

Policy For Processing Biohazardous Samples on FlowCore Cell Sorters

Attention FlowCore Clients:

Overview:

Please be advised that FlowCore is categorised as a PC2 certified facility. As such, FlowCore will impose a booking policy that requires users to identify possible biosafety hazards related to their samples. In accordance with Monash policy, a <u>risk assessment</u> 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 <u>Biological Risk Management Program</u> must be completed on <u>S.A.R.A.H</u> and submitted to the Monash University WHS Risk Register. Risk assessment submissions are subject to review by FlowCore management and upon approval the client must provide the relevant S.A.R.A.H. risk assessment reference number as a mandatory condition for completing the instrument reservation.

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 AriaFusion are the only cell sorters appropriately equipped for processing approved biohazardous samples.

<u>Universal Precautions and Policy for Handling Primary Human Tissues:</u>

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 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. Human clinical samples are to be treated as potentially infectious unless categorically known to be otherwise. For this reason, 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 whenever they are being transported between PC2 facilities.

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 MREPFlow core flow cytometry facility which caters for infectious sample sorting in a dedicated PC3 environment.

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Policy For Processing Biohazardous Samples on FlowCore Cell Sorters (continued)

Attention FlowCore Clients:

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 Use of Viral Vectors - Viruses are inherently capable of binding to mammalian cells and transferring genetic information into those cells. Each virus has evolved to utilize the host cell's machinery in order to replicate itself. Using viruses for vectors takes advantage of this cell targeting and gene expression system. In the interest of designing safe gene vectors, the virus is generally engineered so that it cannot reproduce (replication-deficient). This is accomplished by removing a gene from the virus genome that is critical for replication. This vector can now be reproduced by incubating it with cells that can compensate for the gene that was deleted, allowing the virus to replicate within the cell, these are known as 'packaging cell lines'. In some cases, another virus can supply the missing replication machinery (helper virus). 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. Moreover, packaging cell lines that we sort in this facility should produce only ecotropic virus that targets a narrow host range (e.g. a small group of species or cell culture lines). The mutually beneficial goal is to end up with a large number of viral particles with the "gene of interest", but to not allow the virus to exert any pathogenic properties associated with the whole or "wild-type" virus.

There are two basic biosafety concerns regarding research using viral vectors. Firstly, with repect to manipulating <u>GMOs</u> on FlowCore analysers and cell sorters, viruses and packaging cell lines must be covered by the <u>OGTR</u> as they are genetically modified and ideally they should be at the low end of regulation, which is <u>NLRD</u> (notifiable low risk dealing). 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 <u>Monash University Procedure</u>, all GMOs must be double contained whenever they are being transported between a PC2 facilities.

As a matter of facility policy, and with respect for the safety of FlowCore staff, biologicals should never be taken into FlowCore office space.

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