# Biosafety - Non-Compliance and Adverse Incidents Procedure

## Section 1 - Summary

(1) The purpose of this Procedure is to ensure appropriate investigation and management of any adverse and non-compliant incident in accordance with the relevant codes, regulations and standards governing Biosafety.

## Section 2 - HESF/ASQA/ESOS Alignment

(2) HESF: Standards 2.3 Wellbeing and Safety; 4.1 Research; 4.2 Research Training; 5.2 Academic and Research Integrity.

## Section 3 - Scope

(3) This Procedure applies across the University and to all personnel, whether internal or external to the University, handling biological material on University premises or working in University biocontainment laboratories.

(4) All personnel must ensure their work is compliant with the relevant Biosafety regulations, codes and standards at all times.

## Section 4 - Definitions

(5) Licensee - The person named on the Victoria University licenses and accreditation applications as the license holder.

(6) IBC non-compliant incident - Any process or procedure that does not comply with Biosafety regulatory requirements, VU Policy and IBC Procedures.

(7) IBC adverse incident - Any process or procedure associated with working with biological material or in containment laboratories that can potentially impact on human and animal health or the environment.

## Section 5 - Policy Statement

(8) Biosafety Policy

## Section 6 - Procedures

### Part A - Roles/Responsibilities

| Roles | Responsibilities |
|---|---|
| Deputy Vice-Chancellor, Research & Impact (DVC-RI) | responsible to the Vice-Chancellor for VU's Institutional Biosafety Committee (IBC) and its implementation of requirements as specified by the relevant regulatory bodies. |
| Executive Director, Research Services | responsible to the DVC-RI to ensure that the Manager, Research Infrastructure and Biosafety, advises and reports on the regulatory and legislative requirements for handling of non-compliant and adverse incidents, and is adequately supported to develop, monitor and review associated procedures and guidelines. |
| Senior Manager, Research Infrastructure and Biosafety | authorised to advise on and report to the IBC on legislative requirements for handling of non-compliant and adverse incidents. |
| Directors, Executive Deans and Heads of Department | ensure that all staff and students receive appropriate information and training necessary for them to handle and report all non-compliant and adverse incidents in accordance with all legislative requirements. |
| Manager, Technical Services | ensure that designated research spaces are adequately supported so that any non-compliant and adverse incidents can be handled in a compliant and safe manner.<br><br>ensure that Technical Managers have resources to develop and implement training and procedures necessary to ensure that all non-compliant and adverse incidents are handled in accordance with all legislative requirements. |
| Technical Managers | ensure that all users of lab spaces are adequately trained and that there are procedures in place to ensure any non-compliant and adverse incidents are reported and handled appropriately. |
| Chief Investigators (including Principal Investigators, Academic Supervisors, Research Supervisors and Unit Conveners) | responsible for the health and safety of the undergraduate and postgraduate students they supervise, in addition to volunteers and staff employed under them.<br><br>ensure that students and staff are aware of and abide by VU's procedures for the handling of non-compliant and adverse incidents. |
| Staff, students, volunteers and external users of University facilities working with biological hazards | ensure that they follow safety guidelines and abide by VU's Procedures for the handling of non-compliant and adverse incidents set out by VU and their respective Technical Manager and Chief Investigators.<br><br>ensure that their actions do not put themselves or any other individual at risk. |
| Senior Officer, Animal Ethics and Biosafety | acts as the IBC Secretary and as such is responsible for receiving and sending communications between Project Supervisor / Subject, Coordinator, End-Users, Facility Managers / Supervisors and the IBC. |

## Part B - Reporting and investigation

(9) All adverse incidents (and near misses) or non-compliant (or suspected non-compliant) incidents must be immediately reported to the Institutional Biosafety Committee (IBC) Chair via the Senior Manager, Research Infrastructure and Biosafety or the IBC secretary (or authorised delegate).

(10) The IBC will investigate and seek a written explanation of the incident from the Chief Investigator (or other relevant persons) on the alleged incident using the IBC Incident Report Form.

(11) Upon notification the IBC Chair will classify the severity of the event in consultation with the Senior Manager, Research Infrastructure and Biosafety as; Insignificant, Minor, Moderate, Major or Severe.

(12) In some circumstances it will not be possible to determine the nature or extent of the incident until an investigation has occurred.

(13) The incident report is distributed to all IBC members for comment and if necessary an extraordinary Committee meeting may be convened for further discussion.

(14) The IBC Chair will report the incident and the Committee's views(s) to the Licensee for information and may provide recommendations for further action.

