

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.

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- 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.