IBC Supplemental Policy #01-2013

PROTOCOL FOR REMEDIATING NON-COMPLIANCE WITH UNL BIOSAFETY GUIDELINES

The procedures outlined below are designed to ensure a swift and decisive response to issues of non-compliance with federal and UNL Biosafety Guidelines. The desired outcome in all incidents of non-compliance is to obtain remediation by the PI or take administrative action within 30 days of discovery of non-compliance.

In case of non-compliance with UNL Biosafety Guidelines, the following actions will be taken:

a. Upon notification of a non-compliance incident, the BSO or delegate will:
   i. Contact the Principal Investigator (PI) by both email and telephone. This email will outline the PI’s responsibilities, instruct the PI of actions needed to remedy the non-compliance, advise the PI to take immediate action, and outline the risks associated with continued non-compliance. The PI will be given 7 days to remedy the situation and will also be directed to suspend the work in question until compliance is achieved.
   ii. Contact and inform the IBC Chairperson and the Associate Vice Chancellor for Research (AVCR) of the incident.

b. If 7 days pass and non-compliance persists, the BSO or delegate will:
   i. Send a second email to the PI, with copies going to the IBC Chairperson as well as the entire IBC committee, the Department Head/Chair, and the AVCR. This email will reiterate the PI’s responsibilities and the risks associated with continued non-compliance, and outline the actions needed to remedy the non-compliance. At this point, the PI will be given an additional 7 days to comply or face immediate suspension.
   ii. Call the Department Head/Chair directly to solicit assistance in obtaining compliance.
c. On the 14th day following notification of the incident, the following will occur if the issues of non-compliance have not been resolved:

   i. The BSO or delegate will inform the AVCR that the PI is still not in compliance.

   ii. The AVCR will send a final email notice of non-compliance to the PI, with copies going to the Department Head/Chair, the IBC Chairperson and the entire IBC committee, giving the PI 24 hours to become compliant or face immediate suspension.

d. If non-compliance is still not addressed at the end of this period, the following will happen:

   i. If the PI has a currently approved protocol, the IBC will take immediate action to suspend all work under the protocol until compliance is achieved. A special meeting of the IBC will be called if necessary to execute this action.

   ii. The AVCR will take additional steps to ensure compliance from the PI or impose appropriate consequences.