Biosafety Program Permit: Quality Assurance Review Procedure 2020

Biological Safety Program

Intent and Application

Quality Assurance Reviews are undertaken to help verify that documentation related to the use of Biological Agents at the University is current and correct after Biosafety Program Permits have been issued and in instances where Permit information may be out of date. The intention of this procedure is to detail under what circumstances the Biosafety Program will undertake Quality Assurance Reviews, the scope of review, the review process, reporting of the review and discusses potential outcomes of a negative review. The procedure is written in the context of the University of Manitoba Biosafety Procedure.

Definitions

Quality Assurance Review: A critical review of a Biosafety Permit Holder's documentation for errors or omissions as they pertain to the use of Biological Agents.

Documentation: Paper or electronic records pertaining to a U of M faculty, staff, or student's use of Biological Agents which may include but are not limited to; Biosafety Permits, e-mails, grant forms, funding forms, research grants, research contracts, previous Biosafety Program documentation, Animal Use Protocol forms, or any equivalent or subsequently derived documentation.

Biological Agents: shall refer to any live or unfixed risk group 1-4 agents which affect humans, animals, plants or insects and can include, viruses, bacteria, mycoplasmas, protozoa, helminths, prions, molds, fungi, biological toxins, allergens, algae, cells, human and animal tissues, human and animal tissue cultures or any other biological material used or stored at the University of Manitoba.

Biological Safety Officer: a person appointed by EHS to fulfill the role and responsibilities of a Biological Safety Officer.

Permit Holder: A University Faculty Member who has been issued a Biosafety Program Permit or who holds any previously issued equivalent.

Biosafety Risk Assessment: An assessment of risks and mitigation strategies as established and approved in a Biosafety Program Permit.

Authority

The Biological Safety Officer is designated to carry out Inspections, Audits and Reports under Part II Section 2.14 of the University Biosafety Procedure. Subsection (c) requires Permit Holders to cooperate with the Biological Safety Officer in the execution of audits or inspections.

Procedure

Quality Assurance Review Criteria

Random Quality Assurance Reviews

Quality Assurance Reviews may be undertaken on randomly selected Biosafety Permit holder or holders. The Biological Safety Officer or their designate will generate a random list of numbers and use those to correlate to permit numbers issued to Biosafety Permit Holders. The Permit Holder will not be advised of the review before it is conducted but may be asked to provide follow up information if there are questions or concerns raised during the process.

Focused Quality Assurance Reviews

A focused quality assurance review will be carried out when there are reasonable grounds to suspect that a Permit Holder, Faculty, Staff, or Student, is carrying out work with Biological Agents without an approved Biosafety Risk Assessment. Indicators of reasonable grounds can include but is not limited to;

- Biosafety Program Permit inactivity for a period in excess of 12 months
- refusal on the part of the permit holder to comply with program requests
- issuance of a second incidence of non-compliance with the Biosafety Policy or Procedure,
- news or media discussions regarding projects that do not have approval
- a Requested Quality Assurance Review that shows significant irregularities.

Requested Quality Assurance Reviews

Quality Assurance Reviews may be requested by agents of the University, most typically from the Office of Research Services who administer research grants and contracts, material transfer agreements, and other documents related to research. It is common that these agents will ask if a Faculty member has approval to use specified Biological Agents or if a University of Manitoba Project number has an approved Biosafety Risk Assessment.

Scope of Quality Assurance Review

Quality Assurance Reviews will specifically exclude any personal and professional communications and files, including paper and electronic records, excepting administrative communications and files, subject to *The Freedom of Information and Protection of Privacy Act (FIPPA)*, and/or any other applicable statutes of the Government of Manitoba and the Government of Canada related to access to information and the protection of privacy, as they may be proclaimed or amended from time to time (2).

Random and focused quality assurance reviews will be comprehensive reviews of all available documentation for projects awarded up to five calendar years prior to the date the review was started. The review will encompass approved Biosafety Risk Assessments, grant and contract documentation, animal care and use documentation,

news and media articles and posts, research publications, and any other reasonable indicators of research activity available either through the University administrative systems or that are publicly available.

Requested Quality Assurance Reviews will be confined to the information provided by the requesting agent and the approved Biosafety Risk Assessments included in a permit holder's Biosafety Program Permit. The outcome of a Requested Quality Assurance Review will be communicated to the requesting agent using the appended Research Grant and Contract Review form or equivalent.

