**SECTION A – Recombinant DNA (rDNA) Registration Form**

The current version of the "NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES" (aka "NIH GUIDELINES" or "NGL") is the April 2016 revision.

See: <http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html> or: <http://www.umkc.edu/ors/ibc/>

|  |  |  |  |
| --- | --- | --- | --- |
| **a1.** | The proposed experiments with recombinant DNA molecules are (check one): | | |
|  | EXEMPT under the NIH Guidelines  (go to question a2) |  | Non-Exempt according to the NIH Guidelines  (go to question a3) |

=====================================================================================

Criteria why your experiments may be considered **EXEMPT** recombinant research.

* If any experiments involving rDNA molecules are not fully within the categories described below at a2, they are by definition “Non-Exempt”. If this applies, continue with question a3.
* *Inclusion of Appendix A-1 for 'Exempt' recombinant research requires completion by the PI of the CITI IBC course "NIH Recombinant DNA (rDNA) Guidelines".*

|  |  |  |
| --- | --- | --- |
| **a2.** | If you checked “**Exempt**” in question 1, indicate under which criteria the experiments are exempt by marking the appropriate check boxes. | |
|  | **Section III-F. Exempt Experiments** | |
| 🞏 | A. | **Section III-F-1 of the NIH Guidelines** The experiments involve synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section. |
| 🞏 | B. | **Section III-F-2** **of the NIH Guidelines** The experiments involve recombinant or synthetic nucleic acid molecules that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. |
| 🞏 | C. | **Section III-F-3 of the NIH Guidelines**  The experiments involve recombinant or synthetic nucleic acid molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. |
| 🞏 | D. | **Section III-F-4 of the NIH Guidelines** The experiments involve rDNA molecules that consist entirely of nucleic acids 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. |
| 🞏 | E. | **Section III-F-5** **of the NIH Guidelines** The experiments involve rDNA molecules that consist entirely of nucleic acids 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). |

|  |  |  |  |
| --- | --- | --- | --- |
| 🞏 | F. | **Section III-F-6** **of the NIH Guidelines** The experiments involve rDNA molecules 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 will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines. | |
| 🞏 | G. | **Section III-F-7 of the NIH Guidelines** The experiments involve genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. | |
|  | H. | **Section III-F-8 of the NIH Guidelines** The experiments involve recombinant or synthetic nucleic acid molecules 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-8 for other classes of experiments which are exempt from the NIH Guidelines. | |
| 🞏 | H-1 | | **Recombinant DNA in Tissue Culture**. (**Appendix C-I**) Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical -- see Appendix C-VIII-E, Footnotes and References of Appendix C), that are propagated and maintained in cells in tissue culture are exempt from these NIH Guidelines with the exceptions listed in Appendix C-I-A. |
| 🞏 | H-2 | | ***Escherichia coli K-12* Host-Vector Systems**. (**Appendix C-II**) Experiments which use *Escherichia coli* K-12 host-vector systems, with the exception of those experiments listed in Appendix C-II-A, are exempt from the NIH Guidelines provided that: (i) the *Escherichia coli* host does not contain conjugation proficient plasmids or generalized transducing phages; or (ii) lambda or lambdoid or Ff bacteriophages or non-conjugative plasmids (see Appendix C-VIII-B, Footnotes and References of Appendix C) shall be used as vectors. However, experiments involving the insertion into *Escherichia coli* K-12 of DNA from prokaryotes that exchange genetic information (see Appendix C-VIII-C, Footnotes and References of Appendix C) with *Escherichia coli* may be performed with any *Escherichia coli* K-12 vector (e.g., conjugative plasmid). When a non-conjugative vector is used, the *Escherichia coli* K-12 host may contain conjugation-proficient plasmids either autonomous or integrated, or generalized transducing phages. For these exempt laboratory experiments, Biosafety Level (BL) 1 physical containment conditions are recommended. For large-scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the host organism unmodified by recombinant or synthetic nucleic acid molecule techniques; the Institutional Biosafety Committee can specify higher containment if deemed necessary. |
| 🞏 | H-3 | | ***Saccharomyces* Host-Vector Systems**. (**Appendix C-III**) Experiments involving *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems, with the exception of experiments listed in Appendix C-III-A, are exempt from the NIH Guidelines. For these exempt experiments, BL1 physical containment is recommended. For large-scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the unmodified host organism; the Institutional Biosafety Committee can specify higher containment if deemed necessary. |
| 🞏 | H-4 | | ***Kluyveromyces* Host-Vector Systems**. (**Appendix C-IV**) Experiments involving *Kluyveromyces lactis* host-vector systems, with the exception of experiments listed in Appendix C-IV-A, are exempt from the NIH Guidelines provided laboratory-adapted strains are used (i.e. strains that have been adapted to growth under optimal or defined laboratory conditions). For these exempt experiments, BL1 physical containment is recommended. For large-scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the unmodified host organism; the Institutional Biosafety Committee may specify higher containment if deemed necessary. |

