Biohazardous Samples- Policy for Cell Sorting

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Overview:

Please be advised that according to AS/NZS 2243.3 definitions, FlowCore is categorized as a PC2 certified facility. As such, FlowCore will impose a booking policy that requires users to classify possible biosafety hazards related to their experimental samples. In accordance with Monash policy, a risk assessment must be undertaken for all activities that involve biological hazards. If the samples submitted for processing on FlowCore cell sorters are categorised as PC2 Level Biohazardous Material, then a Biological Risk Management Program must have been completed on S.A.R.A.H and submitted to the Monash University WHS Risk Register. Risk assessment submissions may be subject to review by FlowCore management upon request. The client may be asked to provide the relevant S.A.R.A.H. risk assessment reference number as a mandatory condition for completing the instrument reservation. FlowCore will make allowance for certain variations to the aforementioned policies for those clients who are operating under institutional governance outside the framework of Monash University.

Regarding FlowCore's Cell Sorting Instrumentation:

All FlowCore cell sorters utilize the "jet-in-air" design. High operating pressures and aerosol production are inherent to jet-in-air cell sorters and must be considered as a potential hazard for aerosol exposure to staff and clients working in close proximity to the cell sorter. Incidental exposure to biohazardous aerosols presents a risk for laboratory-acquired infections. In an attempt to mitigate some of this risk, FlowCore has equipped Influx 1 with an ancillary aerosol management system. Influx 2 has no aerosol management provisions. Presently, Influx 3 and the Aria Fusion are the only cell sorters appropriately equipped for processing approved biohazardous samples.

Universal Precautions and Policy for Handling Primary Human Tissues:

Universal Precautions - Universal precautions is an approach to infection control to treat all primary human tissues as if they were known to be infectious.

Primary Human Tissues - The potential hazard for handling primary human tissues is accidental exposure to pathogenic organisms. Some infections that can be transmitted, through the respiratory route or other pathways, via contact with primary human tissue include: HIV, Hepatitis A, B, C, Staph and Strep infections, Gastroenteritis-salmonella, and shigella, Pneumonia, Syphilis, TB, Malaria, Measles, Chicken Pox, Herpes, Urinary tract infections, and Blood infections. All human clinical samples are to be treated as potentially infectious. Accordingly, all clinical samples are to be manipulated in facilities that, at a minimum, meet PC2 facility and procedural requirements.

It is of the utmost importance, and in accordance with Monash University Procedure, that all biological samples should be double contained within an unbreakable container, whenever they are being transported between PC2 facilities. Samples in 5mL snap-cap tubes should have their caps engaged and be transported in a secondary hard plastic container with a lockable lid. The portable insulated container (esky) constructed of expanded polystyrene (aka Styrofoam) **is not** a suitable transportation container for biologicals. Please take all empty containers and other waste back to your laboratory for disposal.

Resources for working with PC3 Level Biohazardous Material:

The greatest risks are from HIV and Hepatitis B and C, accordingly any tissues that are known to harbour these pathogens, are to be considered as PC3 Level Biohazardous Material and may not be utilised in FlowCore. Researchers who desire to perform flow cytometry analysis and cell sorting of PC3 Level Biohazardous Material should consult the AMREPFlow core flow cytometry facility which caters for infectious sample sorting in a dedicated PC3 environment.

Working with Genetically Modified Organisms:

All work/study utilising recombinant DNA technology is controlled through the Office of the Gene Technology Regulator. All Monash matters concerning gene technology are handled by the Research Office. General information regarding the use of GMOs and appropriate approval can be obtained from the OGTR website.

The Safe Use of Viral Vectors - In the interest of designing safe gene vectors, the virus you are using in your experiments should be engineered so that it cannot reproduce (replication-deficient). Best practice would be to encode all necessary components of the virus using 3 separate plasmids to ensure that any one plasmid cannot mutate to generate replication competent virus. The goal is to allow for propagation of viral particles with the "gene of interest", while not allowing the virus to exert any pathogenic properties associated with the whole or "wild-type" virus. Should clients choose to utilize our cell sorting services to manipulate their packaging cell lines, those cell lines should produce only ecotropic virus.

There are two basic biosafety concerns regarding research using viral vectors. Firstly, with respect to manipulating GMOs on FlowCore analysers and cell sorters, all protocols for manipulating viruses and packaging cell lines must be controlled by the OGTR as they are genetically modified and ideally they should be at the low end of regulation, which is NLRD (notifiable low risk dealing) or below. It is crucial that there is a negligible risk for acquisition of replication competency by any viruses you present for handling by FlowCore staff. Secondly, in accordance with Monash University Procedure, all GMOs must be double contained (as described in the previous page of this document under *Policy for Handling Primary Human Tissues*) whenever they are being transported between a PC2 facilities.

Proposed Terms:

• Be advised that your adherence to the policies specified in this document is obligatory for being in compliance with rules and regulations stipulated by Monash OHS (SAI Global - Health and Safety AS/NZS 4801 and OHSAS 18001 Certified Systems).

• Your knowledge of and acquiescence to these policies is of paramount consideration for your safety, as well as the safety of FlowCore staff and our clients.

• FlowCore reserves the right to deny access to any user who has not submitted acknowledgment of our facility policy documents.