

Flow Cytometry Unit
Research Resources Branch
Gerontology Research Center/NIA/NIH

BIOHAZARD REVIEW FORM FOR LIVE CELL ANALYSIS/SORTING

Investigator Information

Name: _____ Date: _____
Phone: x____ E-mail: _____ Room: _____
Principle Investigator: _____
Project Title: _____
Brief summary of the whole project (include scientific basis) *not just the flow cytometry component*: _____

A signature is required on the last page

Section 1

- Are the cells to be analyzed/sorted from Mouse or rat *Go to Section 2*
 Non-human primate *Go to Section 3*
 Human *Go to Section 4*
 Other *Go to Section 5*

Section 2: Mouse or Rat

Section 2A: Are the samples from primary tissue?

- No *Go to section 2B below*
 Yes

Have the animal experiments been reviewed and approved by the Animal Use Committee (AUC)?

- No Then you cannot proceed and the samples will not be analyzed
 Yes AUC approval date/# _____

Are the rodent cells from an animal that is transgenic or an animal that has been grafted with human cells?

- No
 Yes Please explain below the origin of the cells in sufficient detail to evaluate any biohazard risk of infectious agent for humans.

Are the cells infected with any human virus or pathogen?

- No
- Yes Please explain below:

Section 2B: Is the material to be analyzed/sorted genetically modified cells, i.e. virus-infected or transduced, etc.:

- No
- Yes Describe the vectors and packaging cell lines used in genetically modifying these cells and describe the genetic modifications:

For experiments with genetically modified cells (i.e. retrovirus), you must have NIH Biosafety Committee Approval resulting in an RECOMBINANT DNA REGISTRATION DOCUMENT (RD).

- Yes List RD # and approval date: _____
- No Then you cannot proceed

Section 3: Non-human primate

Describe the species from which the cells originated:

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Does the primate species harbor any known human pathogens or been exposed to any infectious agent (e.g. , HIV,SIV, herpes B). *Include whether the animals have tested positive for herpes B. Tissues from herpes B positive animals will not be sorted or analyzed without fixation.*

- No
- Yes Please explain below:

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Have the animal experiments been reviewed and approved by the Animal Use Committee (AUC)?

- No Then you cannot proceed
- Yes AUC approval date/# _____

Is the material to be analyzed/sorted:

freshly isolated primary cells

cell lines

Please describe the cell line below

genetically modified cells

Please describe the vectors and

packaging cell lines used in genetically modifying these cells and describe the genetic modifications:

For genetically modified experiments, you must have NIH Biosafety Committee Approval resulting in an RECOMBINANT DNA REGISTRATION DOCUMENT (RD).

Yes List protocol # and approval date: _____

No Then you cannot proceed

Section 4: Human

Is the human material from

freshly isolated cells (PBMC, BM, etc) *Go to Section 4A*

human cell lines *Go to Section 4B*

human cells from immunodeficient animals *Go to Section 4C*

Section 4A

Was the human donor screened for infection with hepatitis B or C or human immunodeficiency virus (HIV) and tested negative?

No Then you cannot proceed. All freshly isolated human cells must be derived from donors screened for exposure to the infectious agents listed above.

Yes

Was this a self-sample, purchased material, or excess material (i.e transfusion packs) that lack all patient identifiers?

Yes

No

Do you have Human Subject Approval (IRB)?

Yes List date/protocol #: _____

No Then you cannot proceed

Section 4B

List the name of the cell line and describe its' origin:

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Are the cells infected with any transforming human viruses (EBV, HTLV-1, etc)?

Uninfected

Infected List agent: _____

Have the cells been fixed or otherwise treated in order to reduce the risk of infectious agents to the flow cytometry staff? If Yes, please check here:

Is the human material genetically modified?

No

Yes Please describe the vector and method used to transduce the cells. If a retrovirus was used, describe below and attach the vector map to this form. Describe the packaging cell line below. For adenoviruses and lentiviruses, provide a complete description of the viral construct (i.e. transgene), and attach the viral map to indicate that the vectors have been rendered replication deficient (or list viral genome deletions/inserts below).

For viral experiments, you must have NIH Biosafety Committee Approval resulting in an RECOMBINANT DNA REGISTRATION DOCUMENT (RD).

Yes List protocol # and approval date: _____

No Then you cannot proceed

Section 4C

Describe the prior recipient of the human cells and indicate if the cell population now contains both human and non-human cells. Indicate the type of host animal (nude/SCID, etc.)

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Were the engrafted human cells genetically modified ?

No

Yes Please describe the vector and method used to transduce the cells. If a retrovirus was used, describe below and attach the vector map to this form. Describe the packaging cell line below. For adenoviruses and lentiviruses,

provide a complete description of the viral construct (i.e. transgene), and attach the viral map to indicate that the vectors have been rendered replication deficient (or list viral genome deletions/inserts below).

For viral experiments, you must have NIH Biosafety Committee Approval resulting in an RECOMBINANT DNA REGISTRATION DOCUMENT (RD).

- Yes List protocol # and approval date: _____
- No Then you cannot proceed

Were the engrafted human cells screened for human pathogens ?

- Yes If tested positive, list: _____
- No Then you cannot proceed

Do the experiments have the approval of the NIH Biosafety Committee and Animal Use Committee?

- Yes List #'s approval dates: _____
- No Then you cannot proceed

Section 5: Other

Describe the species of cells (or cell lines). Note that many species carry viruses capable of trans-species transmission (e.g. endogenous retroviruses, influenza, herpes). Provide a detailed description (if cell line- its' name) below:

NIH researchers are required to undergo mandatory training with respect to the handling of human blood, body fluids, and tissues. Investigators that submit samples in a manner inconsistent with these policies will be asked to provide the following information:

HUMAN BLOOD, BODY FLUIDS, AND TISSUE REGISTRATION DOCUMENT (BBF) Number _____
HUMAN PATHOGEN REGISTRATION DOCUMENT (HPRD) Number _____

This form must be filled out in order for either analysis or sorting by the Flow Cytometry Unit and only needs to be submitted for a single project or set of experiments, **provided that no information has changed, especially with regard to BBF, HPRD or RD documents.** If samples to be processed by FCU personnel are part of a study covered by an HPRD or RD, FCS personnel must be appended to that document and a copy provided to the Flow Cytometry Unit. **No analysis or sorting on live, unfixed cells will be performed until this information is received!** Please allow sufficient time for processing through the Division of Safety, when considering a flow experiment. If you have any questions regarding this sample information form, contact Dr. Robert Wersto at 558-8377 or Flow Cytometry Unit personnel at 558-8440.

Signature of Investigator

Date

Flow Biohazard Review-3
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