

**INCOMPLETE APPLICATIONS WILL BE RETURNED WITHOUT REVIEW**



**RUSH UNIVERSITY MEDICAL CENTER**

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) APPLICATION**

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THIS APPLICATION MUST BE COMPLETED FOR ALL  
(EVEN NON-EXTERNALLY FUNDED)  
RESEARCH PROJECT INVOLVING THE USE OF:

- RECOMBINANT DNA (rDNA)
- TRANSGENIC ANIMALS (GENERATION OR INFECTION)
- AGENTS INFECTIOUS TO HUMANS OR ANIMALS
- BIOLOGICAL TOXINS AND DNA CLONES OF BIOLOGICAL TOXINS

THIS APPLICATION **DOES NOT NEED TO BE COMPLETED** FOR RECOMBINANT PROTEINS, ONLY EXTRACTING OR AMPLIFYING NUCLEIC ACIDS, USING LESS THAN 2/3 GENOME OF AN ORGANISM, OR FOR HANDLING HUMAN MATERIAL KNOWN NOT TO BE INFECTIOUS

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APPLICATION MUST BE RECEIVED TWO WEEKS BEFORE THE MEETING IN ORDER TO BE REVIEWED. CALL OFFICE OF RESEARCH AFFAIRS x25498 FOR APPLICATION DEADLINES.

1. SUBMIT AN ORIGINAL AND TWO (**2**) COPIES OF THE IBC APPLICATION WITH THE FOLLOWING MATERIALS TO THE OFFICE OF RESEARCH AFFAIRS:
  - A COPY OF THE PROTOCOL OR GRANT APPLICATION
  - A COPY OF THE SAFETY RULES POSTED IN YOUR LABORATORY (AN EXAMPLE IS APPENDED TO THE END OF THE APPLICATION)
  - ANY SUPPLEMENTARY INFORMATION OR PUBLICATIONS THAT MIGHT BE USEFUL IN REVIEWING THIS APPLICATION (GRANT, APPENDIX M, INVESTIGATORS BROCHURE, RAC LETTER, ETC.)
2. THE IBC MAY VISIT YOUR LABORATORY EITHER BEFORE APPROVING YOUR APPLICATION OR ANYTIME AFTER .
3. **REMINDER**: PROJECTS INVOLVING INFECTIOUS AGENTS, BIOHAZARDOUS MATERIALS, AND RECOMBINANT DNA CORRESPONDING TO CATEGORIES IIIA, IIIB, IIIC, AND/OR IIID MAY NOT COMMENCE UNTIL IBC APPROVAL IS RECEIVED.
4. THIS FORM MUST BE COMPLETED REGARDLESS OF FUNDING SOURCE.
5. IF YOU HAVE ANY QUESTIONS REGARDING THE APPLICATION PLEASE CONTACT THE OFFICE OF RESEARCH AFFAIRS AT 312-942-5498. UNLESS YOU HAVE ADOBE ACROBAT WRITER, YOU WILL NOT BE ABLE TO SAVE AND EDIT THIS DOCUMENT. IF YOU WOULD LIKE TO RECEIVE THIS

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APPLICATION AS A WORD DOCUMENT, PLEASE CALL 312-942-5498 AND ASK FOR COORDINATOR.

For ORA Use Only
ORA # _____



**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) APPLICATION**

Principal Investigator:	Department:
Dept. Address:	Telephone:
E-mail Address:	Fax:
Alternate Contact:	Alt. Contact's Telephone/Email:
Project Title:	
<b>BIOLOGICAL AGENT</b> (see list on pp11-12):	
FUNDING SOURCE:	
This application is similar to ORA#: <b>Include this protocol for reference</b>	
Anticipated Start Date:	Anticipated End Date:

<p><b>AGREEMENT TO ABIDE BY REGULATIONS</b></p> <p><i>I agree to abide by the NIH Guidelines for Research Involving Recombinant DNA and other appropriate state and federal guidelines. I understand that my lab may be inspected by the IBC. If I plan to revise this protocol I will file a "Continuing Review Certification Application" and wait to receive approval from the IBC, if required, before implementing the changes.</i></p> <p>PI Signature _____ Date _____</p>
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1. Briefly describe the rDNA, types of manipulations, and infectious agent work that you propose to perform at Rush, and what will be done by collaborators elsewhere. Describe any type of patient samples to be used, any rDNA to be used in patient treatment, and potential complications. Include any alternatives specified in protocol. Use additional pages if necessary.

