process. All forms and templates are available on the Biosafety Office webpage. If you have any questions or concerns, please contact the Biosafety Office at biosafety@augusta.edu, or 706-721-2663.

Biosafety Protocol Application Forms			
Type of Research	**If your work involves:**	**For your initial application:**	**For protocol changes:**
Basic Research (i.e. works with biological materials in a basic lab setting)	Recombinant or synthetic nucleic acids, human/animal cell lines or tissues, biological toxins, nanoparticles, etc.	Complete a *Biosafety Protocol (BSP) "Full" Application*	Complete a *Biosafety Protocol (BSP) Amendment Application*
Clinical Research (i.e. involves human research subjects)	Collection of biological materials from human research subjects Introduction/exposure of human research subjects to biological materials	Complete a *Clinical Biosafety Protocol (CBSP) Application* **Note:** Each human subjects research protocol requires a separate CBSP application	Complete a *Clinical Biosafety (CBSP) Protocol Application*

Notes and Instructions:

- BSPs must be approved by the Institutional Biosafety Committee (IBC) or the Biological Safety Office (Administrative Review) prior to the initiation of research.
- Approval is valid for three years, but protocols must be amended as needed in the interim.
- Whenever you amend or initiate a new Animal Use Protocol (AUP) or human subjects research protocol, obtain new grant funding or otherwise add agents, change personnel/location, or modify a procedure, you must amend your BSP.
- BSPs requiring Full IBC review must be submitted to the Biosafety Office by the 1st of the month to be placed on that month's agenda.
- Submit the electronic documents to biosafety@augusta.edu. To authenticate, the Principal Investigator (PI) must send from his/her Augusta University email account/mailing address or the preparer must copy the PI in the email.

Standard Operating Procedures (required):

Standard Operating Procedures (SOPs) are safety measures which are expected to be followed by all members of your research team. The Biosafety Office has developed general SOPs for use in BSL1

and BSL2 laboratories and for use in clinical research. If these SOPs cannot be followed as they are written, please include modified SOPs for review with this application. The SOPs are available on the Biosafety Office webpage.

Additionally, the IBC may require supplemental SOPs for specific, higher hazards agents or operations in the laboratory. If applicable, the Biosafety Office will communicate this requirement to you during the review process.

Biosafety and laboratory specific training requirements:

