# University of Massachusetts/Amherst Biological Safety Program Responsibilities



## **Biosafety Program Responsibilities**

### **Biosafety**

The Chancellor is the institutional official for Biosafety. The Vice Chancellor for Administration and Finance has the primary delegated role in the Biological Safety Program. Those with contributing responsibilities at this level are: Vice Chancellor for Research and Engagement; within Environmental Health and Safety the Executive Director, Assistant Director for Academic Safety & Environmental Health, and Biosafety Officer; Deans and Department Heads; Institutional Biological Safety Committee and the Compliance Coordinator.

The primary role for overall compliance of biological research falls to the Vice Chancellor for Research and Engagement, with the primary delegated role belonging to the Director of Research Compliance. Those with contributing responsibilities at this level are: Deans and Department Heads, Assistant Director for Academic Safety & Environmental Health, Biological Safety Officer, IACUC and Institutional Biosafety Committee.

The applied health and safety practices are primarily seen to by the Principle Investigators. Deans and Department Heads may support the PI's with oversight and training.

USDA, CDC and NIH audits for bio-research are the primary responsibility of the Chancellor with the Vice Chancellor in the primary delegated role. Those with contributing responsibilities at this level are: Director of Research Compliance, Assistant Director for Academic Safety & Environmental Health, Biological Safety Officer, Director of Animal Care Services.

The Development of Policy and Protocols related to Biological Safety are the responsibility of the Vice Chancellor for Administration and Finance with the primary delegate being the Executive Director of Environmental Health & Safety. Those with contributing responsibilities at this level are: Assistant Director for Academic safety & Environmental Health, Biological Safety Officer and Institutional Biosafety Committee.

The approval of policy and protocols related to biological safety is the responsibility of the Vice Chancellor of Research and Engagement with the IBC as the primary delegate for this duty. Those with contributing responsibilities at this level are: Director of Research Compliance and Biological Safety Officer.

Institutional Biosafety Committee oversight is the responsibility of the Vice Chancellor of Research and Engagement with the Director of Research Compliance as the primary delegate for this duty. Those with contributing responsibilities at this level are: Biosafety Officer and the Institutional Biosafety Committee.

Research registration of pathogenic organisms and toxins is the responsibility of Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety as the primary delegate for this duty. Those with contributing responsibilities at this level are: Biosafety Officer, Assistant Director for Academic Safety & Environmental Health, Institutional Biosafety Committee and the Director of Research Compliance.

The rDNA and synthetic nucleic acid molecule research oversight is the responsibility of the Vice Chancellor of Research and Engagement with the Director of Research Compliance as the primary delegate for this duty. Those with contributing responsibilities at this level are: Biosafety Officer and the Institutional Biosafety Committee.

University biosafety inspections are the responsibility of the Executive Director of Environmental Health and Safety with the Assistant Director for Academic Safety & Environmental Health and the Biological Safety Officer having contributing responsibilities.

Review and approval of research involving biosafety/biohazard issues; BSL-2 level research, pathogenic microorganisms and toxins are the responsibility of Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety as the primary delegate for this duty. Those with contributing responsibilities at this level are: Biosafety Officer, Assistant Director for Academic Safety & Environmental Health, Institutional Biosafety Committee and the Director of Research Compliance.

Review and approval of research involving biosafety/biohazard issues with rDNA is the responsibility of the Vice Chancellor of Research and Engagement with the IBC as the primary delegate for this duty. Those with contributing responsibilities at this level are: Director of Research Compliance and the Biosafety Officer.

The Director of Research Compliance is responsible for reporting to NIH as well as responding to queries regarding rDNA/IBC. The Director of Research Compliance is the primary delegate for these duties and the Biological Safety Officer has contributing responsibilities as well.

The Select Agent program is the responsibility of the Executive Director of Environmental Health and Safety, with the primary delegate being the Biological Safety Officer. Those with contributing responsibilities at this level are: PI's and the Assistant Director of Academic Safety & Environmental Health and the Director of Research Compliance.

Inventory of biologicals on campus is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety as the primary delegate for this duty. Those with contributing responsibilities at this level are: Assistant Director for Academic Safety & Environmental Health, Biological Safety Officer and the Institutional Biosafety Committee.

Biosafety cabinet inspections/certifications are the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety as the primary delegate for this duty. Those with contributing responsibilities at this level are: Deans and Department Heads, Biological Safety Officer, Assistant Director for Academic Safety & Environmental Health and PI's.

Safety and health of laboratory staff, researchers and students are the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and the Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. Those with contributing responsibilities at this level are: Deans and Department Heads, Biological Safety Officer, Institutional Biosafety Committee, Director of Research Compliance and PI's.

Bloodborne pathogen training is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. The Biological Safety Officer has contributing responsibilities in this area.