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2. Indicate location of the lab in which the work will take place.

Building:	Room #
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3. Indicate the highest containment level required for this project: BL1 BL2 BL3 BL4

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**IF YOUR PROJECT DOES NOT INVOLVE THE USE OF RECOMBINANT DNA,  
SKIP TO QUESTION #5.**

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**4. If your project involves the use of recombinant DNA, check the box(es) in front of the appropriate category(ies) from the list below.** *Numbers correspond to categories detailed in the May, 1999 "NIH Guidelines for Research Involving rDNA Molecules." Consult these Guidelines for further information. (<http://www.nih.gov/od/oba>)* (Hint: Many routine laboratory plasmid clones fall under IIIF2)

IIIA Experiments that require IBC review, RAC (Recombinant DNA Committee), and NIH review prior to initiation

<b>NIH Approval Date:</b>	(please submit documentation to ORA)
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A1 Deliberate transfer of a drug resistant trait to microorganisms not known to acquire this trait naturally

IIIB Experiments that require IBC and NIH/ORDA (Office of Recombinant DNA Activities) review before initiation

<b>NIH Approval Date:</b>	(please submit documentation to ORA)
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B1 Cloning of toxic molecules with LD 50 of less than 100 nanogram per kg of body weight (*See NIH Guidelines for E. coli exceptions*)

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IIIC Experiments that require IBC and Institutional Review Board approval and NIH/ORDA registration prior to initiation

**NIH Approval Date:**

(please submit documentation to ORA)

- C1 Deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA into one or more human subjects

Submit answers to Appendix M questions from the NIH recombinant DNA guidelines with this form  
Submit review letter from RAC

IIID Experiments that require IBC approval before initiation

- D1 Using Risk Group 2, 3, or 4 restricted agents as Host-Vector Systems (see *NIH Guidelines* section IIA, Risk assessment)
- D2 Cloning DNA from risk group 2, 3, or 4 restricted agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems (i.e. using an adenovirus or retrovirus as a vector to express another gene)
- D3 Using infectious DNA or RNA or defective viruses in the presence of helper virus in tissue culture systems
- D4 Infections of transgenic animals

**RPSLMC IACUC PROTOCOL NO:**

- D5 Using whole plants (see also E2)
- D6 Using more than 10 liters of culture

IIIE Experiments that require IBC notice simultaneous with initiation

- E1 Forming rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus
- E2 Generating transgenic plants(see also D5)
- E3 Generating transgenic rodents

IIIF Experiments that are exempt from the *NIH Guidelines* (still requires IBC notification)

- F1 Using rDNA outside of organisms or viruses
- F2 Using DNA segments from a single nonchromosomal or viral DNA source
- F3 Using DNA entirely from a prokaryotic host propagated only in that host
- F4 Using DNA entirely from an eukaryotic host propagated only in that host
- F5 Using DNA segments entirely from different species that exchange DNA by known physiologic processes

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**STOP HERE if your research only involves Recombinant DNA  
in categories IIIE or IIIF**

**PROJECTS ONLY INVOLVING rDNA IN CATAGORIES IIIE OR IIIF MAY COMMENCE UPON SUBMISSION OF PROTOCOL AND THIS DOCUMENT (QUESTIONS #1-4 COMPLETED) TO THE OFFICE OF RESEARCH AFFAIRS.**



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**7. Personal Protective Equipment**

List the personal protective equipment used while working with this agent:

1.	5.	9.
2.	6.	10.
3.	7.	11.
4.	8.	12.

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**If your project involves the use of recombinant DNA, complete #8 A-E.  
If it does NOT, skip to Question #9.**

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**8. PROJECTS INVOLVING RECOMBINANT DNA (LEVELS IIIA, IIIB, IIIC, AND/OR IIID)**

A. Describe the type of organism from which the DNA will be isolated:

B. Describe the nature of the inserted DNA sequences (i.e., regulatory or coding region, entire genome, synthetic antisense sequences, etc.):

C. List the specific strains of hosts to be used (i.e. *E. coli* K-12) and any other pertinent details. Cloning into K-12's may exempt this project- refer to NIH Guidelines.