(15) Should an IBC member, after the above procedures have been exhausted, still be unsatisfied that appropriate action has or will be taken, then that member should advise the Licensee.

(16) Actions taken by the IBC Chair, and outcomes, shall be reported to the next meeting of the IBC.

## Categorisation of an event

(17) Categorisation is based on:

a. AS/NZS IEC 31010, Risk management – Risk assessment techniques (available via SAI Global);
b. OGTR Risk Analysis Framework (2013);
c. Risk Management Policy and Risk Management Procedure; and,
d. Bureau of Animal Welfare Regulations, Australian Code for the Care and Use of Animals for Scientific Purposes and the VU Animal Ethics Committee AEC Incident Guide.

### Insignificant event

(18) No harm/ near miss.

(19) Minimal or no damage to the environment or disruption to biological communities.

### Minor event

(20) An administrative error or minor deviation from the approved protocol that is extremely unlikely to impact on human or animal welfare or the environment, as outlined in the Health and Safety - Hazard Management Procedure and AEC Incident Guidelines (e.g. activities undertaken as part of most Exempt Dealings).

(21) Incident causing harm which can be instantly, locally addressed through first aid or self-care.

(22) Incident causing health effects that are reversible.

(23) Damage to the environment that is reversible or limited in time or space on numbers affected.

### Moderate event

(24) An accidental deviation from the approved protocol with moderate impact to human or animal welfare or the environment as outlined in the Health and Safety - Hazard Management Procedure and AEC Incident Guidelines.

(25) Any deviation from an approved NLRD application.

(26) Incident causing harm that requires more than first aid or results in minor irreversible health effects i.e. ambulance or medical treatment required.

(27) A failure to comply with Biosafety legislation, VU Policy and IBC Procedures that do not need to be reported to external regulators and can be managed by the IBC.

(28) Damage to the environment or disruption to biological communities that is widespread but reversible and of limited severity.

### Major event

(29) Deliberate or negligent deviations from approved protocol where there has or there is the potential for significant

impact to human or animal welfare or the environment as outlined in the Health and Safety - Hazard Management Procedure and AEC Incident Guidelines.

(30) Severe injury requiring intensive care or hospitalisation.

(31) All adverse events and non-compliance incidents that need to be reported to external regulators.

(32) Extensive damage to the environment or extensive and physical disruption to whole ecosystems, communities or an entire species that persists over time and is not readily reversible.

**Severe event**

(33) Permanent Disability, One or more deaths, or exposure to an incurable disease.

(34) Environmental damage that is irreversible.

(35) All adverse events and non-compliance incidents that need to be reported to external regulators and managed by external regulators.

# Part C - Actions following an Event

(36) The action taken will be determined by the severity of the event. In all cases the Chief Investigator will be contacted by the IBC to provide a report to the IBC outlining the circumstances of the potential event.

## Insignificant event actions

(37) The IBC will review the event at the next IBC meeting and make recommendations on improvements to work practices.

## Minor event actions

(38) The IBC will review the information at the next IBC meeting. The IBC may choose to meet with the Chief Investigator who must be notified of the meeting date and informed attendance at the meeting may be required.

(39) The IBC will assess the information provided to determine if a non-compliant event has occurred.

(40) The IBC will determine any actions to be taken by the Chief Investigator to resolve the incident. The IBC may choose to require additional information, review of records, and submission of a request for minor amendment form or other documentation to satisfy the committee that such an event will not occur in the future.

(41) Consideration will be given to the need to review other approved projects with which the Chief Investigator is also involved.

(42) The focus of investigation and review should be on improvements in processes or protocols.

(43) On completion of the review if it is determined that an incident/ non-compliant event has occurred the IBC will inform the Licensee of the outcome of the assessment of the event, actions required and improvements that have been made.

(44) In order to determine that ongoing improvement has taken effect the IBC may set an appropriate time point to review the project and all related projects.

(45) The IBC secretary will ensure that all records relating to the event are filed.

## Moderate event actions

(46) All steps outlined in minor events will be followed. In addition:

a. The IBC Chair may determine that the event is to be considered by an out of session executive. The executive may elect to suspend all activity associated with the project until the next full IBC meeting where the event can be discussed.
b. The Licensee will be informed of the event and kept up to date with progress of any investigations or decisions.
c. In the event that the executive determines that activity is to be suspended, the executive will establish an investigation team to review the project under investigation and all related projects. The investigation team will meet with the Chief Investigator. This team will make all efforts to complete the review in order to present the finding at the next IBC meeting. The Chief Investigator will be required to attend this meeting to discuss the findings and required actions with the IBC.

