

Institutional Biosafety Committee (IBC) BIOSAFETY REVIEW FORM

Please complete this document thoroughly and e-mail the completed form to <u>safety@ohio.edu</u>. By submitting this form, the researcher is verifying that they have read the O.U. Biohazards Policy, CDC/NIH Biosafety Guidelines, and/or NIH rDNA Guidelines, have conducted an initial risk assessment and will comply to the best of their ability. If future projects differ significantly in scope, type or hazard level from those approved on this form, a new "Biosafety Review Form" or an addendum request must be submitted. This is a public document. If assistance in determining biosafety levels (BSL) or other information is needed, contact the Biosafety Officer, Risk Management & Safety, 740-597-2950.

O.U. Biosafety Manual

O.U. Biohazards Policy

CDC/NIH Guidelines

NIH rDNA Guidelines

Section 1 – Background

Name			Date		Email Address		
Title					Telephone Number		
Departr	nent						
Mailing	Address						
Locatio	n: Ather	ns Campus					
	Regio	onal Campus (specify)					
	Privat	te Company (enter compa	iny name)				
Materia	ls listed are to l	be used in: Res	search	Teach	ing/Classroom	Both	
This is a	a:	New Proposal	Renewal (enter current approv	val number)		
If this is a renewal summarize any changes							
from the	e previous appr	oval					

Section 2: Abstract

Abstract – Please	
include an	
overview of the	
research and a	
brief description of	
the procedures	
conducted with the	
biohazardous	
agents.	

Section 3: Biohazardous Materials Used

Recombinant DNA – Please review the <u>NIH rDNA Guidelines</u> .				
Risk Group \Box 1 \Box 2 \Box 3				
Source of DNA Animal Plant Human Bacterial	Viral Other (specify):			
Identify the nature of the inserted DNA sequence:				
What does the DNA code for (ex. an oncogene, a toxin, a receptor)?				
Will expression of the foreign gene be attempted?	Yes, what gene product will be produced?			
Will genes encoding proteins toxic to vertebrates (with an LD ₅₀ <100ng/kg) be	cloned and expressed?			
If yes, what toxin?	If yes, what is the LD ₅₀ , if known?			
What is the rDNA Host? Bacteria Fungus Yeast	Other, specify			
What are the vectors? Plasmids Virus Other, specify:				
Will the rDNA be used in Clinical Trials?	No Yes – IRB Approval #			
Will the rDNA be used in Human Gene Therapy?	No Yes – IRB Approval #			
Will the rDNA be used in Experiments with Whole Animals?	No Yes – IACUC Approval #			
Will the rDNA be used in Experiments with Whole Plants?	No Yes			
Will the rDNA be used in Experiments with More Than 10 Liters of Culture?	No Yes			

	Eukaryoti Cell Lines	c For each c infectious demonstra	The sell line complete a row below (include human cell lines here). Human cells lines must be treated as potentially materials, handled at BSL 2, and follow the OSHA Bloodborne Pathogen program, unless testing has test the absence of bloodborne pathogens - see EHS for details.				
Type:		Type:	Source				Was this cell tested
Cell	Name	primate, or other?	Company or Collaborator	Web site, email address or phone number	Physical address or Catalog number	Biosafety Level	which pathogens and what is the status?

	Eukaryotic Cell Lines Continued					
	Type: human,	Source				Was this cell tested for pathogens? If yes,
Cell Name	primate, or other?	Company or Collaborator	Web site, email address or phone number	Physical address or Catalog number	Biosafety Level	which pathogens and what is the status?

	Infectious	Include microbial h	nclude microbial hosts, microbial vectors and oncogenic viruses. Please include any microbial hosts or vectors used in				
	Agents	rDNA work, such a	DNA work, such as E. coli.				
			Biosafety	Source: Company	Source: Web site, email	Source: physical address or	
Infe	ctious Agent		Level	or Collaborator	address or phone number	catalog number	

Infectious Agents Continued				
	Biosafety	Source: Company	Source: Web site, email	Source: physical address or
Infectious Agent	Level	or Collaborator	address or phone number	catalog number

Select Agents	Select agents and toxins are regulated, please see this link for the current list of agents and toxins
or Toxins	http://www.cdc.gov/od/sap/docs/salist.pdf
What select age	ent or toxin?