|  |  |  |
| --- | --- | --- |
| 🞏 | H-5 | ***Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems**. (**Appendix C-V**) Any asporogenic *Bacillus subtilis* or asporogenic *Bacillus licheniformis* strain which does not revert to a spore-former with a frequency greater than 10-7 may be used for cloning DNA with the exception of those experiments listed in Appendix C-V-A, Exceptions. For these exempt laboratory experiments, BL1 physical containment conditions are recommended. For large-scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the unmodified host organism; the Institutional Biosafety Committee can specify higher containment if it deems necessary. |
| 🞏 | H-6 | **Extrachromosomal Elements of Gram Positive Organisms** (**Appendix C-VI**) Recombinant or synthetic nucleic acid molecules derived entirely from extrachromosomal elements of the organisms listed in the NIH Guidelines at Appendix C-VI (including shuttle vectors constructed from vectors described in Appendix C), propagated and maintained in organisms listed in the NIH Guidelines at Appendix C-VI, are exempt from the NIH Guidelines. |
| 🞏 | H-7 | **Purchase or Transfer of Transgenic Rodents** (**Appendix C-VII**) The purchase or transfer of transgenic rodents for experiments that require BL1 containment (See Appendix G-III-M, Footnotes and References of Appendix G) are exempt from the NIH Guidelines. |
| 🞏 | H-8 | **Generation of BSL-1 Transgenic Rodents via Breeding** (**Appendix C-VIII**) The breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment will be exempt from the NIH Guidelines if:  (1) Both parental rodents can be housed under BL1 containment; and  (2) neither parental transgenic rodent contains the following genetic modifications:  (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or  (ii) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and  (3) the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses. |
|  | | |

* If any experiments involving recombinant or synthetic nucleic acid molecules are not fully within the categories described above at a2, they are by definition “Non-Exempt”. If this applies, continue with question **a3**.

=====================================================================================

=====================================================================================

Criteria that define the classification of **NON-EXEMPT** recombinant research.

* *Inclusion of Appendix A-1 for 'Non-Exempt' recombinant research requires completion by all listed researchers of the CITI IBC courses "Training for Investigators, Staff and Students Handling Biohazards" and "NIH Recombinant DNA (rDNA) Guidelines".*

|  |  |
| --- | --- |
| **a3.** | If you checked “**Non-Exempt**” in question a1, indicate under which criteria the experiments are non-exempt by marking the check boxes for the appropriate registration category (or categories) for experiments covered by NIH Guidelines. |
|  | For a searchable database of risk groups go to <http://www.absa.org/riskgroups/index.html> |

Experiments considered as **Major Actions under the NIH Guidelines cannot be initiated** without submission of relevant information on the proposed experiment to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax), the publication of the proposal in the Federal Register for 15 days of comment, review by RAC, and specific approval by NIH. The containment conditions or stipulation requirements for such experiments will be recommended by RAC and set by NIH at the time of approval. **Such experiments require Institutional Biosafety Committee approval before initiation.** Specific experiments already approved are included in Appendix D, Major Actions Taken under the NIH Guidelines, which may be obtained from the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

|  |  |
| --- | --- |
|  | **Sections III-A – III-E. Non-Exempt Experiments**  **Major Actions under the *NIH Guidelines.*** |
| **A** | ***Section III-A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation*** *(See Section IV-C-1-b-(1), Major Actions).* |
| 🞏 | **Section III-A-1-a.** The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, *Footnotes and References of Sections I-IV*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC. |
| **B** | ***Section III-B. Experiments That Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation*** |
| 🞏 | **Section III-B-1.** Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight. |
| 🞏 | **Section III-B-2.** Experiments that have been approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines. |
| **C** | ***Section III-C. Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment*** |
| 🞏 | **Section III-C-1.** Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants.   * *Human gene transfer research requires completion by all listed researchers of the CITI IBC course "Human Gene Transfer Trials".* |
| **D** | ***Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation*** |
| 🞏 | **Section III-D-1.** Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as host-vector systems*.* |
| 🞏 | **Section III-D-2.** Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems. |
| 🞏 | **Section III-D-3.** Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems. |

