

UNIVERSITY OF MINNESOTA

IBC Office: (612)626-5654 or ibc@umn.edu

Recombinant DNA and Artificial Gene Transfer Form

Internal IBC Use Only			
IBC Code #:		Approval Date:	
Approved Biosafety Level(s):	<i>Laboratory</i>	<i>Animal Housing</i>	Method of Review:
NIH Guidelines Experiment Designation:			

1. Project Identification and Signatures

1.1 Type of Application: New Protocol 3-year Renewal of IBC # _____

(If this is a 3-year resubmission, do not use language referring to the previous protocol or grant in this form.)

Anticipated Start Date:	
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1.2 Project Title: (Project title must match grant title. If different, provide grant title also)

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1.3 Principal Investigator (Must be faculty or academic professional administrative staff.)

Name (Last name, First name MI):	Phone Number:
Mailing Address:	Pager or Cell Phone Number:
	Fax:
U of M Employee ID:	Email:
U of M x.500 ID (ex. smith001):	University Department (if applicable):
Occupational Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff (must be P & A) <i>Note: Students cannot be Principal Investigator.</i>	

Assurance by Principal Investigator

Electronic submission of this form from the Principal Investigator's X.500 e-mail address confirms his/her agreement to perform all activities according to the [NIH Guidelines for Research Involving Recombinant DNA Molecules](#) and use biosafety practices described in the CDC/NIH Publication *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, and to report any research-related accidents or incidents to the IBC as required by the NIH Guidelines. If applicable, this application accurately and completely reflects the activities described in any grant or contract supporting this research. Additional conditions required by the Institutional Biosafety Committee on behalf of the University of Minnesota will also be followed.

Principal Investigator: _____ **Date:** _____

If PI is not a University of Minnesota faculty member, IBC may require additional signatures

1.4 Person preparing this document

Name:	Phone number:	Email:
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1.5 Personnel conducting the experiments

List the personnel that will be working on this study below (including students and temporary staff). For each individual conducting the experiments, list their degree, applicable training, relevant experience (including duration) and their role in the project and indicate whether they should receive correspondence about the study from the IBC.

Name (Last Name, First Name MI)	U of M Employee or Student ID	U of M x.500 ID (ex. smith001)	Role in Project	Degree/ Years of Experience with rDNA Activities	Date NIH-Required Training Modules Completed*		Receive Mail from IBC**
					Biological Safety in the Lab	Implementation of the NIH Guidelines	
			<Select>				<input type="checkbox"/>
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* Section IV-B-1-h of the [NIH Guidelines](#) requires that Principal Investigators and laboratory staff working with rDNA complete training in laboratory safety and implementation of the *NIH Guidelines*. This training requirement can be satisfied by viewing the two 45-minute NIH Required Training modules online at: [NIH-Required Training Sessions](#)

Please note that attendance at one of the live training sessions on 11/15/2007 and 11/16/2007 qualifies as completion of the training. Please note that if you attended one of the live training sessions, it will appear on your training record as "Dept Research Ethics Training" with a date of 11/15/2007 or 11/16/2007.

** Provide a separate attachment with the mailing address, telephone and fax number and e-mail address of non-University of Minnesota personnel to receive correspondence from the IBC.

1.6 **Bloodborne and Other Pathogens Training** is required if you will work with infectious microorganisms, human blood, human body fluids, and/or human/primate cell lines. Will you use any of these materials?

- Yes
- No

1.7 **Source of Funding**

Please do not send grant applications to the IBC.

Name of funding source:	
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- Grant:**
- Will be submitted.
 - Submitted.
 - Approved. The duration of approval: 5 years Other: _____

This application must be written for a maximum of three years only. IBC applications expire after 3 years, at which time a new application will be requested.

