Biosafety - Non-Compliance and Adverse Incidents Procedure

Section 1 - Summary

(1) This procedure outlines Victoria University's (VU) processes for the investigation and management of any adverse and non-compliant incident in relation to biosafety, in accordance with the relevant codes, regulations and standards.

Section 2 - Scope

(2) 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.

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

Section 3 - Policy/Regulation

(4) Biosafety Policy

Section 4 - 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 regulatory bodies in relation to the handling of biological materials.
Executive Director, Research Services	Responsible to the DVC-RI to ensure that the Senior Manager, Research Infrastructure & Biosafety, has resources and support to advise and report on the regulatory and legislative requirements for handling of non-compliant and adverse incidents, and to develop, implement, monitor and review associated procedures and guidelines.
Senior Manager, Research Infrastructure & Biosafety	Authorised to advise on legislative and regulatory requirements for the handling of non-compliant and adverse incidents, and report to advise the IBC.
Directors, Executive Deans and Heads of Department	Responsible for ensuring all staff and students receive appropriate information and training, and comply with biosafety procedures and guidelines, including the handling of non-compliant and adverse incidents.
Manager, Technical Services	Responsible for oversight of technical staff and ensures facilities meet compliance standards for containment and safe handling of non-compliant and adverse incidents.

Roles	Responsibilities
Technical Managers	Implement biosafety procedures in facilities, maintain inventories, verify training and competency of end-users, and ensure compliance with permit conditions and ethics approvals. Ensure any non-compliant and adverse incidents are reported and handled appropriately
Project Supervisor / Subject Coordinator (including Primary/Chief Investigators, Academic Supervisors, Research Supervisors, and Unit Conveners)	Responsible for health and safety of students, volunteers, and staff under their supervision. Ensure compliance with biosafety procedures and ethics approvals, including procedures for the handling of non-compliant and adverse incidents.
Staff, Students, Volunteers and External Users	Follow all biosafety procedures, complete required training and competency assessments, and ensure their actions do not compromise safety or compliance.
Senior Officer, Animal Ethics & Biosafety	Acts as IBC Secretary, manages communications between IBC, supervisors, and facility managers, and supports compliance monitoring.

Part B - Reporting and Investigation

(5) 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 IBC Secretary or Senior Manager, Research Infrastructure & Biosafety (or authorised delegate).

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

(7) Upon notification the IBC Chair will consider the severity of the event in consultation with the Senior Manager, Research Infrastructure & Biosafety as potentially Insignificant, Minor, Moderate, Major, or Severe (see categorisations below).

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

(9) The incident report is distributed to all IBC members for comment and if necessary an Executive established to assess the incident, or an extraordinary committee meeting may be convened for further discussion.

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

(11) 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.

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

Categorisation of an incident

(13) 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. Animal Welfare Regulations, Australian code for the care and use of animals for scientific purposes and the VU

Animal Welfare Non-Compliant Events Procedure and associated guidelines.

Insignificant incident

(14) No harm or a near miss.

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

Minor incident

(16) 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).

(17) Incident causing harm that can be instantly locally addressed through first aid or self-care.

(18) Incident causing health effects that are reversible.

(19) Incident resulting in reversible, time- and/or space-limited damage to the environment.

Moderate incident

(20) 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.

(21) Any deviation from an approved NLRD application.

(22) Incident causing harm that requires medical treatment beyond first aid (e.g. ambulance transport or hospital care), but does not result in life threatening injury or prolonged recovery.

(23) A failure to comply with biosafety legislation, VU Policy and/or IBC Procedures, but does not need to be reported to external regulators and can be managed by the IBC.

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

Major incident

(25) Deliberate or negligent deviations from approved protocol where there is, or has 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.

(26) Severe injury requiring hospitalisation or prolonged care/recovery.

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

(28) 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 incident

(29) Permanent disability, one or more deaths, or exposure to an incurable disease.

(30) Environmental damage that is irreversible.

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

by external regulators.

Part C - Actions Following an Incident

(32) The action taken will be determined by the severity of the incident. In all cases the Primary/Chief Investigator will be contacted by the IBC to provide a report to the IBC outlining the circumstances of the incident.

Insignificant incident actions

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

Minor incident actions

(34) The IBC will review the information at the next IBC meeting. The Committee may choose to meet with the Primary/Chief Investigator who must be notified of the meeting date and advised that attendance at the meeting may be required.

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

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

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

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

(39) 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 implemented.

(40) In order to determine that ongoing improvement has taken effect the IBC may set an appropriate timeframe in which to review the project and all related projects.

(41) The IBC Secretary will ensure that all records relating to the incident are filed.

Moderate incident actions

(42) All actions outlined for minor incidents will be followed. In addition:

a. The IBC Chair may determine that the incident 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 incident can be discussed. In some circumstances, an extraordinary committee meeting may be convened.
b. The Licensee will be informed of the event and kept informed of the progress of the investigation.
c. In the event that the IBC/Executive determines that activity is to be suspended, an investigation team will be established to review the project in question and all related projects. The investigation team will meet with the Primary/Chief Investigator and make all efforts to complete the review in order to present the finding at the next scheduled IBC meeting. The Primary/Chief Investigator may be required to attend this meeting to discuss the findings and identified actions.

Major & Severe incident actions

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

(44) 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 Primary/Chief Investigator (and instruct the Primary/Chief Investigator that all work on the project, other than ongoing maintenance or care of the animals or patients, be stopped immediately pending an investigation).

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

(46) 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 meet with the Primary/Chief Investigator and review all related projects. The team will make all efforts to complete the review in order to present the finding at the next scheduled IBC meeting. The Primary/Chief Investigator will be required to attend this meeting to discuss the findings and identified actions.

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

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

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

(50) 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, actions required and improvements that have been implemented.

(51) In order to determine that ongoing improvement has taken effect the IBC will set an appropriate timeframe in which to review the project and all related projects.

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

Additional Actions

Reporting incidents that affect human health

(53) Any hazards or incidents that cause, 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.

(54) IBC members will provide advice as required on any Worksafe notification.

(55) 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 and make recommendations to improve processes.

Reporting incidents that affect animal welfare

(56) 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).

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

(58) 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

(59) Any unintentional release/escape of GMOs or Risk Group Agents must be reported to the IBC as soon as practicable using the IBC Incident Report Form. This includes incidents both within the facility and outside the facility.

(60) 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.

(61) Failure to secure the appropriate OGTR certification for a facility, use of an inappropriate facility, use of GMOs without a current assessment from the IBC or not adhering to Gene Technology procedures, will each be considered in breach of the University's requirements and may also attract criminal charges.

Part D - Penalties

(62) 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. Damage to reputation for the individual and for the University.
f. Loss of accreditation by the organisation.

Section 5 - HESF/ASQA/ESOS Alignment

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

Section 6 - Definitions

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

(65) IBC non-compliant incident - Any activity that does not comply with Biosafety regulatory requirements, VU Policy and/or IBC Procedures.

(66) IBC adverse incident - Any activity associated with working with biological material or in containment facilities that can potentially impact human and animal health or the environment.

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