|  |  |
| --- | --- |
| 🞏 | **Section III-D-4.** Experiments involving whole animals. This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BL1-N containment. A minimum containment of BL2 or BL2-N is required. |
| 🞏 | **Section III-D-5.** Experiments involving whole plants. Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules, may be conducted under the containment conditions described in Sections III-D-5-a through III-D-5-e. If experiments involving whole plants are not described in Section III-D-5 and do not fall under Sections III-A, III-B, III-D or III-F, they are included in Section III-E. |
| 🞏 | **Section III-D-6.** Experiments involving more than 10 liters of culture. |
| 🞏 | **Section III-D-7.** Experiments involving influenza viruses. |
| **E** | ***Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*** |
| 🞏 | **Section III-E-1.** Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus. |
| 🞏 | **Section III-E-2.** Experiments involving whole plants. This section covers experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F. |
| 🞏 | **Section III-E-3.** Experiments involving transgenic rodents. This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under Section III-D-4, Experiments involving whole animals. |
|  | *Experiments not included in NIH Guidelines Sections III-A, III-B, III-C, III-D and III-F, and their subsections are considered in Section III-E.* |
| 🞏 | **IF your experiments fit neither one-or-more of the specific ‘Exempt’ or ‘Non-Exempt’ categories,** the NIH Guidelines define any such research as subject to Section III-E.  **Section III-E-other.** Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, and their subsections, are considered in Section III-E. All such experiments may be conducted at BL1 containment. For experiments in this category, a registration document (see Section III-D, Experiments that Require Institutional Biosafety Committee Approval Before Initiation) shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated. The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required (see Section IV-A, Policy). For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under Section III-E and may be conducted at BL1 containment. |

**SECTION B – Vectors, Hosts, and rDNA Agents**

|  |  |  |
| --- | --- | --- |
| **b1.** | Do you generate, use, or otherwise conduct any processes with synthetic nucleic acids? Include PCR, RT-PCR, shRNA, etc.  (Uses of in vitro nucleic acids and oligonucleotide work that relates to Section III-F-1 of the NIH Guidelines) | |
|  | Yes |
|  | No |
|  | If “Yes”, explain. | |
|  | | |
| **b2.** | List all plasmid, phage and other bacterial and eukaryotic cell vectors used.  Enter "NA" if none.  (Note: viruses and viral vectors are listed in SECTION C.) | |
|  | | |

|  |  |
| --- | --- |
| **b3.** | Identify DNA sequences that will be inserted into vectors listed in b1. Include:   * the **species** from which the insert is derived; * the gene product that is expressed, if any.   Enter "No insert" if no inserts are used. |
|  | |

|  |  |
| --- | --- |
| **b4.** | List known oncogenes, or inserts listed in b2 that have oncogenic properties.  Enter "NA" if no oncogene sequences are used. |
|  | |

|  |  |
| --- | --- |
| **b5.** | List host organisms for recombinant DNA transformations (e.g. *E.coli*, *S.cerevisiae*, other fungi, any plants, mammalian cells or human cell lines). List all metazoan vertebrate *and* invertebrate host species, including insects and worms.  (More information related to use of animals as rDNA hosts is requested in SECTION D.)  (Note: Recipient hosts for transient transfections need not to be listed. This type of experiment is currently not subject to NIH Guidelines for Research Involving Recombinant DNA Molecules.) |
|  | |

|  |  |
| --- | --- |
| **b6.** | List any sequences used to manipulate gene function (e.g. siRNA) or as adjuvants (e.g. CpG-containing DNA) either in cell culture or *in vivo*. Enter "NA" if none are used. |
|  | |

|  |  |  |
| --- | --- | --- |
| **b7.** | Are human toxins to be expressed and released as part of this research?  Note: In case of significant human toxicity, BSL-2- and/or BSL-3-related Appendix A-2 and/or Appendix A-3 must be completed. | |
|  | Yes |
|  | No |
|  | If “Yes”, describe the toxic product(s) (including the LD50) that could be produced or released and the containment precautions that will be used. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **b8.** | Is there any potential for increased virulence of the vector used due to recombinant manipulation on any host organism used? | |
|  | Yes |
|  | No |
|  | If “Yes”, explain in detail. | |
|  | | |

