NDSU NORTH DAKOTA STATE UNIVERSITY Institutional Biosafety Committee Guiding Principles and Procedures	Effective: 2011 Revised: June 2014, October 2016, August 2021, October 2022, February 2023
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1.0 GUIDING PRINCIPLE

1.1 Reports of allegations of noncompliance

The IBC considers all concerns or complaints regarding noncompliance with NDSU regulations or policies.

1.2 Reporting procedures

Any person with knowledge of a complaint, concern, or alleged noncompliance may report (anonymously if desired) to the IBC office, IBC chair or member, Director of Sponsored Programs Administration, or the Institutional Official (IO). Reporters may include:

- investigators, or research team members
- Institutional Official
- NDSU faculty, staff or students
- IBC chair or members

Investigators and research team members are required to report any noncompliance, as well as unanticipated problems, or complaints to the IBC in a prompt manner. When reported by other parties, the reporter's identity will generally not be disclosed.

2.0 FEDERAL AND INSTITUTIONAL GUIDELINES

NIH Guidelines - (herein referred to as "NIH Guidelines"), U.S. Department of Health and Human Services, National Institutes of Health. 59 FR 34496 (Final Rule) and subsequent amendments. https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/

The NIH Guidelines require that any significant problems, violations, or any significant research-related accidents and illnesses" be reported to OSP within 30 days. 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 OSP (as well as the IBC). In addition, Appendices G-II-C-2-q and G-II-D-2-k require that spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to OSP (as well as the IBC and BSO).

NSF 712.2 Policy - Recombinant DNA research subject to the NIH Guidelines must be registered with the IBC indicating compliance with the containment requirements specified in Part III of the Guidelines. IBCs are required to keep records of recombinant DNA research conducted at their organization in a form that is available to NSF upon request.

USDA-APHIS - APHIS regulations (340.4(f)(10)) require responsible persons who have permits or acknowledged notifications to report the following incidents to APHIS: Environmental release, substantially different characteristics, any unusual occurrence.

NSDU Policy 347 – Institutional Biosafety Committee applies to projects conducted at NDSU facilities, or conducted by representatives of NDSU. Project investigators are responsible for submitting the protocol required for review and approval by the NDSU IBC. The NDSU IBC's purpose is to assure the safe use of recombinant DNA, infectious agents, and human blood, bodily fluids, or tissues, in research and teaching, and to maintain compliance with NIH Guidelines and additional federal regulations.

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.

3.0 DEFINITIONS

3.1 Serious Noncompliance:

an act or omission that negatively impacts the health or well- being of researchers or the environment, or compromises the integrity of validity of the research.

Examples of serious noncompliance may include, but are not limited to: conducting research involving recombinant DNA, infectious agents or human blood without appropriate IBC review and approval, performing experiments not addressed by the approved protocol, performing experiments with improper technique or safeguards which puts either the staff or environment at risk, failure to obtain or follow USDA APHIS permits.

3.2 Continuing noncompliance:

any noncompliance that occurs repeatedly after appropriate remedial education or corrective action.

Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IBC approval, repeated failure to obtain IBC approval for biohazardous research, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

3.3 Minor Noncompliance:

any noncompliance that is not serious or continuing.

Examples of minor noncompliance include: not informing the IBC of additional personnel, failure to document changes in procedures, not maintaining detailed research records per IBC policy and/or protocol requirements, personnel not attending training within the required time frame, personnel accessing facilities without authorization.

Examples of noncompliance:

- Conduct of biohazardous research without appropriate IBC review and approval;
- Failure to adhere to IBC-approved protocols;
- Implementation of any significant change to IBC-approved protocols without prior IBC approval;
- Conduct of biohazardous research activities beyond the expiration date established by the IBC:
- Participation in biohazardous research activities by individuals who have not been determined by the IBC to be appropriately qualified and trained;
- Failure to maintain appropriate laboratory records for transgenic materials
- Failure to obtain proper USDA permits for transgenic whole plant research

4.0 PROCEDURE

All incidents involving biohazards should be reported to the IBC for immediate review, investigation, and appropriate intervention as needed.

