KU- Lawrence Campus

rDNA Committee Registration

**Name:**

**Title:**

**Campus Address:**

**Campus Phone:**

**Campus Email:**

**Dept./Unit:**

**PI:**

**Project/Protocol Title:**

**Protocol: New: \_\_\_\_\_ Amendment:** \_\_\_\_\_\_\_\_\_ (if amend., previous rDNA approval #)

**Provide a brief description of the rDNA protocol/investigation** (summary of the proposed rDNA activity using language that can be understood by the general public; please avoid technical terms and acronyms. Limit your response to 3 to 4 sentences if possible).

(1) I hereby affirm that I have reviewed the NIH recombinant DNA web site to determine the status /classification of the project for which I seek approval. The applicable section of the NIH Guidelines the research falls under is:

\_\_ Section III-A. \_\_ Section III-D

\_\_ Section III-B \_\_ Section III-E

\_\_ Section III-C \_\_ Section III-F

(2) NIH rDNA Guidelines Risk Group Assessment Determination

\_\_ Risk Group 1 (RG1): Agents that are not associated with disease in healthy adult humans.

\_\_ Risk Group 2 (RG2): Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available

\_\_ Risk Group 3 (RG3): Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).

\_\_ Risk Group 4 (RG4): Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk) (NOT ALLOWED AT KU-LAWRENCE CAMPUS).

Risk Group Comments:

(3) Identify appropriate biosafety level of containment and practices for working with the materials based on risk and confirm that you have the appropriate facility and capability.

\_\_ Biosafety Level 1

\_\_ Biosafety Level 2

\_\_ Biosafety Level 3

\_\_ Biosafety Level 4 (NOT ALLOWED AT KU-LAWRENCE CAMPUS)

Biosafety Level Comments:

(4) Are any of the genes or organisms on the "select agents" list from CDC/USDA or do they encode toxins from the lists: \_\_Yes or \_\_No. If yes. Identify: \_\_\_\_\_\_\_\_\_\_\_\_

(5) Affirmation that PI and lab staff who will participate inthe research have been appropriately trained for safe conduct of the research \_\_\_\_

(6) Please providethe source(s) of DNA inserts, vectors and constructs where non-commercially provided. Are any restrictions placed by the donor on usage of the provided material.

(7) Please provide the name and function (where known and speculation about function where unknown) of each gene product to be encoded by the DNA. This should include its characteristics (e.g. virulence, pathogenicity, environmental stability and any other relevant traits).

 (8) Please describe the completed construct to be used accompanied by a not-to-scale (even crude) vector map that defines promoters, enhancers, antibiotic resistance genes and other genes and names their functions.

(9) Identify host/target cells into which each gene will be introduced

(10) Will an attempt will be made to obtain expression of a foreign gene?

if so, identify the organism source, the protein that will be produced and its function.

(11) Will there bedeliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine or agriculture?

(12) Will there be deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight?

(13)Will there be deliberate introduction of genes coding for the biosynthesis of molecules that are toxic for vertebrates with an LD50 greater than 100 nanograms/kg but less than or equal to 100 micrograms/kg?

(14) Will there be deliberate transfer of rDNA material into human research participants?

(15) Will the protocol involveDNA from Risk Group 3, 4, or restricted organisms or cells known to be infected with these agents?

(16) Will whole plants be regenerated from plant cells and tissues cultures that do not remain axenic cultures?

(17) Will the protocol involve large-scale experiments (more than 10 liters of volume in a single culture vessel)?

(18) Will animals be used in this protocol?