Yale *Environmental Health & Safety*

Core Facility Acquisition Biohazard Questionnaire
Cell Sorter Registration

Please complete the form below and include copies of the following:

- Cell sorting standard operating procedure (biosafety protocol for use);
- Emergency response procedures to clean up and decontaminate the sorter in the event of a spill, clog or deflection within the sorter;
- Training transcript for each researcher who will utilize the sorter. This should include confirmation of Biosafety Training Part I and Part II, Laboratory Chemical Safety Training at a minimum and Bloodborne Pathogen Training, as applicable.

Please send the completed form and above information to:
Yale Environmental Health & Safety
Attn: Biosafety Officer
135 College Street, Suite 100
New Haven, CT. 06510
OR
email-to ehs@yale.edu.

Today's Date:		
Principal Investigator		
Principal Investigator:		
Lab Location (building/room#):	Department:	
Phone:	Email:	
Cell Sorter Manager:		
Cell Sorter Information		
Make:	Model:	Serial #:
Describe the biosafety containment with the sorter (i.e., a biocontainment enclosure or hood or a HEPA filtered aerosol management system):		
What is the standard for determining if someone is trained appropriately for sorting? Number of hours? Manufacturer training?		

Cell Sorter Information (Continued)
Location where it will be used:
Number of individuals who use this room daily:
Area Location Within Room (include map, as applicable showing traffic patterns, door locations, door swing, etc.). Please also describe the other lab equipment in this room in your response here:
Describe the nature of the research materials, including biohazards you plan to use with the sorter (list all that may ever be utilized with this sorter):

Materials (Check all that apply)	
BSL-I Materials	
☐	Uninfected rodent cells and other animal cells excluding human and non-human primate?
☐	Fixed cells? (If yes, detail the following): • Chemical fixative: • Concentration used: • How long have cells been in fixative:
☐	Other (such as yeasts, bacteria or other microorganisms)? If yes, please provide details below:
	BSL-2 Materials
☐	Animal tissues/cells from animal that was exposed to a Risk Group 2 human pathogen? • Name of pathogen: • Date of inoculation: • Number of days sample was taken post inoculation: *If you believe the cells are no longer infectious, please provide a peer-reviewed reference to verify the cells are no longer infectious.*
☐	Human cells, tissues or body fluids?
☐	Non-human primate cells, tissues or body fluids?
☐	Risk Group 2 human pathogens? (Note: cannot be used in the Core Facility prior to authorization by the State of CT DPH and EHS).

Materials (Continued) (Check all that apply)	
☐	Cells transformed with HTLV, EBV, HPV or other transforming virus?
☐	Materials that contain known human oncogenes or oncogenic material?
☐	Cells that have been exposed to Risk Group 2/BSL-2 defective recombinant pathogen vectors (i.e., Lentiviral, Retroviral, Adenoviral vectors)?
☐	Other? (Please detail):

Project Details
Provide a summary or description of the project (include details related to the samples that will be analyzed):
Describe the program to verify that the HEPA filter associated with containment for the sorter is evaluated and confirmed to be functional before work and annually thereafter:
Describe how you plan to test your sorter to verify that aerosols from clogs or deflections do not spread form the sorter and its containment:
List the Personal Protective Equipment that will be worn while using the sorter:
How many other researchers will be allowed to use this sorter? *Please note: Only trained and qualified users can operate the machine and the sorter cannot be left unattended for any period of time or monitored by individuals who are not certified to run the sorter.*

Signature:	Date:

In order to assess the appropriate biosafety level and associated containment practices, the Questionnaire must be completed in its entirety. This form will be retained in a file for future reference, but it is the responsibility of the researcher to complete an updated form for any new materials proposed for use with this Cell Sorter.

New Research Materials

As specific precautions for worker protection must be taken with known and potential biohazardous materials, any new cell sorting facility users introducing NEW BIOHAZARDS must complete and submit this Questionnaire to the Facility Manager and receive authorization for use prior to the initiation of work in the facility by the Facility Manager and Yale EHS.

Restrictions and Requirements

- No work with Risk Group 3 Agents or biohazards that require Biosafety Level 3 containment is allowed on this Cell Sorter.

- No work with Risk Group 2 human pathogens can be initiated without authorization from the State of Connecticut Department of Public Health and the Office of Environmental Health & Safety. ***Note: Researchers who are currently registered for work with human pathogens must obtain authorization for work in the Core Facility as this qualifies as a new location.***

- All non-exempt recombinant DNA experiments must be approved by the Yale Biological Safety Committee prior to initiation (this includes new locations for existing authorized experiments). Non-exempt recombinant DNA experiments include research with defective viral vectors and other pathogen vectors.

- Investigators must register all locations where biohazards are handled with the Office of Environmental Health & Safety.

- All applicable biosafety training courses must be completed prior to using this sorter with known or potential biohazards.