D. List vectors to be used, briefly specifying their purpose (i.e. expression vector, etc.), their risk group classification, and source (PI, company, etc.):

E. Will a deliberate attempt be made to express a foreign gene?  No  Yes  
If yes, what proteins will be produced? Indicate possible toxicity or other hazards, if any:

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**If project involves infectious agents or biological toxins, complete #9 A-D.  
If it does NOT, skip to Question #10.**

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**9. INFECTIOUS AGENTS AND BIOLOGICAL TOXINS**

A. List infectious agents, biological toxins, and/or viral vectors to be used and check appropriate categories:

<i>Infectious Agent or Biological Toxin</i>	<i>Risk Group?</i>	<i>Human Hazard?</i>	<i>Animal Hazard?</i>	<i>Plant Hazard?</i>
		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

B. If using a human pathogen, is a vaccine available? No Yes N/A  
 If yes, have all personnel potentially exposed been offered the vaccine\*? No Yes

Which vaccine?

\*If a vaccine is available, all potentially exposed personnel must be informed of the potential hazards and benefits, and offered the option of receiving the vaccine.

C. Will you be culturing large volumes of organism (>10 liters)? No Yes N/A

D. If human blood components, body fluids, or tissues are used, list the specific substances and their source (i.e., normal healthy adult volunteers, etc.). Briefly describe how the substances will be used (i.e., approximate quantity, assays to be done): *or* NONE USED

<b>Substance</b>	<b>Source</b>	<b>Usage</b>

**10.** If not previously covered in this form by *NIH Guidelines for Research Involving Recombinant DNA Molecules*, list Center for Disease Control and Prevention (CDC) [<http://www.cdc.gov>], National Institute of Health (NIH) [<http://www.nih.gov>], Animal and Plant Health Inspection Service (APHIS), and/or USDA [<http://www.aphis.usda.gov>] guidelines applicable to your project. Cite specific applicable sections.

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11. Describe the specific decontamination and disposal methods to be used for any waste containing recombinant DNA, infectious agents, biological toxins, or human blood components, body fluids and/or tissues.

<i>Type of Waste</i>	<i>Decontamination/Disposal Methods</i>	
	<input type="checkbox"/> Autoclave	<input type="checkbox"/> Rush biohazard removal
	<input type="checkbox"/> Chemical disinfection	<input type="checkbox"/> Other:
	<input type="checkbox"/> Autoclave	<input type="checkbox"/> Rush biohazard removal
	<input type="checkbox"/> Chemical disinfection	<input type="checkbox"/> Other:
	<input type="checkbox"/> Autoclave	<input type="checkbox"/> Rush biohazard removal
	<input type="checkbox"/> Chemical disinfection	<input type="checkbox"/> Other:

12. Spill Procedures. List the steps to take in the event of a spill of this agent in the laboratory.

13. Exposure/Needlestick. List the procedures to take in the events of an exposure (including needlesticks) to this agent.

14. Surveillance for Infections. Describe any surveillance of laboratory personnel for evidence of infection (i.e. serotesting.)

**DO NOT WRITE BELOW THIS SPACE. FOR IBC USE ONLY.**

**Rush-Presbyterian-St. Luke's Medical Center  
Institutional Biosafety Committee Review Form**

Principal Investigator:

ORA#:

Title of project:

Brief description of relevant rDNA or infectious agent work:

Experiments with:	P.I. states	Reviewer's assessment
rDNA that falls under Guidelines section:		
Highest necessary Biological Containment Level:		
Infectious Agent(s) in the Risk Group Level:		
Necessary Biological Containment Level:		
Patients samples (potentially infectious)?		
Biological Containment Level/Precautions:		
Documented blood-borne pathogen training for all?		
Generating Transgenic Animals, Guidelines section:		
Infecting Animals? Transgenic?		
Necessary Containment Level:		
Proper waste disposal?		
Lab rules attached?		
If patient treatment is involved, are answers to Appendix M questions included? Complete and appropriate?		
Is NIH/RAC assessment needed?		
Received and documented?		
Transfer of drug resistance to a microorganism not known to acquire it naturally, or cloning highly toxic molecules under Guidelines Section:		
Necessary Containment level:		
Is a full IBC review required?		
Comments:		
Signature of reviewer:	Review Date:	

**(Example of Posted Lab Rules) ATTACH YOUR OWN LAB RULES HERE**

## **Common Laboratory Procedures**

- ✍ All pipetting is done by mechanical devices, not by mouth.
- ✍ No food, eating, drinking, smoking in the laboratory.
- ✍ Wear your lab coat while working in the laboratory, **and** remove it before leaving.

