
IMPLEMENTATION DIRECTIVE
USE OF HUMAN SPECIMENS IN RESEARCH AND TEACHING
LABORATORIES

Implementation Directive

Use of Human Specimens in Research and Teaching Laboratories

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INTRODUCTION

Human samples that are collected for use at McMaster University have not previously been categorized according to their use and infectious state. As such, risk assessments and risk group assignments have been problematic. To this end, as of October 27, 2014, the PBAC has re-categorized human samples into the following categories:

- a) Reasonably expected to contain infectious materials, organisms or toxins and culturing¹
- b) Reasonably expected to contain infectious materials, organisms or toxins and not culturing
- c) Unknown and culturing
- d) Unknown and not culturing
- e) Proven to be free of infectious materials organisms and toxins and culturing
- f) Proven to be free of infectious materials organisms and toxins and not culturing

APPLICABILITY UNDER RMM#600 – BIOSAFETY PROGRAMME

The purpose of the Biosafety Programme is to provide University-wide oversight with respect to the use of infectious materials, organisms and toxins. The scope of the Biosafety Programme determines which samples do and do not require biosafety oversight. Section 2.5 of RMM#600 states:

“The biosafety programme applies to stakeholders using, in any manner, any material collected from any human, terrestrial animal, aquatic animal, plant or environmental locale which is reasonably expected to contain, infectious materials, organisms or toxins.”

and Section 2.6 of RMM#600 states:

“The biosafety programme applies to stakeholders culturing any material collected from any human, terrestrial animal, aquatic animal, plant or environmental locale.”

These two sections describe the inclusion within the scope of the programme any material that is cultured and any material that is reasonably expected to contain infectious materials, organisms or toxins. These effectively include groups a, b, c and e. This leaves groups d and f out of the scope of the Biosafety Programme and thus use of these materials does not require biosafety oversight.

ASSESSING INFECTIOUS STATE

REASONABLY EXPECTED TO CONTAIN INFECTIOUS MATERIALS, ORGANISMS OR TOXINS²

This category shall be selected if any of the following apply:

- the specimen was taken from a human, animal, plant or environmental locale whose history or current information indicates that the sample will be infectious;
- the specimen was taken from a human, animal, plant or environmental locale that was intentionally infected;

¹ Culturing – *in vitro*, propagative activity with the intention to grow/isolate cells or grow/isolate microorganisms. Does not include sealed-container diagnostic culture where the culture vessel is not opened prior to disposal.

² Definition taken directly from RMM600 section 4.9.

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- the specimen was proven to be infectious

PROVEN TO BE FREE OF INFECTIOUS MATERIALS, ORGANISMS AND TOXINS

This category shall be selected if any of the following apply:

- the sample was tested and proven free of infection at the manufacturer
- the sample was tested and proven free of infection after collection
- the sample was obtained from a donor or patient that was tested and proven free of infection at the time of collection

UNKNOWN

This category shall be selected if none of the above statements apply. If there is not enough information to rule out the above statements, use of the sample should be re-evaluated since such a lack of information indicates reasonable grounds to re-evaluate the risk or otherwise handle the sample at BSL2.

INTENDED USE

If there is any intent to put the sample into culture for cell/tissue harvest or for pathogen isolation or to keep the sample alive, “culturing” must be selected. For the purposes of the biosafety programme, sealed container culturing i.e. where the sample is cultured in a closed/sealed container for diagnostic purposes and which is never opened prior to disposal, is not included in the definition of “culturing”.

RECOMMENDATIONS FOR HANDLING REQUIREMENTS

For those culture and non-culture samples which are reasonably expected to contain infectious materials, organisms or toxins handling requirements must be at the **containment level suitable for manipulation of the pathogens expected to be in that sample**. A risk assessment will be provided by PBAC and Biosafety Training is provided by the Biosafety Office. In some cases, handling precautions for infected samples are offered by the Public Health Agency of Canada.

For those samples which are unknown or proven to be free of infection, cultures should be handled at **Biosafety Level 1**. Biosafety Training is provided by the Biosafety Office.

For those samples which are unknown or proven to be free of infection, non-culture samples should be handled using **Universal Precautions/Routine Practices**. This training is to be provided online through Mosaic.

For those laboratories which have both exempt and non-exempt samples, it is recommended that the Supervisor assess the risk of identification error by performing a risk assessment based on concurrent manipulation of both types of samples. If the risk is deemed to be **medium** or **high**, it is recommended that all samples be handled at the prescribed containment level for the non-exempt samples.

It is acknowledged that commercial sources, other institutes, other countries and governments may provide handling requirements for their products or samples at a level above that which is required by these McMaster standards. Administration of containment levels where none are deemed necessary will not be provided i.e. BUPs and biosafety audits will not be provided for laboratories which do not require them. Should any laboratory wish

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to operate at a higher containment level than that prescribed by the PBAC, the Biosafety Office will act as a resource for information and training. Those laboratories may not post signage on doors or storage units which indicates such an elevated containment level.

REVISION OF EXISTING BIOHAZARD UTILIZATION PROTOCOLS

For those Supervisors who no longer require biosafety oversight, notification to indicate such changes will be sent as documentation. *The notice will indicate the currently funded projects also no longer require follow-up from the funding offices.* The BUP information will be archived. Should the supervisor require biosafety oversight in the future, the same BUP will be re-activated.

For those Supervisors who now can be downgraded from BSL2 to BSL1, notification to indicate such a downgrade and facilitation of BUP changes will be carried out by the Biosafety Manager. In the case of BSL1 labs who routinely use control, non-culture (and therefore exempt) samples, the Supervisor may choose to retain the exempt samples in their biological inventory for the sake of completeness. The biosafety level of exempt samples may be changed to *Exempt*.

For those Supervisors who have both exempt and non-exempt samples, notification to indicate such downgrades and facilitation of BUP changes will be carried out by the Biosafety Manager. In the case of BSL2 labs who routinely use control, non-culture (and therefore exempt) samples, the Supervisor may choose to retain the exempt samples in their biological inventory for the sake of completeness. The biosafety level of exempt samples may be changed to *Exempt*.

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