ATTACHMENT A
Instructions for Completing the IBC Application Form

Instructions:

1. **All 12 sections on the attached form must be completed**. This form has been placed on the LANL Biosafety Web page for your convenience. See http://int.lanl.gov/safety/biosafety/biosafety.shtml Do not alter wording in any text section. In the event that there is a box for which there is no entry or the item does not apply, please use N/A to identify this response. **If you need assistance or have questions concerning form completion contact the IBC Chair or the BSO.**
2. Send an electronic copy of your completed registration form to the IBC Chair and copy the BSO. Send a hard copy to the BSO.
3. PIs and their safety-responsible line managers must receive notification of the IBC approval date, IBC number, and a copy of the approved form for their records.
4. If an approval letter is required for a funding agency, the BSO must be contacted as early as possible.
5. The PI must notify the BSO when significant changes occur in the project. Changes that require proposal amendments include but are not limited to the following:
    - Change in personnel
    - Change in laboratory location
    - Change in hazard control plans
    - Change in experimental methods
    - Change in infectious agents
    - Use of human cell lines
6. The IBC shall review ongoing projects on an annual basis. Accordingly, the PI must be contacted for updates within one year after the initial IBC approval date.
    - **If the "human samples" include human or primate tissues, body fluids, blood, or blood products AND this is the ONLY above category involved in your work, fill out sections #1 - #6 of this form and stop. Next go to the Exposure Control Plan (ECP) in the Biosafety LIR:** http://labreq.lanl.gov/pdfs/ops/lir/LIR40253000.pdf#acrohls=/cgi-bin/w3vdkhgw?DSP=XML;qryCFAh_K_c_;ops-212. **Determine whether you need to supplement or annotate the LANL ECP (Attachment B). Submit both forms together.**

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IBC Application Form

Principal Investigator(s):

NAME	DIVISION	MAIL STOP	E-MAIL ADDRESS	WORK PHONE #	DATE

PROJECT TITLE:

---------- **Do Not Write Below This Line** ----------

INSTITUTIONAL BIOSAFETY COMMITTEE ONLY

DATE RECEIVED:	
IBC #:	
DATE PROVIDED TO IBC (DATE)	
PROPOSAL APPROVAL	☐ APPROVED ☐ APPROVED WITH CONDITIONS ☐ NOT APPROVED ☐ DEFERRED
DATE MEMO SENT TO PI/MANAGER	
DATE FINAL PROTOCOL RECEIVED BY IBC	
DATE OF FINAL APPROVAL	

IBC Application Form

1. PROJECT TITLE/LAY SUMMARY:

2. PROJECT SPONSOR:

3. ANTICIPATED STARTING DATE:

4. PERSONNEL INFORMATION:

PI'S AND OTHERS NAMES	LANL LOCATION	MAIL STOP	E-MAIL ADDRESS	WORK PHONE #	EDUCATION, TRAINING, AND EXPERIENCE

TA, building(s) & rooms where work will be conducted:

_____

TA, building(s) & rooms where materials will be stored:

_____

5. EMERGENCY CONTACT PERSON FOR LAB OPERATIONS:

Name	Home Phone #	Work Phone #

6. CLASSIFICATION:

Identify the Biological Agent(s) or Cell Culture(s) used and the corresponding Risk Group (RG) and proposed Biosafety Level (BL). Identify all strains and include ATCC or comparable information when required.

	SPECIFIC NAME	STRAIN	SOURCE INFO	RG	BL
VIRUS					
BACTERIA					
FUNGI					
PARASITE					
CELL CULTURE*					

* For Cell Cultures, list all hosts, vectors, and donor genes.

See the following references, or contact the BSO for help. Guidance Note: In most instances the Risk Group defines Biosafety Level; for example, Risk group 2 Agents are usually handled at Biosafety Level 2.
http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html
http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

7. DESCRIPTION OF PROJECT:

Provide a concise summary of the project in the space below. Be sure the sources and quantities of the biological agent are clearly defined and the reader can determine the nature of the biological materials used (e.g., fixed, fresh, a commercial kit, replication deficient, etc.). Remember the goal of this form is to be able to understand and assess biological risk. **NOTE: This registration form may serve for more than one research project (title) if all the biological agents, personnel, and locations are the same.**

Document the risk assessment. See the BMBL or contact the BSO for further information.
http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s5.htm