Quality Assurance Review Process

Random and Focused Quality Assurance Reviews

Random and Focused Quality Assurance Reviews only differ in way they are started as described above. In both cases the review will include a full review of the Permit Holder's current permit including the approved scope of work, agents in use, procedures, and the list of approved University of Manitoba Project numbers. This information will be compared to all available documentation on file with the Office of Research Services for awarded research grants and contracts for the preceding five years as well as any publicly available information.

If there are no errors, omissions, or other inconsistencies with the approved Biosafety Program Permit a report is filed and attributed to the Permit holder with no further actions taken. If errors, omissions or other inconsistencies are found, a report will be written by the Biological Safety Officer or their designate to detail the problem. The report will be forwarded to the Office of Research Services and the Associate Dean of Research for the relevant faculty for their action.

Requested Quality Assurance Reviews

In a Requested Review an agent of the University, typically from the Office of Research Services will forward a document for review or a specific question to ask if a researcher has an approved biosafety risk assessment. These are commonly Material Transfer Agreements, Research Grants, Research Contracts or other documents collected in their internal processes. The review in a case like this will be limited to the documents supplied by the requestor and will be compared to the University of Manitoba Project numbers and Biological Agents included in the most recently approved Biosafety Program Permit. If the documentation is in order the requestor will be advised that the permit holder has approval or that approval is not required. If the review shows inconsistencies, they will be communicated back to the requestor.

If significant inconsistencies are discovered in a Requested Quality Assurance Review, it may trigger a Focused Quality Assurance Review.

Reporting Results

Potential Outcomes of Quality Assurance Reviews

If no inconsistencies are found, no further actions are taken.

If inconsistencies are found as part of any Quality Assurance Review the Biosafety Officer or their designate will ask the Permit Holder to correct the error if the University of Manitoba Project number is still active. If the correction is not made in the time period specified in the notification, the Permit Holder will be considered in non-compliance with the University Biosafety Policy and Procedure. In cases of non-compliance the Biosafety Procedure Part II Enforcement Section 2.16 is initiated.

Inconsistencies are concurrently reported to the Office of Research Services and the Associate Dean of Research for the faculty in question as a potential "Breach" (3) as described in the Responsible Conduct of Research – Investigation Procedure. This may trigger a Responsible Conduct of Research investigation at the discretion of the Associate Dean of Research and the Office of the Vice President of Research and International. During a Responsible Conduct of Research Investigation the Biological Safety Officer or their designate may be called upon to clarify their report, provide additional details, or interpret the Biosafety Policy and Procedure as it relates to the Breach.

	Random	**Focussed**	**Requested**
Reason for review	Periodic review of permit holders	Discrepancies, suspect or evidence of NInJA projects	Agents of the university (eg ORS, office of the VPRI)
Scope	Comprehensive review of internal and public documentation and approvals for projects from the last 5 calendar years		Confined to information being requested. ORS provides documentation to be reviewed.
Review Process	No errors/omissions – report is filed in Permit Holder's records Errors/omissions found – report written by biosafety program and sent to permit-holder, ORS and the ADR of Permit Holder's faculty.		RGC Review is provided to requestor with outcome of review and next steps. If significant inconsistencies found, focussed QAR may be launched.
Reporting Results	In all QAs, the permit holder will be notified if there are errors/omissions found. The permit-holder's ADR and ORS will also be notified. Depending on the nature of the error/omission further investigation may be undertaken as part of the Responsible Conduct of Research policy and procedure		

Table 1: Summary of types of quality assurance reviews, scope and reporting results (ORS = Office of research services, ADR = Associate Dean of Research)

References

1) Biosafety Procedure 2020
2) University of Manitoba Faculty Association 2017-2021 Collective Agreement
3) Responsible Conduct of Research – Investigation Procedure 2017

Appendices

Research Grant and Contract Review Sheet 2019

University of Manitoba

Biological Safety Program

Biosafety Officer
Steven Cole
(204) 789-3675
steven.cole@umanitoba.ca

Biosafety Specialist
Vanessa Pinto
(204) 789-3477
vanessa.pinto@umanitoba.ca

Research Grant/Contract Review Sheet - 2019

Principal Investigator:

Date:

Grant-Contract Title:

University of Manitoba Project Number (or equivalent):

Review requested by:

Grant ◯ Contract ◯ Material Transfer Agreement ◯

Requires Biosafety approval? Yes ◯ No ◯

Activities that require biosafety approval:

Additional notes:

Sincerely,