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Date: April 18, 2019 9:25:24 AM Print Close

View: SF_Study Team - View 1

1. STUDY TEAM

* ***1.1. Principal Investigator*** Click for Guidance Notes *Please select the Principal Investigator (PI) for the project. Once you hit "...", you can enter the PI's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.* Fred Woo	The Principal Investigator must have a Faculty Appointment (i.e. Professor, Associate Professor, Assistant Professor, Adjunct Professor, Clinical Professor, Clinical Associate Professor, Clinical Assistant Professor, Professor (PT), Associate Professor (PT), Assistant Professor (PT), Professor Emeritus/a, Associate Professor Emeritus/a, Assistant Professor Emeritus/a). This includes Clinical Faculty appointments in the Faculty of Medicine. If you cannot see your name in the Principal Investigator list and you are the Principal Investigator of the study, please contact the Office of Research Services at risesupport@ors.ubc.ca.
1.2. Primary Contact Click for Guidance Notes *Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence regarding this project. This primary contact will have online access to read, amend, and track the application.*	Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence. The certificate of approval and notifications regarding the project will be emailed to this primary contact in addition to the PI.
Click for Guidance Notes ***1.3. Co-Investigators*** *List all personnel working on this project who WILL have online access to read, amend and track the application. Once you hit "...", you can enter the member's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically*	If animals are to be used, the head of the animal housing unit must be included in this section. Please make sure you have added yourself as either the Principal Investigator, primary contact, or a project team member in order to continue with the application. If you do not see your name or any of your associates' names in the list, please have

*by First name, Last name by clicking on the appropriate heading. To delete a member from the list below, select the box "**x**" next to his or her name.*

Last Name	First Name	Institution/Department	Rank	Biosafety Course Certificate Number

There are no items to display

1.4. Project Team with Online Access

Last Name	First Name	Institution/Department	Rank	Biosafety Course Certificate Number

There are no items to display

them added or inform them to add themselves by contacting the Office of Research Services at risesupport@ors.ubc.ca with their particulars (name, department, rank, email, UBC employee number (if applicable), and phone number). Once added to RISe, the new user will receive an email with his or her researcher number.

The Biosafety Course, offered through Risk Management Services, is compulsory. Please update your profile on RISe with the completion date. If the course has not been completed, please have personnel register through http://rms.ubc.ca/training-and-general-education-courses/research-safety-training-courses/ (Vancouver Campus) or http://riskmanagement.ok.ubc.ca/safety/biosafety.html (Okanagan Campus).

Click for Guidance Notes

1.5. Project Team without Online Access

*List all personnel who WILL NOT HAVE online access to the application. To remove a member from the list below, select "**x**" next to his or her name.*

Last Name	First Name	Institution/Department	Rank/Job Title	Biosafety Course	Biosafety Certificate Number

There are no items to display

The personnel listed in this section do not have online access to RISe. Please print off the application and ensure that each member listed in this section has read and understood the objectives and procedures of this project.

The Biosafety Course, offered through Risk Management Services, is compulsory. Please enter the BioSafety Certificate number or a course completion date for all personnel. If the course has not been completed, please have personnel register through http://rms.ubc.ca/training-and-general-education-courses/research-safety-training-courses/ (Vancouver Campus) or http://riskmanagement.ok.ubc.ca/safety/biosafety.html (Okanagan Campus).

Click for Guidance Notes

* ***1.6. Project Nickname***

Nickname of the Project. What would you like this project to be known as to the Principal Investigator and Project Team?
Biosafety RG 2

The name entered here will be what the project is known as on your home page, to the Principal Investigator and the Project Team. This title will not be printed on the certificate.

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top OR bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.