Risk Assessment Category	**Discussion**
Pathogenicity	
Route of transmission	
Agent Stability	
Infectious Dose	
Concentration	
Origin	
Availability of Animal Data	
Availability of effective prophylaxis	
Medical Surveillance	
Experience and skill level of personnel	

8. SPECIFIC QUESTIONS THAT REQUIRE A RESPONSE:

a) Does the research Involve the use of rDNA? Yes _____ No _____

If the answer is YES to question (a), continue with questions (b)-(g).
If the answer is NO to question (a), skip ahead to question (f).

b) Are the experiments Classified as Large Scale?
(Volume greater than or equal to 10 liters) Yes _____ No _____

c) Will transgenic or Knockout animals be generated as part of the project? Yes _____ No _____

d) Do the experiments Require the use of viral vectors? Yes _____ No _____

If yes, provide a restriction and genetic map of vectors and insert as well as promoters and other control sequences. Indicate packaging cell line and assay system used to detect and measure replication competent virus.

Include a description of the host range of packaged viral vector. If transfection is used, indicate vector, recipient or host cell line.

e) Is an rDNA gene expressed? Yes____ No____

If yes, describe the expression vector and indicate in which organism the rDNA gene will be expressed.

f) Do these experiments involve the use of live animals? Yes _____ No _____

If the answer is YES to question (f), note that the work must also be registered with the Animal Care and Use Committee (IACUC).

g) Do these experiments involve the use of human material? Yes ____ No ___

If the answer is YES to question (g), note that the work may have to be registered work with the Institutional Review Board for Human Subjects Research.

h) Do these experiments involve the use of radionuclides? Yes ____ No ___

If the answer is YES to question (h), note that the Health Physicist/HSR-1 must also be contacted.

IBC Application Form

9. OTHER INSTITUTIONAL APPROVALS:

If an approval has been received from the responsible review committee, indicate the registration number in the corresponding box below.
If the process of applying to these Committees is in progress, check "Pending".

	YES	NO	PENDING	REGISTRATION #
IACUC				

IRB HSR				
HSR-1				

10. SPECIFY WORK PRACTICES AND PRIMARY BARRIERS:

	TYPE/NAME	LOCATION
HCP(s)		
Biosafety Cabinet		
Face Protection		
Clothing		
Gloves		
Waste Disposal/ Disinfection		
Emergency Contact		
Transport within Building		

11. MEDICAL SURVEILLANCE:

Medical Surveillance requirements are usually determined on a case-by-case basis. Identify in the box below if there are any medical surveillance requirements or practices that should be considered for the work to be conducted. If none, state, "none."

12. CERTIFICATION AND INVESTIGATOR SIGNATURE:

I accept responsibility for the safe conduct of work with the recombinant DNA, microorganisms, cell cultures, and/or human samples involved in this project. I have informed all personnel who may be at risk of potential exposure to these materials and have determined that the procedures to be implemented are required for this work. I also understand that I bear the responsibility for ensuring that all personnel are correctly trained. For research that involves the use recombinant DNA, I will implement the National Institute of Health (NIH) and LANL guidelines/requirements.

For all work, I will abide by the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" (BMBL). The information above is accurate and complete.

X _____ _____
Principal Investigator **Date**

X _____ _____
Resource Manager/Group Leader **Date**

----------Do Not Write Below This Line----------

BIOSAFETY WORK AUTHORIZATION (Two Options)

I certify that the Institutional Biosafety Committee (IBC) has reviewed the proposed project and has approved it, and if required (i.e., if the project involves the use of rDNA), has found it to be in accordance with the provisions of the NIH Guidelines for research with rDNA molecules. The IBC will annually monitor the project to ensure it is being conducted in accordance with both LANL and NIH requirements and guidelines.

X _____ _____
Signature of Chairperson, IBC Date

_____
PRINTED NAME of Chairperson, IBC

X _____ _____
Signature of Resource Manager/Group Leader Date

_____ _____
PRINTED NAME of Resource Manager/Group Leader Title

OR

I certify that I have been authorized by the IBC to administratively review and approve exempt and Biosafety Level 1 experiments. The proposed project has been found to be in compliance with the NIH Guidelines.

X _____ _____
Signature of Chairperson, IBC or Biosafety Officer (BSO) Date

_____
PRINTED NAME of Chairperson, IBC or BSO