1.8 **Externally Funded Projects** (Complete this section if you will receive external funds for this research)

Name of Sponsor:	
Address:	
Contact Person:	

- Funding decision:**
- pending
 - awarded

Agency-assigned grant number(if available):

Nature of funding source:

- Federal grant.
- Other grant or contract. Specify:

1.9 Conflict of Interest

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the IBC. Examples of potential conflicts of interest may include, but are not limited to:

- A researcher or family member participating in research on a technology, process or product owned by a business in which the faculty member holds a financial interest
- A researcher participating in research on a technology, process or product developed by that researcher
- A researcher or family member assuming an executive position in a business engaged in commercial or research activities related to the researchers University responsibilities
- A researcher or family member serving on the Board of Directors of a business from which that member receives University-supervised Sponsored Research Support
- A researcher receiving \$10,000 or more in consulting income from a business that funds his or her research

University of Minnesota Researchers, please refer to:

http://www1.umn.edu/regents/policies/administrative/Individual_COI.htm

Fairview Researchers, please refer to:

<http://www.fairview.org/prof/research>

Do any of the Investigators or personnel listed on this research have a potential conflict of interest associated with this study?

- No. Continue to section 2
 Yes.

If yes, identify the individual(s):

Has this potential conflict of interest been disclosed and managed?

- No.

If you are a University of Minnesota researcher, please disclose your potential conflict of interest online for review by your Department Head and Dean via the Report of External Professional Activities (REPA) at <https://egms.umn.edu/REPA/>

- Yes.

The IBC will verify that a management plan is in place with the Conflict Management Committee (CMC). If the CMC does not have an approved management plan for this research, the CMC will contact the individual(s) listed for additional information.

Final IBC approval cannot be granted until all potential conflict matters are settled. The IBC requires a recommendation from the CMC regarding disclosure to subjects and management of the conflict.

2. Scientific Summary and Rationale

2.1 Please provide the committee with a brief explanation of the proposed project. Use language that is understandable to those with a general knowledge of biology, and define all acronyms. *Do not attach grant applications.*

[Empty text box for response to 2.1]

2.2 Describe the goals/specific aims of the recombinant DNA or artificial gene transfer activities proposed in this application. Explain how the use of recombinant DNA technology will further the goals of this research.

[Empty text box for response to 2.2]

3. Gene Transfer

3.1 Gene Transfer will involve (check and describe):

- Physical methods (e.g., pronuclear injection, electroporation, “gene gun”, etc)
Describe: _____
- Host-Vector system
Vector used: _____
- Other
Describe: _____

3.2 List genetic material to be transferred (e.g., genes, DNA or RNA)

Genes, DNA or RNA	Species of Origin	Function of Gene

3.3 Describe the vector(s), including any regions that increase the biological safety of the construct.


[Empty text box for response to 3.3]

3.4 Explain the host range of each vector (e.g., is the vector amphotropic, ecotropic, is the vector pseudotyped?)

[Empty text box for response to 3.4]

3.5 Provide scientific rationale for using the viral vector(s) proposed.

[Empty text box for response to 3.5]

3.6  Attach a map of each vector.

4. NIH Guidelines Experiment Designation

The IBC will designate the section(s) of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* under which these experiments are covered (e.g., III-D-1-a, III-E, etc).

If you would like to suggest a designation, please refer to the NIH experiment classifications described in Section III (pages 14-20) of the [NIH Guidelines](#)*. Please note that University of Minnesota Board of Regents Policy requires that all rDNA and artificial gene transfer activities are approved by the IBC prior to initiation.

Section(s): III- _____

*The University of Minnesota IBC has developed a summary of the experiments covered by the *NIH Guidelines*. The document can be viewed by clicking on the following link: [Summary of Experiments Covered by NIH Guidelines](#)

5. Activities involve the use of (check all that apply):

Human subjects

IRB protocol number: _____ Pending

If the study involves use of gene transfer to humans you must submit a detailed addendum in which each topic of Appendix M in the NIH Guidelines is addressed.

