Registration Document for the Use of Exempt Recombinant DNA

IUPUI requires that all recombinant DNA work conducted at or supported by this university be registered with and approved by the Institutional Biosafety Committee (IBC). While certain levels of exempt studies are not required by the NIH Guidelines to be reviewed and approved by the IBC, Research and Sponsored Programs at IUPUI does require documentation that the investigator has utilized the Guidelines to define studies that are exempt. This form is to be used to provide information to Research and Sponsored Programs and the IBC of the types of studies an investigator conducts and deems exempt from the NIH Guidelines. Investigators are cautioned to use this form only to register the exempt portions of their research programs and not to view this as a blanket registration for all recombinant DNA studies. Additional registration of human and primate cell lines which in many cases are used in conjunction with exempt recombinant DNA molecules is required as these cell lines are utilized under BL2 conditions. The form for registering human and primate cell lines is located at the Research and Sponsored programs website: http://www.iupui.edu/%7Eresgrad/spon/human_cell_app08151.rtf
Studies which are not classified as exempt require approval by the IBC and for this the investigator will use the **IBC Protocol Submission Form** located on the Research and Sponsored programs website.

Please allow up to 15 business days for exempt studies processing.

Instructions:

1. If your recombinant DNA experiments meet the definition of any of the **Exempt** categories described in Appendix A of this form, complete this registration form. However, if you have answered "yes" to any of the questions, this form is not applicable, and you must complete the **IBC Protocol Submission Form.**
2. Please provide complete information for every item. Blank or incomplete items may delay the processing of your application. If an item is not applicable to your study, **please type "NA."**
3. Submit the completed form and one copy to the Institutional Biosafety Committee, Research Compliance Administration, UN618. If off-campus, submit to 620 Union Drive, Room 618, Indianapolis, Indiana, 46202-5167. Keep a copy for your records.
6. Please consult the *NIH Guidelines for Research Involving Recombinant DNA Molecules* for information needed to complete this registration form.
7. For more information, please contact Shawn Axe, Research Compliance Coordinator, at 317-274-8289.

Part A: Basic Information

A.1 Principal Investigator:

Department:
Campus Mail Address:
E-Mail:
Office Phone(s):
Lab Phone:

Location(s) of Experiments (e.g. Building/Room - indicate all sites used):

A.2 Project Title(s):

A.3 Sponsor(s) of the research:

Part B : Exempt rDNA Information

B.1 Do the constructs contain viral DNA that represents more than 2/3 of any eukaryotic viral genome?

☐ **No.**

☐ **Yes. This registration is not exempt:**
Do not use this form - please complete the IBC Protocol Submission Form.

B.2 Is the viral construct from DNA of Risk Group 3, 4, or restricted agents?

☐ **No.**

☐ **Yes. This registration is not exempt:**
Do not use this form - please complete the IBC Protocol Submission Form.

B.3 Does the Study involve the deliberate transfer of rDNA into Human Subjects?

☐ **No.**

☐ **Yes. This registration is not exempt:**
Do not use this form - please complete the IBC Protocol Submission Form.

B.4 Does the Study involve generation of Transgenic Animals or Plants?

☐ **No.**

☐ **Yes. This registration is not exempt:**
Do not use this form - please complete the IBC Protocol Submission Form.

B.5 Does the Study involve the generation of Toxin Molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight?

☐ **No.**

☐ **Yes. This registration is not exempt:**
Do not use this form - please complete the IBC Protocol Submission Form

B.6 Does the Study involve the generation of more than 10 Liters of Culture?

☐ **No.**

☐ **Yes. This registration is not exempt:**
Do not use this form - please complete the IBC Protocol Submission Form.

B.7 Please provide the following information:

Nature/Source of DNA*	Host(s)	Vector(s)	Experimental Use**

* Indicate organism, clone bank, species, etc., with literature citation, if appropriate.

** Describe the intended use of the recombinant DNA molecule. Refer to Appendix B of this form for examples.

B.8 Briefly describe your research projects (in lay terms) and include the general biological function of the gene products (proteins) that you wish to express.