**SECTION C – Viruses and virus vectors**

|  |  |  |
| --- | --- | --- |
| **c1.** | * Does this project involve the use of viruses or viral vectors?   (For bacterial and eukaryotic plasmid-like vectors, see SECTION B.) | |
|  | Yes |
|  | No |
|  | If “No”, skip to SECTION D. | |

|  |  |
| --- | --- |
| **c2.** | List all viruses and/or viral vectors used:   * Specify the virus family and/or subfamily (e.g. herpesvirus, oncogenic retrovirus, adenovirus, adeno-associated virus, etc). * State the species of origin for each virus or vector used. |
|  | |

|  |  |
| --- | --- |
| **c3.** | Identify nucleic acid sequences that will be inserted into vectors listed in c2. Include:   * the **species** from which the insert is derived; * the gene product that is expressed, if any.   Enter "No insert" if no inserts are used. |
|  | |

* + **For lentiviruses (e.g. FIV, HIV, SIV, etc) and lentiviral vectors**, complete ONLY questions c8 – c13.
  + **For all other viruses**, complete ONLY questions c4 – c7.

|  |  |  |
| --- | --- | --- |
| **c4.** | Is the virus/viral vector able to enter or infect human cells? | |
|  | Yes |
|  | No |
|  | If “Yes”, indicate whether it is a productive or limited infection, and state whether infection can cause disease. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c5.** | Is a helper virus used in this project? | |
|  | Yes |
|  | No |
|  | If “Yes”, describe the helper virus used. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c6.** | Is the virus/viral vector replication-defective? | |
|  | Yes |
|  | No |
|  | If “No”, skip question c6.  If “Yes”, describe the deletions rendering it defective, and complete question c6. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c7.** | Has the preparation of replication-defective vectors been tested for the presence of replication competent virus? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide details of the assay used.  If “No”, what is the likelihood of conversion to replication-competent virus? | |
|  | | |

**For viruses other than lentiviruses, skip to SECTION D.**

|  |  |
| --- | --- |
| **c8.** | List the specific lentivirus or strain and species of origin (e.g. HIV, human; FIV, feline). |
|  | |

|  |  |  |
| --- | --- | --- |
| **c9.** | Is the lentivirus/lentiviral vector obtained from a commercial source? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide the name of the commercial source.  If “No”, provide the source of the lentivirus/lentiviral vector (e.g. the name of the institution or individual supplying the material). | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c10.** | Is the lentivirus/lentiviral vector generated from a multi-component system (e.g. separate plasmids for packaging, envelope and gene transfer)? | |
|  | Yes |
|  | No |
|  | If “Yes”, describe the system used. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c11.** | Is the lentivirus/lentiviral vector pseudotyped (e.g. expressing a different envelope gene)? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide whether the pseudotyping alters the host and cell tropism. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c12.** | Is the lentivirus/lentiviral vector replication-defective? | |
|  | Yes |
|  | No |
|  | If “No”, skip to SECTION D.  If “Yes”, describe the deletions rendering it defective and complete question c12. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **c13.** | Has the preparation of replication-defective vector been tested for the presence of replication-competent virus? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide details of the assay used.  If “No”, what is the likelihood of conversion to a replication-competent virus? | |
|  | | |

**SECTION D – Animal Use Information**

**Note that under NIH Recombinant Guidelines all metazoan species are included in this section.**

**This includes the use of insects, worms, molluscs and any vertebrate species.**

* *Research using small mammals requires completion by all listed researchers of the CITI IBC course "Animal Biosafety".*

|  |  |  |
| --- | --- | --- |
| **d1.** | Does the work involve animal use? | |
|  | Yes |
|  | No |
|  | If “Yes”, list all animal species and strains  If “No”, skip to SECTION E | |

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **d2.** | Identify all recombinant sequences and their associated biological risk. |

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
| **d3.** | Do the experiments involve breeding of any transgenic animals, other than BSL-1 rodents?  Note, this includes the use of breeding for maintenance of strains. (Only strain maintenance and cross-breeding of BSL-1 transgenic rodents is generally Exempt (see section A, a2, F-7 above).)  Breeding of any other transgenic animals or of transgenic rodents requiring BSL-2+ containment is never Exempt. | |
|  | Yes |
|  | No |
|  | If “Yes”, please provide detailed information about breeding strategies and associated animal Biosafety concerns. | |

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
| **d4.** | Is rodent breeding for transgenic strain maintenance performed, including maintaining Knock-Out strains? | |
|  | Yes |
|  | No |
|  | If “Yes”, describe associated animal BSL containment (ABSL1, ABSL2 or ABSL3) and the basis for this containment. | |

