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rDNA Registration Form

All activity involving the use and/or storage of recombinant DNA must be registered with and, if necessary, approved by the IBC. Please submit this form at least one month prior to initiation of your project/course activities. The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) can be found at: [http://osp.od.nih.gov/sites/default/files/resources/NIH\\_Guidelines.pdf](http://osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines.pdf). For a quick guide to what constitutes exempt categories of rDNA use, refer to *Appendix A* at the end of this form.

1. Principal Investigator Name: \_\_\_\_\_ E-mail: \_\_\_\_\_
2. Department : \_\_\_\_\_ Phone: \_\_\_\_\_
3. Laboratory Location: \_\_\_\_\_
4. Funding Agency: \_\_\_\_\_
5. Project Title/ Course#: \_\_\_\_\_
6. Risk Group of the recombinant DNA: (*Appendix B*)     RG1     RG2\*     RG3\*     RG4\*
7. Laboratory Biosafety Level: (*Appendix B*)     BSL1     BSL2     BSL3  
Involving Plants (*Appendix P of NIH Guidelines*)     BL1-P     BL2-P     BL3-P  
Involving Animals (*Appendix Q of NIH Guidelines*)     BL1-N     BL2-N     BL3-N
8. Identify the *NIH Guidelines* category of recombinant DNA research (check all that apply)  
 Section III-A\*     Section III-B\*     Section III-C\*  
 Section III-D\*     Section III-E\*     Section III-F
9. Provide a brief summary of the proposed use of recombinant DNA in layman's terms (approximately 3-5 sentences).

\* RG2-4 recombinant DNA experiments and experiments falling under Section III-A-E are not exempt from NIH guidelines and require a full application and review by the IBC.

10. Provide the following information:
  - a. Sources of recombinant DNA: \_\_\_\_\_
  - b. The nature of the inserted DNA sequence (i.e. gene name or designation, antibiotic resistance marker, promoter region, etc.) and function/activity of the cloned insert or its product: \_\_\_\_\_
  - c. Do you plan to propagate the recombinant?     Yes     No
  - d. What are the host recipient(s)? \_\_\_\_\_  
Vector(s)/specific phage or plasmid: \_\_\_\_\_
  - e. Is a helper virus to be used?     Yes     No

If yes, what is the helper virus: \_\_\_\_\_

f. Are plants or animals to be exposed to the recombinant?  Yes  No

g. Will an attempt be made to obtain expression of a foreign gene?  Yes  No

If yes, what protein(s) will be produced? \_\_\_\_\_

h. Describe the containment conditions to be implemented (See Appendices G, I, P, & Q of *NIH Guidelines*, as applicable) \_\_\_\_\_

11. Applicant's Assurance. I certify that:

- a. The following conditions apply to the proposed activities:
- The construct does not contain viral DNA that represents more than 2/3 of any eukaryotic viral genome.
  - The viral construct is not from DNA of Risk Group 3, 4, or restricted agents.
  - The study does not involve the deliberate transfer of rDNA into one or more human subjects.
  - The study does not involve generation of transgenic animals or plants.
  - The study does not involve the generation of toxin molecules lethal for vertebrates at an LD<sub>50</sub> of less than 100 nanograms per kilogram body weight.
  - The study does not involve the generation of more than 10 liters of culture.
  - The study does not involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally or, by doing so, compromises the use of the drug to control disease agents in humans, animals, and/or plants.
- b. I have familiarized myself with the federal regulations governing recombinant DNA research as compiled in the *NIH Guidelines*.
- c. I have disclosed the nature of the recombinant DNA work done in my laboratory and attest that it is in the category that has been declared exempt from federal regulation by *NIH Guidelines Section III-F*.
- d. I will not conduct recombinant DNA experiments that are subject to regulation by *NIH Guidelines* without the authorizations mandated therein, and will submit a **separate** form (IBC Application) to the Institutional Biosafety Committee covering this use of recombinant DNA before initiating any experiments.
- e. I have read and understand my responsibilities as Principal Investigator as outlined in Section IV-B-7 of the *NIH Guidelines*, and will comply with these responsibilities.
- f. The information provided herein is accurate to the best of my knowledge. I also understand that, should I use the project described above as a basis for a funding proposal (either intramural or extramural), it is my responsibility to ensure that the description of the work in the funding proposal is identical in principle to that contained in this registration.

\_\_\_\_\_  
Electronic Signature of Principal Investigator

\_\_\_\_\_  
Date

**Submit this completed form electronically to [ibc@middlebury.edu](mailto:ibc@middlebury.edu)**

## Appendix A – Definitions

### 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 the *NIH Guidelines* [Section IV-C-1-b-\(1\)-\(c\)](#), [Major Actions](#). For a list of natural exchangers that are exempt from the NIH Guidelines, see *NIH Guidelines* [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 *NIH Guidelines* [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 *NIH Guidelines* [Appendix C](#), [Exemptions under Section III-F-6](#) for other classes of experiments, which are exempt from the NIH Guidelines.

## Appendix B - Definitions of Risk Groups and Biosafety Levels

As researchers, it is extremely important to consider all the possible health risks (real and theoretical) associated with the use of recombinant DNA molecules and infectious agents. Careful planning prior to the initiation of a project will allow the researcher to select the proper physical containment application(s) (referred to as Biosafety Levels) thereby decreasing the risk of an accidental exposure to the staff, the general public, and the environment. Researchers should familiarize themselves with the terminology and definitions commonly applied to these two important areas - Risk and Containment. These definitions are provided for you below.

### \*Risk Groups: Pathogens (microorganisms) and agents (rDNA)

Risk group definitions taken from NIH guidelines (2009) and World Health Organization (2004) guidelines.

**RG-1** (no or low individual and community risk). A microorganism that is unlikely to cause human disease or animal disease. Agents not associated with disease in healthy adult humans.

**RG-2** (moderate individual risk, low community risk). A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited. Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.

**RG-3** (high individual risk, low community risk). A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available. Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).

**Note: Middlebury College facilities are not equipped to handle risks associated with RG-3+ agents.**

#### **Biosafety Levels:**

**Biosafety Level 1:** BSL-1 is suitable for work involving well-characterized agents not known to cause disease in health adult humans, and of minimal potential hazard to laboratory personnel and the environment.

**Biosafety Level 2:** BSL-2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.

**Biosafety Level 3:** BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents, which may cause serious or potentially lethal disease as a result of exposure by inhalation.

**Biosafety Level 4:** BSL-4 is required for work with dangerous and exotic agents, which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Restrictions apply to personnel training, lab accessibility and construction, and the use of protective equipment and clothing. Research activities involving BSL-3 and BSL-4 containment are prohibited on the Middlebury College Campus. **There are no BSL-3 or BSL-4 facilities at Middlebury College.**

--[Biosafety in Microbiological and Biomedical Laboratories, 5th Edition](#)