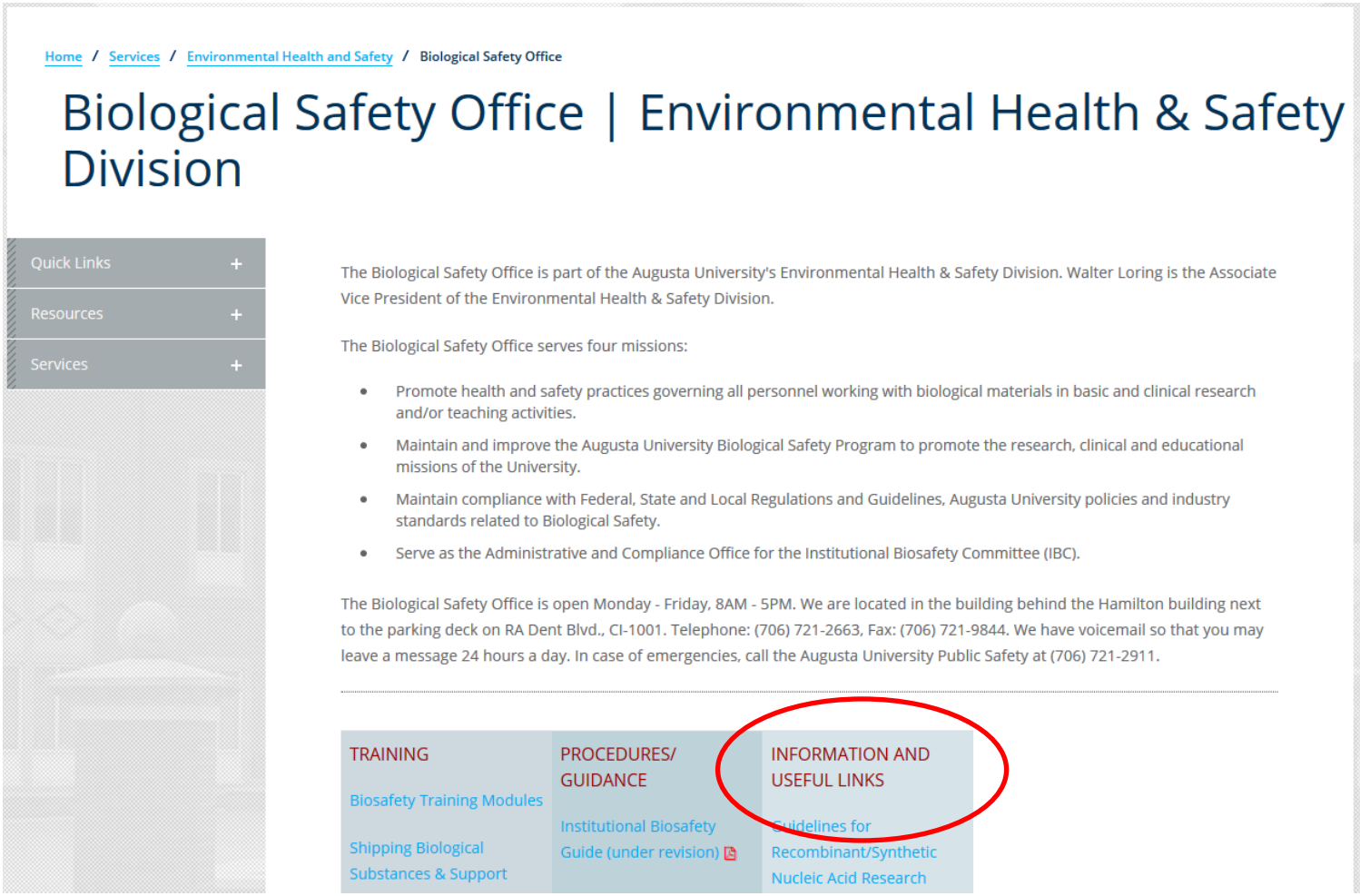
The Biosafety Office provides training as outlined in the table below. All training is available electronically through Workforce Learn Online and will be assigned by the Biosafety Office based on the information provided in your BSP application.

Additionally, the Principal Investigator is responsible for laboratory specific and procedure specific safety training. Once the application and review process has been completed, a copy of the approved BSP and SOPs should be made available in the laboratory for reference. The PI should provide laboratory specific safety training with all personnel, including review of these documents, and should maintain a record of that training (i.e. signature log).

Augusta University/ Augusta University Medical Center Biosafety Training Requirements	
University and Health System personnel and/or personnel who work in University or Health System facilities on research projects, if you:	**You must satisfactorily complete the following training:**
Work with biological materials in a basic/wet laboratory setting, including clinicians who have a basic/wet laboratory.	**Biosafety and Bloodborne Pathogen Training** *An initial online training session is required prior to initiation of work.* *Annual Biosafety Refresher required thereafter.*
Work with biological materials in a clinical laboratory setting. *Involves taking human blood, tissues or fluid specimens from patients who are not considered infectious with any agent ≥RG3, preparation of serum or plasma samples, aliquotting of specimens.	**Biosafety and Bloodborne Pathogen Training** *An initial online training session is required prior to initiation of work.* *Annual Biosafety Refresher required thereafter.*
Involved in research that is subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules. *Introduction of genetically modified materials into human research subjects (i.e. DNA vaccines, personalized therapies)	**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** *An initial online training session is required prior to initiation of work.*
Responsible for marking, labeling, packaging, shipping, transporting, or receiving Biohazards (infectious agents, biological toxins, human clinical specimens, animal diagnostic specimens, dry ice, liquid nitrogen, genetically modified organisms)	**Shipping Biological Substances and Support Materials** *Current training is required for anyone involved in the shipping process. Required biennially (i.e. once every 2 years)*

Risk Assessment and Mitigation:

The PI is asked to conduct an initial risk assessment and to propose methods to reduce that risk. This information should be provided in the **Risk Assessment and Mitigation** questions found in the forms. Procedures with increased risk of exposure to biological materials (i.e. due to splash, aerosol production, sharps handling, etc.) should be discussed in these sections along with proposed methods to reduce the risks and potential consequences of exposure (i.e. vaccinations, additional PPE, use of a biosafety cabinet or safety sharps, etc.). Safety standards and guidelines that may pertain to your research are provided in the **Information and Useful Links** section of the Biosafety Office webpage:



Laboratory Assistance Visits:

Routine Laboratory Assistance Visits (LAVs/lab inspections) are conducted twice a year by Environmental Health and Safety. In many cases no additional inspection is required as part of the protocol review process. However, if the protocol is associated with a new laboratory space, or if the proposed experiments present an increased risk requiring additional safety measures, the Biosafety Office or the IBC may require an LAV. The inspection checklist is available on the Biosafety Office webpage.

Occupational Health Requirements:

Occupational health clearance may be required prior to release of Biosafety or Institutional Biosafety Committee (IBC) approval to handle biohazardous agents or to enter patient care areas or areas

where biohazardous agents are used. Clearance is required if the proposed research involves any of the following:

- Human or non-human primate materials, including cell lines
- Direct contact with human research subjects
- Influenza Virus (wild-type or genetically modified)
- Vaccinia Virus (wild-type or genetically modified)
- Rabies Virus (wild-type or genetically modified)
- Biological Toxins

In order to obtain clearance

- Complete an **Occupational Health Clearance Form**
- Provide the form to the Employee Health and Wellness Office, the Student Health Office, or to your licensed health care provider at the time of your evaluation
- If seen outside the Employee Health and Wellness Office, return completed and signed form to Employee Health and Wellness Office (FG-1174)
  1515 Pope Avenue
  Augusta, GA 30901
  employeehealth@augusta.edu
  706-721-3418

Important Note: Occupational Health Clearance may also be required by the Institutional Animal Care and Use Committee (IACUC). If you will be working with research animals in additional to biohazardous agents, please contact the IACUC occupational health Coordinator (ANIMALOHP@augusta.edu) to coordinate your Occupational Health Clearance visit.

BSP Application Review Process Checklist	
☐	**1. Complete the BSP Application/Amendment form found at** http://www.augusta.edu/research/ibc/apps.php ➢ Do not forget to electronically "sign" your application by typing your name in the signature field following the attestation statement.
☐	**2. Submit the application to the Biosafety Office:** biosafety@augusta.edu ➢ You will receive a "Confirmation of Receipt" email from the Biosafety Office when your application is received. ➢ The Biosafety Office will pre-review the application and correspond with you in a "Notice of Review" email regarding the review track that has been assigned and any personnel training requirements, edits to the application and to request that you schedule a Laboratory Assistance Visit (LAV), if needed. ➢ If your BSP will require Full IBC review, it must be submitted by the 1st of the month for review during that month's meeting.
☐	**3. Address the pre-review concerns and resubmit the edited documents to the Biosafety Office:** biosafety@augusta.edu ➢ Once all training is completed and all pre-review concerns have been addressed your application will be sent to the IBC for review: • Clinical or Basic Subcommittee Review (Expedited) – After Subcommittee review, you will receive an email indicating the status of the review, either: ○ Approval, ○ Approval with Stipulations ○ Recommendation for Full Committee review, or ○ Tabled for further information and re-submission. • Full Committee Review (Occurs on the third Wednesday of every month). PIs are invited and encouraged to attend the Full Committee meetings in order to directly address concerns. After Full Committee review, you will receive an email indicating the status of the review, either: ○ Approval, ○ Approval with Stipulations, or ○ Tabled for further information and re-submission ➢ If approved, skip to Step #5. ➢ If approved with stipulations, go on to Step #4. ➢ If recommended for Full Committee review, you will receive an invitation to the next Full IBC meeting.
☐	**4. Complete stipulations of approval. Address concerns and email edited documents to** biosafety@augusta.edu ➢ Note: The IBC will return your application with "no action" if the required stipulations are not completed within two months of receipt of this email notification.
☐	**5. Receipt of Approval Email to allow you to initiate experiments.** ➢ Experiments included in the application may begin upon receipt of this email. ➢ Do not forget to review the approved BSP and SOPs with all research personnel and make copies available for reference.
☐	**6. Receipt of the official, signed Approval Memo and Registration (via email)** ➢ Retain a copy of the Approval Memo and Registration for your records.