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View: SF_Study Dates and Funding - View 2

2. STUDY DATE AND FUNDING

2.1. Start Date *What is the Start date of this Project? Use the calendar box to select the date (Internet Explorer)* **Start Date:** 6/26/2019	
2.2. Title of Project *If there is no research funding application associated with this project, please enter the title of the project below. If there is an associated research application with this project, please proceed to question 2.3.*	
Source of Funds Click for Guidance Notes *Clearly identify the application for research funding associated with this biosafety project. This will ensure that awarded research funds can be made available to you once this project receives approval.* **2.3. Research Funding Application/Award Associated with the Project Submitted to the UBC Office of Research Services**	**Question 2.3 lists the research funding applications/awards that have been submitted to the UBC Office of Research Services and entered into our database. Identifying the associated research funding application/award will**

Please click "Add" to identify the research funding application/award associated with this project. Selecting "Add" will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding application/award associated with this project is not listed below, please enter those details in question 2.4. **UBC Number Title Funding PI Sponsor** There are no items to display	**ensure that awarded research funds will be made available to you once this biosafety application receives approval.** **Please ensure you select the correct application. Note that the first two digits of the application number indicate the year the application was submitted (eg. Application #06-0001 was submitted in 2006).** **A fee of $600 will be charged for applications requiring review by the UBC Biosafety Committee that are funded by a for-profit agency. The fee is a one-time-only fee for each specific application and covers initial review, annual renewals, and minor amendments for the next four years.**
2.4. Research Funding Application/Award Associated with the Project not listed in question 2.3. *Click "Add" to enter the details for the research funding application/award associated with this project that is not listed in question 2.3.* **Project Title Sponsor** There are no items to display	

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top OR bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.

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View: SF_Study Overarching Category - View 3-Version June 2013

3. STUDY OVERARCHING CATEGORY

Note for applicants:

- If you are using both RG1 and RG2, only a RG2 application needs to be filled out.
- If you are using plant pathogens then please fill out an RG1 application.
- Use the provided Environmental Hazard Tool, to determine if your organism is considered an invasive plant, plant pest, or aquatic pest.

Genetically engineered organisms are defined as:

- the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
- the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
- one or more characteristics no longer fall within the anticipated range for that plant, animal or microorganism.

* Please select the Overarching Category for this study
RG2 (Biohazardous materials, including toxins)

List of Shared Research Facilities

Please list the research locations where work will be occurring in a centrally run research facility such as an animal unit, containment level 3, or imaging facilities.

Housing Location

There are no items to display

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View: SF_Procedures and Methodology- View 3-2-Version January 2018

3. MATERIAL INFORMATION, PROCEDURES

*** 3.1. Objectives of Research** *Describe how you would explain to a non-scientist, the aim, specific objective(s) and general experimental approach. Please do not submit the abstract from your funding application. The summary should provide the requested information in lay terms, so that someone who is unfamiliar with your work will be able to appreciate what you do.* x	
*** 3.2. Summary of Methodology and Procedures** Click for Guidance Notes *This section is your demonstration of lab wide understanding of the risks associated to the tasks/techniques of your SPECIFIC projects.* *The Reviewers **require** the following information.* *Note: this includes animal experiments involving biological materials or toxins as well.* • *Short procedure or methodology name* • *Brief description* • *Risks of the procedure or methodology (including if there is a risk of cross reaction between organisms)* • *PPE needed* • *How risk is mitigated (administrative and engineering controls)* • *Decontamination of materials and surfaces* *Please attach your exposure control plan for pathogens infecting humans, below.* x *Please attach additional documents if required below by selecting the "Add" button.*	3.2 - Cut and pasting methodologies from grant applications is not sufficient. Propagation of Influenza • Virus will be propagated in pathogen-free, embryonated chicken eggs. Eggs will be inoculated, incubated at 37'C for 48h, and the allantoic fluid collected

Title There are no items to display	• Influenza poses an inhalation risk; needles used to inoculate the egg pose a sharps risk • Long pants, full covering shoes, dedicated lab coat, double gloves, and N95 respirator if work occurs outside the BSC • All work will occur in a biosafety cabinet Class II A2. Safety needles will be used to prevent accidental inoculation. All workers will enroll in the Medical Surveillance Program. • 10% bleach or 70% ethanol will be used to decontaminate. Minimum contact time of 15 minutes. Sharps will be collected in approved sharps container.
* **3.3. Biosecurity** Click for Guidance Notes *Describe the three parts of your biosecurity plan for RG2 organisms and toxins:*	3.3 - Biosecurity is defined as security measures designed to

