This written program outlines the compliance and regulatory components referenced in OSHA Sections 5199 and 5199.1 Aerosol and Transmissible Diseases. Described herein are all those who must maintain compliance with the aforementioned regulations and implement the approved campus Biosafety Plan.
Aerosols and Transmissible Diseases (ATD) Program

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Description of the ATD Program:
The ATD program is designed to protect employees from diseases or exposures in the work place. Specifically, ATD’s are infectious agents which include a inhalation as a primary mode of transmission. These infectious agents can include Select Agents, and zoonotic agents but share the properties of ATD’s because they can infect humans (and sometimes animals as well) if they are dispersed as an aerosol and subsequently inhaled by the subject. In this program, we take a look at the requirements of the ATD Program which are in direct response to the following OSHA Regulations:

- Title 8 Section 5199 Aerosol and Transmissible Diseases
- Title 8 Section 5199.1 Zoonotic Aerosol and Transmissible Diseases

In compliance with these regulations, this written program describes the requirements for ATD use as well as reference the Biosafety Plan which shall be used in any areas conducting or in the possession of ATD agents. (See Table) The Biosafety Plan will also satisfy the requirement for an Exposure Control Plan and should be used appropriately. Please contact Environmental Health and Safety with any questions regarding regulatory requirements, compliance, written programs or plans.

Note to Principle Investigator:
As a PI, it is your responsibility to comply with these regulations and guidelines as well as maintain compliance in any laboratory areas where applicable research is being performed. This program is intended for informational purposes and to notify the PI (and others) of the requirements which must be met in order to safely conduct research with ATD Agents. Areas that are planning to conduct future ATD research must be approved by EH&S and must file an application to the Institutional Biosafety Committee (IBC) before research begins. The PI may contact EH&S for additional information regarding these processes.

Notes on IBC Approval:*
Use of infectious agents classified as Risk Group 2 or higher must have IBC approval prior to initiation of experiment(s). Additional information regarding the IBC submission process can be accessed on the EH&S website (www.cpp.edu/~ehs) or by contacting the Biosafety Officer. Approval may require an on-site compliance inspection or additional requirements depending on the specific agent and any additional safety concerns.

*Note: If the ATD of concern is classified as a Select Agent, additional requirements may be required, including security parameters, a site specific risk assessment, and authorized user approval through FBI-CJIS etc.
Environmental Health and Safety Notification Process:
Prior to receiving any funding for grants or otherwise that pertains directly to ATD research, any regulated agents which are intended to be used for research must be approved by EHS and finally by the IBC. IBC submissions do not occur until EHS approval has been issued. Before any research begins, the PI must notify EH&S in writing, indicating the intended research scope and an annual registration application. The application should be submitted at minimum 90 days prior to any anticipated start date as additional time may be required for IBC approval. A written protocol is recommended to facilitate this process. EHS will consider any applicable exemptions as well as security or safety concerns. Once deemed satisfactory, EHS will advise the PI on starting the IBC process as well as facilitate the submission process. Once approved by the IBC, a letter will be issued to the PI granting the initiation of the regulated research. Compliance inspections will be done initially and as deemed necessary during the course of conducting the research.

Registration/Termination Processes:
As mentioned above, the PI is required to submit an annual registration (application) to EHS both initially, as well as each year the research continues. The application must be submitted at least 90 days prior to any anticipated start date. Additional time may be required if IBC approval is required.

A Termination form must be submitted within 90 days of any anticipated cessation date. Receipt of the termination form will trigger a close-out inspection by EHS which will consider decontamination steps and material removal from the facility. Once the close-out inspection is complete and any corrective actions are complete, the lab will no longer be regulated as an ATD facility.

Scope:
The scope of this program includes all individuals, employees, students, graduate level students, interns, faculty members, etc. who work with infectious agents which pose a risk of being inhaled and resulting in a disease. Agents which are prone to vaporization, atomization, forming droplets, mists or aerosols and are infectious by inhalation are of critical concern. All those mentioned above who belong to Job Safety Classifications Laboratory Worker- Infectious, or Medical Worker must also comply with this program as their duties include special precautions which are within the scope of this document.

