GUIDING PRINCIPLE

All adverse events or protocol deviations must be reported to the IBC. Timely reporting allows the institution to provide the highest quality response by engaging all available resources. The report is forwarded to the IBC for designated review of the incident and any corrective actions already taken or proposed by the PI.

1.0 Definitions

1.1 Adverse Events Outcomes that adversely affect the health or well-being of personnel or the environment during the course of research or teaching; incidents related to experimental procedures that resulted in an unforeseen event or exposure.

1.2 Protocol Deviation Any departure from methods approved in an IBC protocol or the conduct of biohazardous activities without appropriate IBC review and approval.

1.3 Noncompliance Failure to adhere to IBC protocols, policies, procedures, or decisions; Preforming biohazardous experiments without IBC approval. Noncompliance can occur in a variety of ways, either intentionally or unintentionally.

NDSU Safety Office All NDSU incidents/accidents must be reported to the NDSU UP&SO immediately or within 24 hours by completing and submitting the NDSU Incident Report Form. If the event/incident involves recombinant or synthetic nucleic acids it must also be reported to the NDSU IBC Office within 24 hours to meet the institutional requirements prescribed by the NIH Guidelines. The event must be reported by submitting the IBC Adverse Event Reporting Form.

2.0 Examples

2.1 Adverse events

- Unexpected environmental release of transgenic material
- Accidental exposure to biohazardous materials

2.2 Protocol deviations

- Any intentional or unintentional use of biohazardous material that was not described in the approved IBC protocol;
- Failure to adhere to procedures within an IBC approved protocol;
- Implementing protocol amendments prior to obtaining IBC approval.

3.0 PROCEDURE

3.1 Principal Investigator Responsibilities

3.1.1 The first priority is to protect the health and welfare of staff that are or may be affected.

3.1.2 Within 48 hours of learning of the adverse event, protocol deviation, or noncompliance the Principal Investigator (PI) and/or staff must report the event to the IBC Office. Protocols in Novelution contain a panel for reporting either an Adverse Event or Protocol Deviation. For Legacy protocols, AEs and Protocol Deviations are reported via the IBC Adverse Event Reporting Form on the IBC website.

3.1.3 If IBC review suggests that modifications in the protocol are required to prevent further instances, the PI shall file a change in protocol request.

3.2. Institutional Responsibilities

3.2.1 The IBC is responsible for ensuring that PIs are aware of their responsibilities to report adverse events and protocol deviations.

3.2.2 Upon receipt of an adverse event or protocol deviation the IBC Office forwards the report to the IBC Chair, and if necessary, the Institutional Official.

3.2.3 The IACUC Administrator reviews the Adverse Event/Protocol Deviation Report, gather additional information, and develop a summary report for the IBC.

3.2.4 The reports are provided to the IBC at regularly convened meetings. The IBC reviews the report and determines whether any further action is required. Further action may include but is not limited to:

- Additional training

- Cessation of specific biohazardous activities
- Protocol suspension

3.2.5 It should be noted that any action taken by the IBC that stops research on a protocol may have an effect on the granting agency involved. PIs should be prepared to make appropriate adjustments in funding.

3.2.6 The IBC Office informs the PI in writing of any decisions, corrective actions, or amendments required by the IBC.