## Major & Severe event actions

(47) Refer to the Critical Incident, Emergency Planning and Business Continuity Procedure.

(48) The IBC Chair will immediately notify:

a. the Licensee,
b. the Deputy Vice-Chancellor, Research and Impact (for consideration of broader University critical Incident procedures);
c. Governance Committees (research and Research Training Committee and / or Academic board;
d. Technical Managers;
e. OHS;
f. IBC Members; and,
g. The Chief Investigator (and instruct the Chief Investigator that all work on the project, other than ongoing maintenance or care of the animals or patients, be stopped pending an investigation).

(49) The Chief Investigator will be required to submit a report to the IBC outlining the incident.

(50) The IBC will establish an investigation team; the Licensee may elect, or be asked by the IBC, to be part of this team. The investigation team will also review all related projects. The investigation team will meet with the Chief Investigator. This team will make all efforts to complete the review in order to present the finding at the next IBC meeting. The Chief Investigator will be required to attend this meeting to discuss the findings and required actions with the IBC.

(51) If the investigation team establishes that a serious event of non-compliance has occurred, the IBC Chair or nominee will contact the relevant regulator to seek assistance in determining appropriate actions to be taken.

(52) If determined necessary by the IBC, Licensee or the relevant regulator, outcomes of required actions will be reported to the regulator.

(53) The focus of investigation and review should be on improvements in processes or protocols to ensure continued safety and compliance.

(54) On completion of the review if it is determined that a non-compliant event has occurred the IBC will inform the Licensee of the outcome of the assessment of the event, actions required and improvements that have been made.

(55) In order to determine that ongoing improvement has taken effect the IBC will set an appropriate time point to review the project and all related projects.

(56) The IBC secretary will ensure that all records relating to the event are filed.

## Additional Actions

### Reporting incidents that affect human health

(57) Any hazards or occurrences which have caused injury or illness to any person, or have the potential to cause injury or illness to any person in an IBC approved project or containment facility, must be reported via the OHS Incident Reporting System (as per the Health and Safety - OHS Incident Reporting and Investigation Procedure) and the IBC Incident Report form to the IBC.

(58) Members will provide advice as required on any Worksafe notification.

(59) The IBC will:

a. provide immediate incident triage advice;
b. where appropriate, report incidents to the relevant biosafety regulator and Licensee. This may result in an external inquiry, possible loss of certification and possible prosecution;
c. investigate the incident a make recommendations to improve processes.

### Reporting incidents that affect animal welfare

(60) If animal welfare is compromised in an IBC approved project this must be reported to both the AEC (using the AEC Incident Report Form) and the IBC (using the IBC Incident Report Form).

(61) The AEC is responsible for advising and coordinating the animal welfare response.

(62) The IBC will:

a. provide immediate incident triage advice with regard to biosafety compliance;
b. where appropriate, report incidents to the relevant biosafety regulator and Licensee. This may result in an external inquiry, possible loss of certification and possible prosecution;
c. investigate the incident and make recommendations to improve processes.

### Reporting spills/un-intentional release of GMOs or Risk Group Agents to the environment

(63) Any unintentional release/escape of GMOs (GM micro-organisms, GM animals, GM embryos, GM sperm & GM ova) or risk group agents from the facility to the environment both inside and outside the facility must be reported to IBC as soon as practicable using the IBC Incident Report Form.

(64) The IBC will:

a. provide immediate incident triage advice with regard to biosafety compliance;
b. where appropriate, report incidents to the relevant biosafety regulator and Licensee. This may result in an external inquiry, possible loss of certification and possible prosecution;
c. investigate the incident a make recommendations to improve processes.

(65) Failure to secure the appropriate OGTR certification for their facility, use an inappropriate facility, using genetically modified organisms without a current assessment from the IBC, or adhering to the Gene Technology procedure, will each be considered in breach of the University's requirements and may also attract criminal charges.

# Part D - Penalties

(66) Consequences of Non-compliance can include:

a. Disciplinary action.
b. Rejection of subsequent applications (e.g. researchers may be excluded from work with GMOs).
c. Possible loss of funding or inability to secure future funding.
d. Heavy fines and/or imprisonment with a criminal record.
e. Adverse publicity for the individual and for the University.
f. Loss of accreditation by Organisation.

## Status and Details

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| **Status** | Current |
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| **Approval Authority** | Deputy Vice-Chancellor, Research & Impact |
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