Zoonosis and Zoonotic information is available in the appendices of this document and provides important information regarding the infectious nature of agents which posse the unique ability of being able to infect different species (cross species barrier) i.e. animals to humans or vice versa. This information identifies zoonotic agents, their specific hazards and if they are prone to forming droplets or aerosols. We also consider mode of transmission as well as additional agent specific information.
Definitions:

- ACUC: Animal Care and Use Committee
- ATD: Aerosol and Transmissible Disease(s)
- BSAT: Biological Select Agent or Toxin
- BSL-2: Biosafety Level 2
- BSO: Biosafety Officer
- EHS: Environmental Health and Safety
- IBC: Institutional Biosafety Committee
- PI: Principle Investigator
- rDNA: Recombinant DNA
- Recombinant DNA: DNA sequences which result from the use of molecular cloning methods to artificially combine genetic material.
- Regulated Materials: Infectious Agents, rDNA, Select Agents, Controlled Substances.
- RG-2: Risk Group 2
- RO: Responsible Official
- Select Agent: Agent identified by the government to pose a threat of terrorism to the United States (Bioterrorist Agent)
Roles and Responsibilities:

**Principle Investigator:** The PI must conform to all procedures contained in this program and referenced in the Biosafety Plan as well as ensure that all additional requirements have been met. It is the responsibility of the PI to make contact with EHS and to ensure that all deadlines are met and allow enough time for the approval process. It is recommended that the PI allocate additional time for protocol review and any unforeseen complications which may add further delay to the approval process.

**Biosafety Officer:** The BSO is responsible for maintaining this program and monitoring future changes in compliance to ensure the program address future changes and compliance is maintained. The PI may contact the BSO for questions regarding agents and the approval process. The BSO shall work with EHS to facilitate EHS approvals and IBC submissions.

**EH&S:** Environmental Health and Safety shall be responsible for facilitating the submission of research protocols to the IBC. In the process of advising on IBC submissions, the EHS department shall require annual registrations for all labs performing ATD research as well as maintaining compliance inspections for those labs. Upon termination of ATD research, EHS shall perform a close-out inspection before the ATD designation is removed from the lab area. EHS is responsible for confirming that any corrective actions have been completed before ATD restrictions are lifted.

**IBC:** The Institutional Biosafety Committee is responsible for reviewing all submissions related to Infectious Agents, Recombinant DNA etc. The committee will review research protocols and submission forms to assess the safety required to conduct such research and if said safety requirements have been sufficiently addressed and enforced.

**ORSP:** Office of Research and Sponsored Programs shall be responsible for facilitating the grant application and funding process as well as addressing questions the PI may have regarding the funding process in lieu of pending IBC approvals.
Exposure Control Plan:
The requirement of an exposure control plan is to ensure that employees are protected by means of exposure. The scope of the exposure control plan is specifically for employees who do not work in a lab setting. This pertains to individuals with person-person contact as a direct result of their job duties. This includes, but is not limited to, Medical Workers, First Responders (Police, Fire Department, and EMT’s), and Nurses etc.

A wide majority of campus operations includes laboratory work so the laboratory counterpart of the exposure control plan is the Biosafety Plan. The Biosafety Plan meets the requirements of the exposure control plan and should be used to that effect. In the event that a true exposure control plan is needed for entities with person-person contact i.e. campus police, it may be advisable to develop an exposure control plan for these areas. The Biosafety Plan is currently being used due to the use in laboratory settings.

The current Biosafety plan is in the form of a template and meets the requirements outlined above. In some areas where SOP’s are mentioned, general SOP’s have been drafted to meet base level compliance. Depending on the needs of the PI or the unique requirements of the agent being used, the PI may opt or be required to create specific SOP’s that are specific to the agent in question. All amended or drafted SOP’s including substitutions must be evaluated by EH&S before submission to the IBC may occur. The PI must fill in all areas which are indicated on the template form before seeking EHS approval.

Training Requirements:* 
Depending on the agent being used and the unique requirements of the proposed research, a variety of training modules may be required. Some training modules that may be applicable to the proposed research may include some of the following.

- Biosafety Level 2 (BSL-2)
- Aerosol Transmissible Disease Training (ATD)
- CITI Biosafety Training
- Animal Care and Use Training (ACUC)
- Medical Waste Management
- Blood Borne Pathogen Training
- Hazard Communication
- Laboratory Safety
- IBC Submission Process

*Note: EHS will make the final determination as to which training modules are required. All training shall be completed before the initiation of any regulated research.
Appendix:

I. Principle Investigator Certification Form
II. Annual Registration Form
III. Registration Termination Form
IV. Table of Aerosol and Transmissible Diseases