## **Biosafety Level 2 (BL2) Procedures**

### **Access**

- ✍ Always work with infectious organisms in the biosafety hood.
- ✍ Access to the laboratory is restricted to laboratory personnel when work with infectious organisms is in progress, particularly if those organisms contain recombinant DNA molecules.
- ✍ A “Biohazard” sign is posted on the laboratory door when vaccinia or hepatitis B virus is being used.

### **Procedures**

- ✍ Wear disposable gloves. Remove them when leaving the hood. In no case, wear gloves outside the lab.
- ✍ Don't use needles when working with infectious agents.
- ✍ Avoid the creation of aerosols.

### **Decontamination**

- ✍ Decontaminate the work surface after any spill of viable material, and after every use.
- ✍ Mix contaminated liquid waste with bleach (to a final concentration of at least 10%) for at least 30 min before dumping it down the drain and flushing with water.
- ✍ Collect contaminated plasticware, drained of liquid, in the biohazard containers. When full, take the whole container to the autoclave room before removing the bag, to avoid dripping in case the bag is punctured.
- ✍ Report organism spills outside the hood immediately to the P.I.
- ✍ Always wash your hands after working with an infectious agent **and** prior to leaving the laboratory.

## **CDC SELECT AGENTS AND TOXINS LIST**

### **Viruses**

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

### **Bacteria**

1. *Bacillus anthracis*
2. *Brucella abortus*, *B. melitensis*, *B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

### **Rickettsiae**

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

### **Fungi**

1. *Coccidioides immitis*

### **Toxins**

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

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### **Recombinant organisms/molecules**

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

### **Other restrictions**

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

### **Additional Exemptions**

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. ? 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. ? 2601 et seq.) are exempt.
2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this Appendix.

Some documents are available for viewing, printing, and downloading (saving) in Adobe Acrobat's portable document file (PDF) format. You will need the Acrobat Reader on your computer and configured to work on your browser to access the file.

## **HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS**

### **USDA only agents and toxins    USDA/HHS overlap agents and toxins**

? African horse sickness virus	? Foot-and-mouth disease virus	mycoides (contagious bovine pleuropneumonia)
? Bacillus anthracis	? Clostridium perfringens	? Shigatoxin
? African swine fever virus	epsilon toxin	? Newcastle disease virus (VVND)
? Botulinum neurotoxins	? Goat pox virus	? Staphylococcal enterotoxins
? Akabane virus	? Coccidioides immitis	? Peste des petits ruminants virus
? Botulinum neurotoxin producing species of Clostridium	? Japanese encephalitis virus	? T-2 toxin
? Avian influenza virus (highly pathogenic)	? Coxiella burnetii	? Rinderpest virus
? Brucella abortus	? Lumpy skin disease virus	? Venezuelan equine encephalitis virus
? Bluetongue virus (exotic)	? Eastern equine encephalitis virus	? Sheep pox virus
? Brucella melitensis	? Malignant catarrhal fever virus (exotic)	? Swine vesicular disease virus
? Bovine spongiform encephalopathy agent	? Francisella tularensis	? Vesicular stomatitis virus (exotic)
? Brucella suis	? Menangle virus	
? Camel pox virus	? Hendra virus	
? Burkholderia mallei	? Mycoplasma capricolum /M.	
? Classical swine fever virus	F38/M. mycoides capri (contagious caprine	
? Burkholderia pseudomallei	? Nipah virus	
? Cowdria ruminantium (Heartwater)	o pleuropneumonia)	
? Clostridium botulinum	? Rift Valley fever virus	
	? Mycoplasma mycoides	