

Appalachian State University Research Protections and Institutional Biosafety Council Standard Operating Procedures		
SOP #5 Revision # 0	TITLE: Unanticipated Events, Non-Compliance, and Emergencies	Date Effective: Revision Date:
Approved By: IBC Chair	Signature <i>Jennifer P. Cecile</i>	Date: 5/22/2017
Approved By: RP Director	Signature <i>Kevin Smith-McMinn</i>	Date: 5/22/2017

### **PURPOSE**

To describe the policies and procedures for identifying and managing unanticipated events or non-compliance, emergency and IBC authority for suspending biohazardous activities.

### **GENERAL DESCRIPTION**

#### *Definitions*

**1. Unanticipated Incident**

An event or occurrence during the course of the approved activity that was not identified in the protocol and does increase risk of harm to humans or the environment.

**2. Unexpected outcome**

A result of the research that was not reasonably anticipated in the protocol. This may or may not result in increased risk to humans and the environment.

**3. Non-compliance**

The conduct of activity using rDNA outside the parameters of or without an approved IBC protocol.

**4. Reportable incident**

A non-compliance event that requires notification to NIH or sponsor.

**5. Emergency**

An unanticipated incident or accident involving biohazardous agents and/or rDNA will require varying degrees of action depending on the type and severity of the emergency. The initial handling of such an event rests with either the person directly involved or the person first alerted to the situation. Much of what follows is of general applicability in any emergency.

### **RESPONSIBILITY**

Unless otherwise exempted by the provisions hereof, this procedure shall apply to all persons who perform research involving recombinant DNA molecules. It is applicable to activities that occur in University facilities as well as other locations whenever projects involve University funding, faculty scholarship or staff/student/agent effort as part of University activities. The provisions of this document shall be interpreted and applied in conformity with Federal, State, and UNC System Policies and Procedures.

Situations that may involve potential criminal activity or human safety should also be reported to the university's law enforcement or Environmental Health, Safety & Emergency Management Office.

### **PROCEDURES**

1. Reporting the incident
2. IBC responsibilities
3. Suspension of an activity
4. NIH reporting
5. Appeals process
6. Emergency Preparedness and Response

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### **REPORTING THE INCIDENT**

1. The PI has the responsibility to report any unanticipated events, unexpected outcomes or noncompliance to the IBC. This can be done in a variety of ways, including but not limited to:
  - a. Notifying a member of the IBC directly
  - b. Reporting minor events during the Annual Review
  - c. Using the "Report a concern" confidential email from the Research Protections website
  - d. Contacting the IBC Administrator
2. Any student, employee or individual has the right and ethical responsibility to report a concern regarding the safety of rDNA to the Appalachian IBC without fear of reprisal
  - a. The IBC will maintain the confidentiality of any complainants to the fullest possible extent.
3. The IBC Chair will consider the magnitude of the incident and whether a convened meeting should be called to discuss
  - a. Incidents that pose immediate harm or resulted in death or injury of personnel must be reviewed by the IBC at a convened meeting
  - b. It is expected that the PI will work with the IBC administrator, Chair and council if reporting procedures are required

### **IBC RESPONSIBILITIES**

1. The IBC has the responsibility and authority to consider the following:
  - a. The magnitude of the incident with regard to possible harm to humans or the environment
  - b. Whether the incident requires reporting to appropriate regulatory bodies
  - c. The appropriate response to the PI
  - d. What steps should be taken to prevent a recurrence of the incident
2. The IBC has the authority and responsibility to suspend the activity while conducting an investigation of the incident, if the incident poses increased risk of harm to humans or the environment.
3. When necessary, the Chair will appoint a person or group to conduct the investigation and make a recommendation to the council
4. The IBC notifies the Institutional Official of the nature of the incident and any recommended actions if any of the following have occurred:
  - a. Notification to regulatory bodies
  - b. Suspension of research activity
  - c. Notification of law enforcement, medical personnel or appropriate EHS&EM personnel
5. The IBC notifies the PI of the reported incident (if not originally provided by the PI) and any recommended actions, including reporting requirements
6. Documentation of the incident, the investigation, and the IBC response are filed in the Office of Research Protections

