

Ⓘ RUSH
RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER
OFFICE OF RESEARCH AFFAIRS

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
APPLICATION INSTRUCTIONS AND INFORMATION

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 OR FOR HANDLING HUMAN MATERIAL
NOT KNOWN TO BE INFECTIOUS

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
2. THE IBC MAY VISIT YOUR LABORATORY BEFORE APPROVING YOUR APPLICATION .
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.

INCOMPLETE APPLICATIONS WILL BE RETURNED WITHOUT REVIEW

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) APPLICATION

Principal Investigator:	Department:
Dept. Address:	Telephone:
E-mail Address:	Fax:
Project Title:	
This application is similar to ORA#: Include this protocol for reference	
Anticipated Start Date:	Anticipated End Date:

AGREEMENT TO ABIDE BY REGULATIONS

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.

PI Signature _____ Date _____

- 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.

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

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

**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

NIH Approval Date: (please submit documentation to ORA)

- 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

NIH Approval Date: (please submit documentation to ORA)

- 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*)

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

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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

**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.

All research projects involving infectious agents, biological toxins, or recombinant DNA (corresponding to levels IIIA, IIIB, IIIC, or IIID) must complete the additional information that follows.

IMPORTANT: THESE PROJECTS MAY NOT COMMENCE UNTIL IBC APPROVAL IS RECEIVED.

5. Information on User(s)

- A. Please list names and job titles of all persons working on this project. Briefly describe their relevant education; training in safe use of biohazardous material used, such as procedures followed for laboratory safety and waste handling; laboratory experience, including duration, type and quantity of biohazardous material used, and experimental procedures employed. (Attach additional information if necessary):

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B. If using human blood components, body fluids, or tissues, have all personnel had Bloodborne Pathogen Training? Yes No Not applicable

List names, employee ID numbers, and most recent Bloodborne Pathogen Training Date

Name	Employee ID #	Date Trained

6. Facility Information

List locations of biological safety equipment (e.g. clean bench, biological safety cabinet, autoclave). Include certification date for biological safety cabinet (enter “failed” if cabinet did not pass certification evaluation):

<i>Biological Safety Equipment Used</i>	<i>Building</i>	<i>Room #</i>	<i>Certification Date(s)</i>	<i>If biosafety cabinet, indicate company, model #, and type</i>

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.

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

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.):

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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:

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

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

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Substance	Source	Usage

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.

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.

Type of Waste	Decontamination/Disposal Methods
	<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.)

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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:		

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Necessary Containment level:		
Is a full IBC review required?		
Comments:		
Signature of reviewer:		Review Date:

(Example of Posted Lab Rules)

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.