Individuals who may report incidents:

a) voluntary reports by the PI,
b) anyone witnessing an incident
c) institutional employee reports

Posted notices advising how to report:

Notices are on the IBC website advising individuals how and where to report identified concerns.

IBC Office, NDSU Office of Research and Creative Activity - (701) 231-8908 or ndsu.ibc@ndsu.edu

The IBC shall attempt to maintain the confidentiality of an individual who reports concerns or misconduct. However, confidentiality cannot be guaranteed, and disclosure of the individual's identity may be necessary in order to fully investigate the concern. There is no retribution or discipline for anyone who reports a concern in good faith.

The Institutional Official (IO), IBC Administrator and IBC Chair will be immediately notified of the reported incident.

4.1 Investigation procedures

4.1.1 The IBC Administrator in conjunction with facility staff, IBC committee members as necessary or requested, investigate the allegation. The investigation includes, but is not limited to:

- Interviewing personnel involved;
- Reviewing pertinent records;
- Initiating any necessary immediate preventative/corrective action, e.g. education on the NIH Guidelines, USDA-ARS Regulations, or institutional policies; or halting of the biohazardous activity.

4.1.2 The IBC Office develops a report documenting the investigation; outlining the incident and all action taken.

4.1.3 The report is shared with the PI to ensure accuracy of the report and allow the PI to supply additional information.

4.1.4 The report is presented to the IBC at a monthly meeting or sooner if circumstances dictate. If necessary, an IBC Subcommittee (IS) will be formed to further investigate. If an IS is not appointed, determination of the report outcome and action will be made by the quorum of members at a convened meeting.

4.1.5 The IS consists of at least, the IBC Chair/designee, members of the IBC, and the IBC Administrator/designee. If appointed, the IS will meet as soon as possible to review the report.

4.1.6 All members of the IBC will be notified of the date and time of the meeting and be invited to attend.

4.1.7 The IS will determine the following:

- Whether or not the investigation is complete or if additional investigation is required;

- Whether or not any immediate preventative/corrective action was appropriate or if additional action is required;
- Whether or not there is evidence of negligence or willful disregard of institutional requirements;
- Whether the incident constitutes a violation of the NIH Guidelines, USDA-ARS Regulations, or institutional policies;
- Whether the activity should be halted pending further review;
- Whether the incident/concern constitutes serious and/or continuing noncompliance or a serious deviation from NIH Guidelines or USDA-ARS regulations is reportable; performing activities without appropriate IBC review and approval; failure to adhere to IBC approved protocols; failure to maintain appropriate experimental records; participation of personnel in biohazard related activities who have not been determined by the IBC to be appropriately qualified and trained.
- The type of review required by the full IBC, i.e. Designated Member Review (DMR) or Full Committee Review (FCR)

4.1.8 On behalf of the IS, the IBC Administrator updates the report summarizing the investigation, preventative/corrective action taken and IS recommendations.
4.1.9 The PI will be sent a copy of the updated report and will be asked to acknowledge receipt of the report, provide any comments, and be given the opportunity to appeal in accordance with a set deadline.
4.2.0 The IBC full committee will review the report containing the IS recommendation.
4.2.1 Following IBC review, the IBC office informs the PI in writing of any decisions, corrective actions, by the IBC. The final determination is copied to the IO and the relevant administrative head.

5.0 Incidents reportable to Federal Government

The IBC and the IO will ultimately make the final determination that the incident is a reportable incident and the IO reports to NIH and USDA as applicable.

In some reported cases, NIH/USDA may request additional information, or that the university contact the funding component with details of the incident to determine whether or not federal funds were used for specific procedures.

The IBC Administrator works with IBC chair/designee to provide any additional requested information to Federal agencies.

Sponsored Programs Administration will be provided with the details of the incident by the IBC office and following consultation with the department provide the funding agency with the necessary information.

Upon response from NIH/USDA, as applicable, indicating no further action is required, the IBC will be notified of the final outcome of the reported incident and the documentation will be filed in the IBC Office. PI will receive a letter of determination at this time.