Biosafety training of students, staff and PI's is the responsibility of the Vice Chancellor for Administration and Finance with the Director of Environmental Health and Safety and the Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. Those with contributing responsibilities at this level are: Deans and Department Heads, Biological Safety Officer, Director of Animal Care Services, Institutional Biosafety Committee and PI's.

Biohazard waste disposal policies and procedures are the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and the Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. The Biological Safety Officer has contributing responsibilities in this area.

HAZWOPER biosafety training is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety as the primary delegate for this duty. The Biological Safety Officer has contributing responsibilities in this area.

Development of biosafety level-2 and 3 protocols and emergency procedures for researchers and staff is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and the Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. Those with contributing responsibilities at this level are: The Biological Safety Officer and the PI's.

Maintenance of the facilities is the responsibility of the Vice Chancellor for Administration and Finance with the Associate Vice Chancellor of Facilities and Campus Services. Those with contributing responsibilities at this level are: The Director of Campus Planning and the Director of the Physical Plant.

Decontamination of facilities is the responsibility of the Vice Chancellor for Administration and Finance with the Associate Vice Chancellor of Facilities and Campus Services. Those with contributing responsibilities at this level are: the Biological Safety Officer, Director of Animal Care Services and the Director of the Physical Plant.

Development of emergency procedures ("SOP's") for emergency personnel is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and the Assistant Director for Academic Safety & Environmental Health as the primary delegate for this duty. The Biological Safety Officer has contributing responsibilities in this area.

Infection control oversight is the responsibility of the University Health Services. Those with contributing responsibilities at this level are: The Vice Chancellor of Research and Engagement, the Executive Director of Environmental Health and Safety, the Assistant Director for Academic Safety & Environmental Health and the Biological Safety Officer.

### **Human Subjects**

The Vice Chancellor for Research and Engagement is the institutional official for human subject research. Those with contributing responsibilities at this level are: Deans and Department Heads and the Institutional Review Board Administrator.

Overall compliance of human subjects' research is the responsibility of the Vice Chancellor for Research and Engagement with the Institutional Review Board Administrator as the primary delegate for this duty. Those with contributing responsibilities at this level are: The Director of Research Compliance, Deans and Department Heads and the Institutional Review Board.

Applied health and safety practices are the responsibility of the PI's with contributing responsibilities delegated to deans and department heads.

NIH audits for human-subject research are the responsibility of the Institutional Review Board Administrator. Those with contributing responsibilities at this level are: the Vice Chancellor of Research and Engagement, Director of Research Compliance, Institutional Review Board and the Institutional Review Board Administrator.

NIH reporting is the responsibility of the Vice Chancellor for Research and Engagement with the Institutional Review Board Administrator as the primary delegate for this duty.

Development of policies and protocols related to human subjects' research is the responsibility of the Institutional Review Board with contributing responsibilities falling to the IRB Administrator.

Approval of policies and protocols related to human subjects' research is the responsibility of the Provost and Senior Vice Chancellor for Academic Affairs. Those with contributing responsibilities at this level are: The Director of Research Compliance, Deans and Department Heads, the Institutional Review Board, and Institutional Review Board Administrator.

IRB oversight is the responsibility of the Provost and Senior Vice Chancellor for Academic Affairs with the Institutional Review Board Administrator as the primary delegate for this duty. The Director of Research Compliance has contributing responsibilities as well.

Research registration of human subjects' research is the responsibility of the Institutional Review Board Administrator with the PI's as the primary delegates for this duty. The Institutional Review Board has contributing responsibilities.

Human studies research registration oversight is the responsibility of the Institutional Review Board Administrator. Those with contributing responsibilities at this level are: the Director of Research Compliance and the Institutional Review Board.

Review and approval of research involving human subjects is the responsibility of the Institutional Review Board. Those with contributing responsibilities at this level are: the Biological Safety Officer, Institutional Review Board and the Director of Research Compliance.

#### **Animal Use**

The institutional official for animal use is the Chancellor. The primary delegated official is the Vice Chancellor for Research and Engagement. Those with contributing responsibilities in this area are: Director of Animal Care Services, the Director of Research Compliance, Deans and Department Heads, Clinical veterinarian, and the Supervisor of Animal Care.

Overall compliance for research using animals is the responsibility of the Chancellor with the Vice Chancellor of Research and Engagement as the primary delegate for this duty. Those with contributing responsibilities in this area are: The Director of Research Compliance, Deans and Department Heads, IACUC, the Director of Animal Care Services, PI's and the IACUC Coordinator.

USDA reports and inspections are the responsibility of the Chancellor with the Director of Animal Care Services as the primary delegate for this duty. Those with contributing responsibilities in this area are: the Director of Research Compliance, IACUC and the IACUC Coordinator.