### **SUSPENSION OF ACTIVITY**

1. The IBC has the authority to suspend any activity that it previously approved if it determines that the activity is not being conducted safely.
  - a. Suspension of research activity by the IBC is a final decision that cannot be reversed by the institution
  - b. The IBC has the authority to recommend appropriate discipline of the researcher to the university, including but not limited to suspension of the individual's right to conduct research, teaching or demonstration activities involving rDNA
2. Any suspended activity which is NIH funded is considered a reportable incident to NIH

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- a. The IBC Administrator contacts the appropriate body in accordance to their reporting procedures
  - b. The IBC reviews and makes recommendations for the report in a convened meeting
  - c. The IBC Chair reviews and approves wording of any formal report
  - d. The Institutional Official in charge of the Office of Research signs final reports prior to submitting to regulatory bodies
3. Any suspended activity or non-compliance must be reported to funding agencies, as required

### **NIH REPORTING**

The *NIH Guidelines* require that “any significant problems, violations, or any significant research-related accidents and illnesses” be reported to the Office of Biotechnology Activities (OBA) within 30 days (regardless of funding status of the project).

- Appendix G of the *NIH Guidelines* specifies certain types of accidents that must be reported on a more expedited basis
  - Specifically, Appendix G-II-B-2-k requires that spills and accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to the OBA (as well as the IBC)
- Any spill or accident involving recombinant DNA research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment must be reported to OBA
  - These kinds of events might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet.
- Failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to OBA
- Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported
- OBA should be consulted if the Institutional Biosafety Council (IBC), investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting; OBA can assist in making this determination

### **APPEALS PROCESS**

Investigators who have been suspended or sanctioned have the right to appeal the IBC’s decision. This will be done by a convened meeting. The appeal will be reviewed and considered by the IBC and the IO will be notified.

### **EMERGENCY PREPAREDNESS AND RESPONSE**

#### **Prepare Before an Emergency Occurs**

Any faculty or staff member using biohazardous agents and/or rDNA must become familiar with Appalachian State University emergency plans and policies. Information is available at or by contacting the Office of EHS&EM at x4008.

#### **Evaluate the Emergency and Call for Help**

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The first person to observe the emergency should try to quickly estimate the severity of the situation and evacuate personnel from the immediate area. For larger emergencies, activate the alarm where the emergency could threaten lives of occupants. Report all emergencies that threaten life or property to on-campus police at x8000.

The IBC Administrator (262-2692 or IBC@appstate.edu) and the facility/laboratory supervisor should be notified as soon as possible.

#### Confine the Hazard

If possible, secure the area and stand by to provide information and assistance. Reduce the spread of contamination by limiting travel from the area and by checking shoes for contamination if practicable.

#### Protect Personnel

Warn other persons in the immediate vicinity and assist any persons who may be contaminated or injured. NOTE: Emergency action personnel who have been notified will take over after this first phase of the emergency. They will prescribe additional action to be taken and begin restoration to normal operating conditions.

#### Reporting

It is the responsibility of the faculty or staff member holding the registration to complete and submit a report on the accident to the IBC Administrator.

#### Injuries

Any time an employee's injury or overexposure requires medical evaluation or attention, the Workers' Compensation guidelines at [www.hrs.appstate.edu](http://www.hrs.appstate.edu) must be followed.

Students should seek medical attention through Student Health Services at 262-3100. If Student Health is not open, seek medical attention at Watauga Medical Center or an Urgent Care facility.

All injuries must be reported to EHS & EM using the Initial Notification of Injury Form located at <https://safety.appstate.edu/>.

#### **SUPPORT PROCEDURES AND PROCESSES**

Appalachian's website for anonymous reporting, <http://researchprotections.appstate.edu/contact/report-concern>

Office of Environmental Health, Safety and Emergency Management, <http://www.safety.appstate.edu/>  
NIH Incident Reporting Assistance <http://www.osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting>

Appalachian Policy #212, *Use of Recombinant DNA in Research and Teaching Laboratories*  
SOP1, Protocol Review

#### **REFERENCES**

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- Biosafety Guidance
- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)
- CDC and HHS Select Agents and Toxins List
- The CDC Publication: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition
- Guidelines for Biosafety Laboratory Competency