• *Security controls* • *Inventory system* • *Emergency procedure for stolen/misused materials* x	prevent loss, theft, misuse, diversion or intentional release of pathogens and toxins.
* **3.4. Recombinant Viral Vectors (including-lentiviral)** Click for Guidance Notes *Does your work involve recombinant viral vectors (including-lentiviral)?* ○ Yes ● **No**	3.4 - Further Details are to be provided in section 4.
* **3.5. Genetically modified organisms** Click for Guidance Notes ***3.5.1.*** *This project uses non-pathogenic E. coli with non-hazardous gene alterations* ○ Yes ● **No** * ***3.5.2.*** *This project uses genetically altered animal cell.* ○ Yes ● **No** * ***3.5.3.*** *This project uses genetically altered human cell lines.* ○ Yes ● **No** *List genetic alterations and the method of genetic modification.* * ***3.5.4.*** *This project uses other **risk group 2** genetically modified organisms?* ○ Yes ● **No**	Tracking genetically engineered organisms has always been required, but will now be specifically tracked using RISe. Due to their minimal risk we are excluding detailed lists for non-pathogenic E.coli, S. cerevisiae, Arabidopsis, Chlamydomonas, Populus, and transgenic mice. If there are other organisms that should be excluded, please contact Janet Hankins (janet.hankins@ubc.ca).
* **3.6. Security Sensitive Biological Agents (SSBA)** Click for Guidance Notes ***3.6.1.*** *Will security sensitive microbial toxins be used?*	The following toxins are security sensitive: • Alpha toxin

○ Yes ● **No**	• Botulinum neurotoxin • Cholera toxin • Clostridium botulinum C2 and C3 toxins • Clostridium perfringens Epsilon toxin • Hemolysin • Shiga-like toxin (verotoxin) • Shigatoxin • Staphylococcus enterotoxins, Type B • Staphylococcus enterotoxins, types other than Type B • Staphylococcus aureus Toxic shock syndrome toxin
* **3.7. Biohazardous Waste** Click for Guidance Notes **3.7.1.** *What procedures are used for the decontamination and disposal of biohazardous waste. For autoclaved waste indicate the RMS approved autoclave room being used.* x *If applicable, attach Standard Operating Procedures (SOPs) below by clicking the "Add" button.* **Title** There are no items to display * **3.7.2.**	3.7 - Describe procedures for liquid waste, solid waste and tissue samples/animal carcasses. Human or animal blood fluid or tissue should be included in 3.8.1. Example All waste contaminated with influenza virus will be treated with 10% bleach for 30min, the liquid removed and the

Is any biohazardous waste generated that is also radioactive?

○ Yes ● **No**

If "Yes", what procedures will be used for the decontamination and disposal of the combined radioactive-biohazardous waste?

If applicable, attach Standard Operating Procedures (SOPs) below by clicking the "Add" button.

Title

There are no items to display

solid waste is held for 48hours and then autoclaved (121deg, 15psi, 60min). The waste will then be picked up with ESF.

Liquid waste is treated with 10% bleach for 30minutes. The solution is neutralized and then poured down the sink.

All sharps waste is autoclaved on their sides (121deg, 15psi, 60min) then be picked up by ESF.

Any radioisotope waste needs to be included in 3.8.2.

Note: Decontamination and disposal methods must be described fully; statements such as "waste will be decontaminated and disposed of as per UBC regulations" are not sufficient.

* **3.8. Recombinant DNA**

3.8.1. *Does this project involve Recombinant DNA?*

○ Yes ● **No**

* ***3.8.2.*** *Do you receive funding from the United States?*

○ Yes ● **No**

Click for Guidance Notes

* **3.9. Inventory**

Type of Biological Material	Host Range	Biological Material	Species/Source/Common Name	Other Information	Building	Room Stored	Room Used	Containment Level
Virus	Humans	Influenza Virus	B	B	BC Centre for Disease Control	123	123	2

3.9 - The Committee and HPTA requires an inventory of what and where materials are stored be kept on file. This inventory may be requested by the Committee for inspection during facility audits.

If the facility or organisms you are using is not listed, please contact the Biosafety Committee at biosafety@ors.ubc.ca.

Appropriate containment levels can be found at the Public Health Agency of Canada website by clicking here.

Please note, the containment level is dependent on **both** the procedures to be used and the organism.

Click for Guidance Notes

* **3.10.** *Are you creating, re-creating or modifying a new or existing pathogen?*

○ Yes ● **No**

* **3.11.** *Is there a potential for research knowledge (e.g. data, methodology, results) technology, intermediate*

Is there a potential for research knowledge (e.g. data, methodology, results) technology, intermediate and final products (e.g toxins) to be misused? For

and final products (e.g toxins) to be misused? ○ Yes ● **No**	instance, will methodologies developed make pathogen or toxin production feasible for relatively inexperienced people without access to specialized equipment?

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View: SF_Ethics - View 6

6. ETHICS

*** 6.1. Human Ethics** Click for Guidance Notes

6.1.1.

Is any human tissue, blood (or other potential infectious material) or body fluid used for this project?

○ Yes ● **No**

If "Yes", complete the following questions in 6.1.

6.1.2.

Provide the Ethics Certificate Number(s) below.

6.1.3.

What is the source of human tissue, blood or fluid?

6.1.4.1. Is your biobank /collection of human research biospecimens registered in the BC Biobank Certification Program?

Yes. If yes, please provide your registration record number.

Please specify the source of human tissue (e.g. primary source, purchased from approved vendor, etc.)

Registration in the BC Biobank Certification Program may be required. If you have already registered, please provide your registration record number. If your biobank is not registered, please answer no and go to www.bcbiobank.ca to get information about the program and determine if it is applicable to your work with human specimens.

☐

No. If no, please go to www.bcbiobank.ca to get information about the program. ☐

6.1.4.2.

This project does not need to register because it is not currently a requirement of my institution. ☐

* **6.2. Animal Ethics**

6.2.1.

Are animals used for this project?

○ Yes ● **No**

If "Yes" please complete the following questions in 6.2.

6.2.2.

Provide the Animal Care Application Number(s) below

6.2.3.

Have all animal care staff been made aware of any precautions required to protect themselves when dealing with animals and handling bedding?

○ *Yes* ○ *No*

6.2.4.

If animals are exposed to the biohazard agents listed in this project, click the "Add" button to specify the agent and route of exposure.

Agent	Routes of Exposure	Procedures to minimize exposure
There are no items to display		

6.2.5.

If there are any zoonotic organisms associated with the animals being used, please list both the species and organism below.

*** 6.3. Radioisotopes**

6.3.1.

Will radioisotopes be used in this project?

○ Yes ● **No**

6.3.2.

Radioisotope License Number

Use the calendar box below for the expiry date of the license.
Expiry Date:

6.3.3.

Explain which isotopes will be used and how this relates to the biological materials used in this project.

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View: SF_Final Page View 7

SAVE AND CLOSE APPLICATION

You have reached the end of the Biosafety Application.

OPTIONS

1) submit application (PI only) - *click the "Continue" button and "Submit application" on the next page.* ***NOTE: the "Submit application" button is only visible to the PI****.*

2) work on this application later - *click the "Continue" button. Your application will be in "Pre Submission" and saved in your inbox.*

* ***Please confirm all staff have been made aware of the UBC Medical Surveillance program. For more information, please refer to*** *http://www.hr.ubc.ca/wellbeing-benefits/workplace-health/occupational-preventive-health/****.***

● **Yes** ○ No

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