OLAW Assurance reports are the responsibility of the Chancellor with the IACUC Coordinator as the primary delegate for this duty. Those with contributing responsibilities in this area are: the Director of Research Compliance, the Director of Animal Care Services and IACUC.

The development of policies and protocols related to animal use is the responsibility of IACUC with the IACUC Coordinator as the primary delegate for this duty. The Director of Animal Care Services has contributing responsibilities in this area as well.

IACUC oversight is the responsibility of the Chancellor with the Vice Chancellor of Research and Engagement as the primary delegate for this duty. The IACUC Coordinator has contributing responsibilities in this area as well.

The applied health and safety practices are primarily seen to by the Principle Investigators. Deans and Department Heads may support the PI's with oversight and training.

Research registration of animal use protocols is the responsibility of the PI's. Those with contributing responsibilities in this area are: The Director of Research Compliance, Director of Animal Care Services, IACUC and the IACUC Coordinator.

Registration oversight is the responsibility of the IACUC Coordinator. Those with contributing responsibilities in this area are: Director of Animal Care Services, IACUC and the clinical veterinarian.

Facilities inspections (ACS) are the responsibility of IACUC with the Director of Animal Care Services as the primary delegate for this duty. Those with contributing responsibilities in this area are: the IACUC Coordinator.

Facilities inspections (research) are the responsibility of IACUC with the IACUC Coordinator as the primary delegate for this duty. Those with contributing responsibilities in this area are: the Director of Animal Care Services.

The semi-annual review of the animal use program is the responsibility of IACUC with the IACUC Coordinator as the primary delegate for this duty. Those with contributing responsibilities in this area are: the Director of Animal Care Services and the clinical veterinarian.

The review and approval of research using animals is the responsibility of IACUC. Those with contributing responsibilities in this area are: Biological Safety Officer, Director of Animal Care Services, IACUC Coordinator and the clinical veterinarian.

Animal welfare (husbandry) is the responsibility of the Chancellor with the Director of Animal Care Services as the primary delegate for this duty.

Animal welfare oversight (medical) is the responsibility of the Chancellor with the Director of Animal Care Services as the primary delegate for this duty. Those with contributing responsibilities in this area are: the clinical veterinarian.

The occupational health and safety of the animal care staff is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and Assistant Director for Academic Safety & Environmental Health as the primary delegate for this duty. Those with contributing responsibilities in this area are: the Biological Safety Officer, Director of Animal Care Services and the University Health Service.

The occupational health and safety of the researchers and students is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. Those with contributing responsibilities in this area are: Deans and Department Heads, Biological Safety Officer, IACUC, IACUC Coordinator, PI's and UHS.

Biosafety training related to animal use (ACS staff) is the responsibility of the Vice Chancellor for Administration and Finance with the Executive Director of Environmental Health and Safety and Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. Those with contributing responsibilities in this area are: the Biological Safety Officer and the Director of Animal Care Services.

Biosafety training related to animal use (researchers and students) is the responsibility of the Vice Chancellor for Administration and Finance with the Director of Environmental Health and Safety and Assistant Director for Academic Safety & Environmental Health as the primary delegates for this duty. Those with contributing responsibilities in this area are: the Biological Safety Officer, PI's and the Deans and Department Heads.

Maintenance of the facilities is the responsibility of the Vice Chancellor for Administration and Finance with the Associate Vice Chancellor of Facilities and Campus Services.

Decontamination of facilities is the responsibility of the Vice Chancellor for Administration and Finance with the Associate Vice Chancellor of Facilities and Campus Services. Those with contributing responsibilities at this level are: The Director of Animal Care Services, Biological Safety Officer, Director of Facilities and Campus Planning and Director of the Physical Plant.

Development of emergency procedures ("SOP's") for emergency personnel is the responsibility of the Vice Chancellor for Administration and Finance with the Director of Animal Care as the primary delegate for this duty. The Executive Director of Environmental Health and Safety, Assistant Director for Academic Safety & Environmental Health, Biological Safety Officer, PI's, Director of Facilities and Campus Planning and Director of the Physical Plant have contributing responsibilities in this area.

Infection control oversight (animals) is the responsibility of the Director of Animal Care Services. Those with contributing responsibilities in this area are: the clinical veterinarian.

Infection control oversight (Zoonoses) is the responsibility of the Vice Chancellor of Administration and Finance with the Executive Director of Environmental Health and Safety as the primary delegate for this duty. Those with contributing responsibilities in this area are: Director of Animal Care Services, Biological Safety Officer, Assistant Director for Academic Safety & Environmental Health, IACUC Coordinator, PI's and University Health Services.

Select agents in animals are the responsibility of the Executive Director of Environmental Health and Safety with the Assistant Director for Academic Safety & Environmental Health, and Biological Safety Officer as the primary delegates for this duty. Those with contributing responsibilities in this area are: Director of Animal Care Services, IACUC Coordinator and PI's.