General Biocontainment Work Practices

Personal Protective Equipment (PPE)

- Protective clothing worn will be dedicated to the laboratory where the sorter is located. PPE worn for biohazard work will not be worn in other areas and removed before leaving the laboratory.
- A lab coat with banded wrists buttoned to the top shall be worn for BSL2 work.
- Gloves shall be worn for all BSL2 procedures and it is recommended that gloves extend over the sleeve of the lab coat to protect the wrists from contamination.
- Eye and/or Face Protection must be worn to protect researchers from procedures that have the potential to generate splash or droplets and the safe handling of laboratory chemicals.
- BSL2 PPE will be removed before leaving the laboratory.
- Contaminated PPE can either be decontaminated by lab personnel (spray with 10% bleach for 10-minute contact time or autoclave is the buttons can withstand the 250 F temperatures), or discarded as biomedical laboratory. BSL2 lab coats may be sent out to a service for laundering only if there is no overt contamination. The lab is responsible for decontaminating lab coats before providing them to the service. Otherwise, select a service that is equipped to effectively process contaminated reusable clothing.
- Hands shall be washed with soap and water after removing PPE and before leaving the laboratory.

Basic Work Practices

- No eating, drinking, or smoking is allowed in laboratory areas.
- Food storage is prohibited in laboratory spaces (food may be stored in non-lab areas only).
- Researchers may not apply cosmetics or touch their face with gloved or unwashed hands in laboratory spaces.
- Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- Procedures must be conducted carefully to minimize the potential for aerosol formation.
- Work surfaces and equipment must be decontaminated with the assigned disinfectant for your protocol after each use and in conjunction with posted emergency response procedures after spills if outside primary containment.
- No fabric covered chairs are allowed in the facility; only chairs that are easily cleanable are allowed within the laboratory.
- Animals and plants are not allowed in BSL2 laboratories unless they are part of an approved Yale IACUC and/or Yale IBC research protocol.
- Any observation of pests must be immediately reported to the Building Services and Operations Department by calling 203-432-6888. Yale University has a comprehensive integrated pest management plan but utilizes the services of outside consultants. Pest management consultants must be escorted into the LEPH 900 facility by an authorized person.

Engineering Controls

- Use plastic will be used in place of glass where feasible.
- If utilized, a vacuum system will be protected by hydrophobic or HEPA filters. The Gelman Vacushield (available in the YSM Stockroom SHM IE7) or an equivalent filter may be used.
- Equipment shall be disinfected with 10% bleach and/or 70% ethanol for 10 minutes after use for terminal decontamination. The disinfectant selected must be demonstrated to inactivate the known or potential biohazards present at the concentration used for the designated contact time required for inactivation.
- Research materials will be transported according to Yale EHS policy as noted below:

Transport of Biohazards

On Campus Transport (between labs or buildings):

- ✓ Must have two leak proof containers, including the following:
  - -a sealed primary container
  - -a sealed secondary container
  - -absorbent (paper towels) between the primary and secondary containers suitable for the volume transported
  - -a biohazard sticker on outside of the secondary container with agent name, lab address and phone number
- ✓ Utilize plastic containers whenever feasible, avoid glass.
- ✓ Sealed plastic (not glass) primary vials can be transported within sealed, labeled plastic bags.
- ✓ If glass primary containers must be used, place containers within a sealed rigid plastic container with absorbent and padding to cushion vials during transport.

Door Signs

- Post a BL2 biohazard sign on the laboratory door. A BL2 door sign and a blank lab information card are enclosed. Please complete the card and post with the biohazard sign at the entrance to your laboratory.
- Also include the name of the agent or material, names and phone numbers for emergency lab contacts, and list the entrance requirements (e.g. immunizations, personal protective equipment).
- Keep lab doors closed while experiments are in progress and restrict access to those directly involved in the experiment.
- A BL2 wall notice (not a door sign) has also been provided for your lab. Place this poster within the lab in the vicinity of BL2 work to remind researcher of the required lab practices.

Labels

- Place the biohazard symbol on all equipment housing BL2 material (including human blood, unfixed human tissue, human cell lines, infectious agents, and defective vectors.
- Label all freezers or incubators housing these materials, and also label any equipment that is not decontaminated between each use (centrifuges, cell sorters, etc.).
- Also ensure that all biowaste containers are either colored red or labeled prominently with the biohazard symbol. Select a waste container that is different from the general lab trash receptacle.
- Biohazard stickers were provided during the inspection for these purposes.

Biowaste

- All waste containers should be emptied when they are 2/3 to 3/4 full to prevent overflow. Items should never stick out of a sharps container or any other waste container.
- Place a sharps container located in the immediate vicinity of use.
- Do not allow waste to accumulate within the laboratory. Either chemically decontaminate, or autoclave, and discard your biological waste at the end of the experiment or at the close of the work day.

Spills and Exposure Incidents

- All researchers will be familiar with the applicable exposure response procedures as developed by EHS before initiating their experiments.
- The attached EHS Biosafety Spill and Incident Response Guide will be utilized for incident response by all laboratory members.