[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

Attach Appendix M 

Attach human subjects' consent form 

Attach NIH OBA Recombinant DNA Advisory Committee (RAC) letter 

Whole animals; Species: _____ Approx number: _____

IACUC protocol number: _____ Pending

Does this project involve the creation of transgenic or knockout animals?*

No

Yes

**If you purchase transgenic or knockout animals from a non-University vendor, check "No".*

Does this project involve inoculation of animals?

No

Yes. Describe the inoculum, the amount and the route of administration:

Can the animals release exogenous DNA into the cage?

No

Yes .Indicate for how long: _____

Whole plants; Species: _____

In vitro work (cell culture):

Cells used in these experiments (check all that apply):

Human Cells


Plant Cells

Non-human Primate Cells

Insect Cells

Animal Cells (non-primate)

Other: _____

- Microorganisms; Species: _____
 List any available information regarding antibiotic resistance associated with the bacterial agents used in this project. If antibiotic sensitivity profiles are available, please provide this information as an attachment 

Fungi; Species: _____

Whole Insects; Species: _____

Viruses; Name: _____

Do activities involve formation of rDNA molecules containing greater than 2/3 of the genome of any eukaryotic virus?

- No
 Yes

Do activities involve the use of infectious human, animal, insect or plant viruses?

- No
 Yes

Do activities involve the use of defective animal or plant viruses in the presence of helper virus?

- No
 Yes

6. Biosafety Levels

6.1 Indicate the biosafety level in the laboratory where activities will be performed.

- BSL1 BSL2 BSL3

Location (room and building): _____

6.2 If animals are used, indicate the biosafety level in which they will be housed.

- No animals
 ABSL1 ABSL2 ABSL3

Location of animal housing (room and building): _____

7. Use of a Biosafety Cabinet

Will work be conducted in a biosafety cabinet for these activities?

- No
 Yes

If yes, what is the date of certification? _____

8. DNA Clones

Do the DNA clones contain genes for the biosynthesis of toxic molecules lethal for vertebrates?

- No
 Yes

If yes, provide LD50 information: _____

9. Volume of Culture

Do individual activities involve more than 10 liters of culture?

- No
- Yes

If yes, provide **location** (room and building): _____

10. Environmental Release

Do activities involve the release of an organism containing rDNA into the environment?

- No
- Yes

If yes, approval of the release must be requested from the state or federal regulatory agency.

Agency: _____ Date filed: _____


 **Attach a copy of the permit. IBC approval cannot be granted until permit is received.**

11. Laboratory Procedures

11.1 Experimental activities

Provide a summary or outline of the laboratory activities that will be conducted to accomplish the goals described in Section 2 above.

11.2 Standard Operating Procedures

 Attach detailed Standard Operating Procedures for the experimental activities described above. The SOPs should include a description of any procedures that may present biosafety risks (i.e., centrifugation, use of sharps, etc.), and how you will mitigate these risks. For information about writing biosafety SOPs, please refer to the following website: <http://www.dehs.umn.edu/PDFs/writingSOP.pdf>


11.3 Potential hazards

Identify potential exposure hazards during sample preparation and experimental manipulations. Examples: aerosol generation when transferring, mixing and/or centrifuging, use of sharps, excretion by animals, culturing, etc.

11.4 Safety procedures

Describe the safety procedures and safety equipment used to minimize risk and prevent release of rDNA and/or infectious agents, e.g. lab coats, gloves, face shield, biological safety cabinet, secondary containment for liquids, spill mats, secondary containment for centrifuge samples, etc.

11.5 Waste disposal

 Attach the [Biological Waste Disposal Plan](#). See [Waste Disposal Flow Chart](#) for more information.

11.6 Decontamination and Spill Clean-up

 Attach the [Decontamination Plan Template](#), including the sections entitled “Lab Specific Requirements”. The template must be customized for your laboratory.

Save an electronic copy of this completed form and submit to IBC@umn.edu

You will receive an electronic message from the IBC staff within 2-3 days acknowledging receipt of your submission.

You have reached the end of this form. Please make sure that you have responded to every question on this application (even if your response is “not applicable”) and that you have filled out all of the applicable appendices.