B.9 Indicate the Biosafety Containment Level at which the project will be conducted (defined in APPENDIX G of the NIH Guidelines):

☐ **BSL 1** ☐ **BSL 2**

B.10 Investigator Assurance

- I agree to use at least Biosafety Level 1 (BSL 1) containment practices with all **exempt** recombinant DNA work. Reference: Biosafety in Microbiological and Biomedical Laboratories, 4th Edition
- I understand that all recombinant DNA work done at the University must be registered with the Institutional Biosafety Committee (IBC), even if it is **exempt** under the NIH Guidelines.
- I have read the NIH Guidelines for Research Involving Recombinant DNA Molecules and verify that all uses listed herein are classified as **exempt**. I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the NIH Guidelines.
- I have the knowledge and training required to safely handle the materials described.
- I agree to conduct these experiments in accordance with all **IUPUI** and IBC policies.
- I acknowledge my responsibility to secure and control the biological agents used in this project.
- Entry doors to the laboratory will be closed and locked when the laboratory is unattended.

_____ _____

Signature of Principal Investigator **Date**

For Biosafety Committee Use Only:

Study Number: _____

IBC Chair Signature: _____

Date: _____

Appendix A – Definitions from the *NIH Guidelines* for use of Exempt rDNA Molecules

Recombinant DNA:

In the context of the NIH guidelines, recombinant DNA molecules are defined as either:

1. Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
2. Molecules that result from the replication of those described in 1.

Exempt Categories of rDNA Experiments (if any apply, Complete this registration):

--*NIH Guidelines* (Section III-F; Appendix A, Appendix C)

1. rDNA containing less than 2/3 of an eukaryotic viral genome propagated in cell culture (with the exception of DNA from Risk Group 3, 4, or restricted agents)
2. rDNA work involving E. coli K12, S. cerevisiae, and B. subtilis hot-vector systems (with the exception of DNA from Risk Group 3, 4, or restricted agents). Exempt registrations are reviewed by an expedited process.
3. Those that are not in organisms or viruses.
4. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
5. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
6. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
7. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers can be found in Section IV-C-1-b-(1)-(c), Major Actions). For a list of natural exchangers that are exempt from the NIH Guidelines, see Appendices A-I through A-VI, Exemptions Under Section III-F-5--Sub lists of Natural Exchangers.
8. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-6 for other classes of experiments which are exempt from the NIH Guidelines.

Appendix B - Example of Completed Table for Question B.7

Nature/Source of DNA	Host(s)	Vector(s)	Experimental Use
Major histocompatibility complex class II (mouse)	E. coli (K-12) E. coli Yeast	Plasmid, Bluescript, pET21 pDHIL	Cloning, sequencing Over-expression of protein in E. coli for structure/function Over expression of protein in yeast for structure/function
cDNA (human) for MAP kinase	E. coli Cultured mammalian cells (not human or primate cells)	Lambda gt10 Commercially available plasmids	CDNA Library, screen for clones
cDNA (human) for protein kinase A (wild-type and mutant forms of) cDNA (mouse) for nonmuscle myosin heavy chain	Cultured mammalian cells (not human or primate cells)	pRC2 and pCMV2	Over-expression of recombinant protein in cultured cells; functional studies
Heme B3-8 gene (human)	E. coli	pUC19	PCR amplification to generate probe for screening cDNA and genomic library
Promoter of BMP2 (mouse)	E. coli F9 cells (mouse)	Reporter plasmid, pGL2-promoter (luciferase)	Transient transfections to study promoter activity
Nitric oxide synthase (bovine)	E. coli Insect cells (SF9) Cultured cells (not human or primate), yeast	Plasmid, pFASTBAC. Baculovirus, AcNPV, pCMV5	Over- expression of protein or mutant forms of the protein in insect or mammalian cells
Beta-Galactosidase (LacZ gene), (E. coli); Green fluorescent protein (GFP)	E. coli	Plasmid, pUB110, pS194, pT127	Gene expression and function studies