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
| **d5.** | Is rodent breeding performed to create new combinations of transgenic strains (e.g. congenics), including breeding of transgenic to non-transgenic/non recombinant lines, that will result in the creation or maintenance of strains which are NOT Exempt as specified in Section A, a2, F-7 ? | |
|  | Yes |
|  | No |
|  | If “Yes”, list the strains being bred and/or cross-bred: | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | x |  |
|  | | x |  |
|  | | x |  |
|  | | x |  |
|  | | x |  |
|  | | x |  |
|  | | x |  |
|  | | x |  |
|  | Explain the rationale for this breeding program, and the intended use of the offspring. Describe the pertinent details of the experiment, including BSL containment requirements, the presence of exogenous eukaryotic viruses and/or the use of gammaretroviral LTRs. | | |
|  | | | |

|  |  |  |
| --- | --- | --- |
| **d6.** | Has an Institutional Animal Care and Use Committee (IACUC) application been submitted? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide the IACUC protocol number to be linked to this rDNA project.  NOTE: REGISTRATION OF THE PROTOCOL WITH AND APPROVAL BY THE IACUC IS REQUIRED BEFORE THE RESEARCH CAN BE INITIATED. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **d7.** | Will recombinant and/ or synthetic agents be administered to live or intact animals?  (e.g. application of plasmids, viral vectors, transfected cells, recombinant stem cells, etc.) | |
|  | Yes |
|  | No |
|  | If “Yes”, list agents.  If “No”, skip to SECTION E. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **d8.** | Do you anticipate that work with animal subjects will be conducted at a different BioSafety Level than any *in vitro* portions of the study? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide the BSL for work with or housing of animal subjects, and explain the rationale or justification for the proposed BSL. | |
|  | | |

|  |  |
| --- | --- |
| **d9.** | Describe the route of administration for each recombinant agent used. |
|  | |

|  |  |
| --- | --- |
| **d10.** | Provide the concentration and volume for each recombinant agent to be administered |
|  | |

**SECTION E – Human Use Information**

(Note: use of human cells, cell lines and tissues requires at least BSL-2 containment: see Appendix A-4.)

|  |  |  |
| --- | --- | --- |
| **e1.** | Does work involve human cell lines (including cell lines such as 293T, HeLa)? | |
|  | Yes |
|  | No |
|  | If “Yes”, list below. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **e2.** | Will primary human tissues or cells be used? | |
|  | Yes |
|  | No |
|  | If “Yes”, describe the use of the tissues or cells | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **e3.** | Has an Institutional Review Board (IRB) application been submitted? | |
|  | Yes |
|  | No |
|  | If “Yes”, provide the IRB protocol number to be linked to this rDNA project.  NOTE: REGISTRATION OF THE PROTOCOL WITH AND APPROVAL BY THE IRB IS REQUIRED BEFORE THE RESEARCH CAN BE INITIATED. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **e4.** | Is this a human gene transfer proposal, i.e. is DNA and/or RNA derived from or consisting of recombinant or synthetic nucleic acids administered to human subjects? | |
|  | Yes |
|  | No |
|  | If “No” you are done because questions e5,e6, and e7 do not apply to this protocol.  If “Yes”, you must submit a detailed addendum in which each topic of Appendix M in the NIH Guidelines for Research Involving Recombinant DNA Molecules is addressed.  PATIENT CONSENT FORMS, PROOF OF SUBMISSION OF PROPOSAL TO NIH, AND RAC APPROVAL MUST ALSO BE SUBMITTED. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **e5.** | Does this protocol use a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk? | |
|  | Yes |
|  | No |
|  | If “Yes”, you must submit a detailed description of the new vector, genetic material or delivery methodology and how risk will be assessed. | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **e6.** | Does this protocol rely on preclinical safety data that was obtained using a new preclinical model system of unknown and unconfirmed value? | |
|  | Yes |
|  | No |
|  | If “Yes”, you must submit a detailed description of this data | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **e7.** | Is the proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known and may render it difficult for oversight bodies to evaluate the protocol rigorously? | |
|  | Yes |
|  | No |
|  | If “Yes”, you must submit a detailed addendum in which each topic of Appendix M in the NIH Guidelines for Research Involving Recombinant DNA Molecules is addressed.  PATIENT CONSENT FORMS, PROOF OF SUBMISSION OF PROPOSAL TO NIH, AND RAC APPROVAL MUST ALSO BE SUBMITTED. | |
|  | | |