McMaster University

RESEARCH

Presidential Biosafety Advisory Committee

IMPLEMENTATION DIRECTIVE

USE OF HUMAN SPECIMENS IN RESEARCH AND TEACHING LABORATORIES

Approved: February 10, 2021

McMaster University

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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 culturing[1]
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 TOXINS[2]

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;

[1] Culturing – *in vitro*, propagative activity with the intention to grow/isolate cells, grow/isolate microorganisms or any protocols used to keep any sample alive for downstream analysis. 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.

- the specimen was taken from a human, animal, plant or environmental locale that was intentionally infected;
- 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.

Specimens Potentially Containing SARS-CoV-2

In the current COVID-19 Pandemic, human samples may pose an unknown risk of containing SARS-CoV-2 virus. All human samples must be assessed for the likelihood of containing SARS-CoV-2 as outlined in the PID – Use of Samples Containing SARS-CoV-2. The likelihood of risk in asymptomatic human samples must be determined by the Supervisor based on the history, community risk, or current status of the participants being sampled. If the Supervisor has determined there is not sufficient information to evaluate the risk out of an abundance of caution the samples must be considered moderate or high risk. If the samples are reasonably expected to contain multiple pathogens, the samples must be handled at the highest containment level prescribed.

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. were 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". For the purposes of the biosafety program, organ culture, electrophysiology and live flow cytometry are considered to be "culturing" (PBAC decision, September 26, 2016).

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, handing 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 containment 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 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.

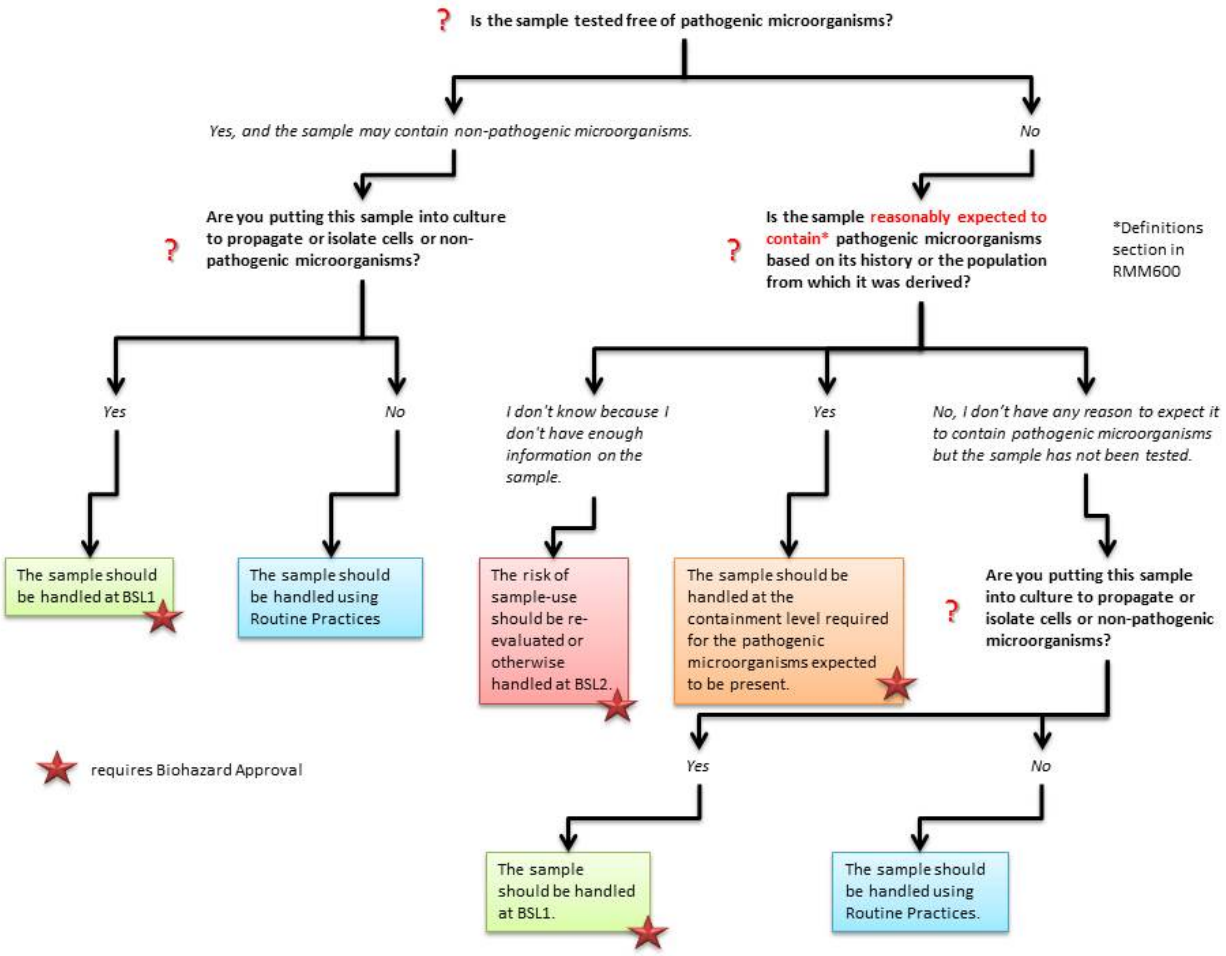
REVISION OF EXISTING BIOHAZARD UTILIZATION PROTOCOLS

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 CL2 to CL1, notification to indicate such a downgrade and facilitation of BUP changes will be carried out by the Biosafety Manager. In the case of CL1 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 risk group 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 CL2 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 risk group level of exempt samples may be changed

to *Exempt*.


Is the sample tested free of pathogenic microorganisms?
Yes, and the sample may contain non-pathogenic microorganisms.
No
Are you putting this sample into culture to propagate or isolate cells or non-pathogenic microorganisms?
Is the sample reasonably expected to contain* pathogenic microorganisms based on its history or the population from which it was derived?
*Definitions section in RMM600
Yes
No
I don't know because I don't have enough information on the sample.
Yes
No, I don't have any reason to expect it to contain pathogenic microorganisms but the sample has not been tested.
The sample should be handled at BSL1
The sample should be handled using Routine Practices
The risk of sample-use should be re-evaluated or otherwise handled at BSL2.
The sample should be handled at the containment level required for the pathogenic microorganisms expected to be present.
Are you putting this sample into culture to propagate or isolate cells or non-pathogenic microorganisms?
requires Biohazard Approval
Yes
No
The sample should be handled at BSL1.
The sample should be handled using Routine Practices.

Revision History

- November 24, 2014 – Initial Approval
- September 26, 2016 – Updated definition of 'culturing'
- February 10, 2021 – Added section regarding SARS-CoV-2, pointer to SARS PID and update of nomenclature for containment level and risk group.