Human Blood and Other PotentiallyAll materials fall under the OSHA Bloodborne Pat bloodborne pathogens - see EHS for details. All m		nogen program, unless testing has demonstrated the absence of aterials must be handled at BSL 2 in the lab.
Infectious Materials		
Human Blood		Source
Human Blood Products, specify		Source
Human Tissue(s), specify		Source
Other Potentially	Infectious Materials, specify	Source

Other	
	Invertebrate vectors of human disease to be infected, specify
	Other, specify

Section 4: Source & Transportation

If not listed above, what is the source/supplier of your material	
For All Applications:	How is the material delivered to you (ex. delivered by commercial carrier, carried across campus by collaborator, etc.)?
	How do you transport the material around campus, including between laboratories?
	Mode (foot, car, etc.)
	Primary Container
	Secondary Container
	Outer Labeling
	Other
	What is the anticipated date material will arrive on campus or work will begin (enter continuing or
	already arrived if appropriate):

Section 5: Regulatory Compliance - Check all that apply to work with these biohazardous agents

OSHA Chemical Hygiene Plan	List the Department whose plan you follow
OSHA Bloodborne Pathogens Plan	List the Department whose plan you follow
Radiation Safety Committee Approval	Approval #
Institutional Animal Care & Use Committee Approval	Approval #
Institutional Review Board Human Subjects Approval	Approval #

Section 6: Waste Regulatory Compliance and Disposal Practices - Check all that apply

Generate	See the Biosafety Manual for a definition and acceptable disposal practices				
Regulated Infectious	What kinds of regulated infectious wastes are	Liquid (including cell cultures, Solid			
Waste	generated?	supernatant, etc.)			
		Sharps (must use approved			
		sharps container)			
	Which disposal methods are used?	Commercial Infectious Waste Vendor			
		Culture treatment with 15% bleach	h solution (see the <u>Biosafety</u>		
		Manual for requirements of this meth	od).		
		Approximately How Much Culture W	aste is Treated Each Week?		
		$1 \le 100 \text{ mL}$			
		□ 100-500 mL			
		□>500mL			
	Are there any special practices for animal waste, c	ctices for animal waste, cages or bedding? Please explain.			
Generate	See the Biosafety Manual for a definition and acceptable disposal practices				
biohazardous waste	What treatment methods are used?	Autoclaving	Treatment with 10-15%		
that is not regulated			Bleach Solution		
infectious waste		Disposal through the Commercial	Other, specify		
		Infectious Waste Vendor			
	Are there any special practices for animal waste, cages or bedding? Please explain.				
Generate multi-	This is any waste that is an infectious waste or a biohazardous waste AND is also a chemical hazardous				
hazard waste	waste or a radioactive waste.				
	Explain your disposal practices				

Section 7: Researcher Qualifications and Training

Provide an explanation of your		
qualifications		
Approximate number of people in your	labs working with the biohazardous materials?	
Provide a brief description of how		
new laboratory personnel are trained,		
particularly on standard		
microbiological practices, and who		
will provide the training.		

Section 8: Basic Safety and Security Employed in this Work

What type of ventilation equipment is used for this biological work?					
Biosafety Cabinet,	1	2A	2 B1	2B2	
specify the Class/Type	2B3	2A/B3			
Fumehood					
Other special ventilation, specify					

What personal protective equipment is used	Gloves, if a special kind are used	Lab Coats
when handling these biological materials?	specify here	
	Safety Goggles or Safety Glasses	Other?, specify
What types of emergency equipment are	Eyewash, Location	Safety Shower, Location
available to the laboratory?	First Aid Kit, Location	Other?, specify
What procedural safeguards are used when	Standard Microbiological Practices (see	Dedicated work areas for certain tasks, specify
handling these biological materials?	the Biosafety Manual for a description)	
	Universal Precautions are used for all hur	nan products (see the <u>Bloodborne Pathogens</u>
	program for a description)	
	Other?, specify	
Does any natural biological containment exist?	□ No	Yes, specify
(natural barriers that limit the infectivity of the		
vector or vehicle for specific hosts or its		
dissemination and survival in the environment)		
What are the employee medical/immunization	Hepatitis B vaccine is offered to all	Other?, specify
practices?	employees as part of the Bloodborne	
	Pathogens program (required).	
Other safety considerations?	Specify	

Where are biohazardo	ous materials	stored and used? (Comp	lete a row for eac	h material or type of n	naterial.)	
If a material is stored	and used in a	separate laboratories or b	uildings, be sure	to complete the transp	ortation Section 4.	
*Please note that restr	ricted access	is required for BSL 2 ma	aterials.			
Material(s)	Activity	Building	Room	Is the room	Other restricted	Specific storage location (ex. refrigerator freezer)
	Storage	Dunung		Lotred.		
	Use					_
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	Storage					
	Use					

Section 9: Emergency Practices - Minimal requirements are found in the Biosafety Manual.

Spill kit/supplies are contained where?	In the lab. Cent	trally in the department.	Other, specify
Spill disinfection is accomplished with?	\Box 10% bleach solution	70% ethanol	Other, specify
Spill and clean-up materials are	As infectious waste	As regular waste	Other, specify
disposed of?			

<u>Section 10: Other Information</u> – Include any other relevant or requested information here.

For Institutional Biosafety Committee Use Only:

Approved by IBC?	Yes	Date
	No	Reason
	Tabled/Pending	Reason
A copy of this form was saved to the biosafety files.	File Name	Date
Assigned IBC Approval Number		
IBC approval letter was sent to the Researcher	Date	

Document Finalization

Work approved at BSL 2 requires the signature of	Signature	Date
the Researcher on the final document.		