Research and Publication Office Biosafety/Biosecurity Committee

BIORISK PROTOCOL REGISTRATION

A protocol registration is required to ensure research conducted with biological materials is consistent with regulatory requirements, Davao Medical School Foundation, Incorporated policy, and prudent safe practices for working with these materials.

Registration is required for all work involving biohazardous agents, such as;

- rDNA/RNA molecules in living cells
- Viable microbial agents
- Biological toxins
- Category A, B, and C biological agents as identified by the Center of Disease Control and Prevention
- human or non-human primate samples or materials (including cell lines)

Complete all sections applicable to the work proposed. Once completed, submit this form electronically to the to the DMSFI Research and Publication Office (<u>dmsfresearch@email.dmsf.edu.ph</u>), together with a copy of summarized Introduction and Methods section of the research proposal. A hard copy of this form, signed by the principal investigator, is required in addition to the electronic submission.

Title of the study:				
Principal investigator	Contact Number:	Email address:		
Location of Project/study/protocol:				
Principal Investigator's Assurance:				
I am familiar with and agree to abide by the provision of the current World Health Organization's Laboratory Biosafety Manual. I accept responsibility for this work and for monitoring the safe work practice of the staff involved. I agree to comply with all national, local, and DMSFI requirements pertaining to the shipment, transfer, storage and disposal of biohazardous materials. I will notify the committee of any significant changes to the protocol prior to institution. I certify that the information provided in this document is accurate.				

Name and Signature of PI

Personnel Involved

Names of all personnel (including PI) that will handle the agents	Experience (provide a summary of members experience with agents)	Biosafety training completed		Blood borne pathogen handling training completed (if necessary)	
	Yes No		No	Yes	No

Protocol type (check all applicable)

Does this study involve microorganism, viruses, or toxins?	Yes	No	If yes, complete section A
Does this study involve viable human, non-human primate or other animal tissues or materials (e.g. blood, tissues, and cell lines)?			If yes, complete section B
Does this study involve recombinant DNA or RNA molecules?			If yes, additional review is required
Does this study involve a Category A, B, and C biological agent as identified by the CDC?			If yes, complete section A
Is this a modification of an approved published protocol?			Provide additional references for this.

Abstract

Provide an abstract describing the procedures undertaken that involve the use of bioagent(s). Orient your discussion to the safety aspects of the research rather than the worthiness of the research undertaken. Include details of manipulation where appropriate. Emphasize the approach(s) that will be used to keep these agents contained within the laboratory that you will be working with. Address medical surveillance. Discuss any special training that will be required. Word your abstract in lay terms, whenever possible, to enhance understanding of non-scientific reviewers

Section A. Microorganisms, virus and toxins

Type of Microorganism:	Toxins or sub-toxins to be used:	Provide genus, species and strain (if possible)			
Source of biological material (indicate how you are going to procure the biological material including shipping details, if any):					
Indicate which location(s) previously identified where you plan to handle this biological material:					
Indicate which location where biological material will be stored:					
Will this require import per	mit?	Maximum concentration or quantity expected to have on hand at any time:			
Is this organism a strain that exempted as a group 2, 3 of by WHO?		Is vaccination available for this organism or toxin? (please indicate what type of vaccine)			
Is vaccination recommende	ed?	Has vaccination been offered to individual with potential exposure?			
Indicate the disposal proce	dure for the biological	agents that you will be using.			

Section B. Use of Viable Human, Non-Human Primate or other animal samples or materials

Does this project involve the use of human sample or materials	Yes	No	N/a	If yes, what is the sample type?
Does this project involve the use of non-human sample or materials				A. If yes, what is the sample type?
				B. Where you able to secure an IACUC permit?
Does this project involve the use of other animal sample or materials				A. If yes, what is the sample type?
				B. Where you able to secure an IACUC permit?
Indicate the primary source of t	L he sample:			
Indicate if there is a need for tra	iining in ha	ndling the	e samples:	
Indicate the protocol on how to	dispose of	the biolo	gical materi	als that you will be using: