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| **KUMC Institutional Biosafety Committee****Registration Form** |

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| 1. **PROJECT DETAILS**
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| **PRINCIPAL INVESTIGATOR** |  | **EMAIL** |  |
| **DEPARTMENT** |  | **PHONE** |  |

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| **PROJECT TITLE** |  |

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|[ ]  **NEW IBC REGISTRATION** |
| [ ]  | **RENEWAL OF EXISTING IBC REGISTRATION**   | **PREVIOUS IBC REGISTRATION NUMBER** |  |

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| --- | --- |
| **FUNDING SOURCE** |  |

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| **IS IACUC APPROVAL REQUIRED FOR THIS PROJECT?** | [ ]  Yes[ ]  No | **ACUP PROTOCOL NUMBER** |  |

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| **IS IRB APPROVAL REQUIRED FOR THIS PROJECT?** | [ ]  Yes[ ]  No | **IRB PROTOCOL NUMBER** |  |

Project submissions are forwarded to the Institutional Biosafety Committee (IBC) for review, comment and approval. The IBC is comprised of scientists and community representatives with varied backgrounds. It is important to tailor your responses in a way that can be understood by individuals that are not specialists in your research area. Please provide sufficient detail so that the IBC can determine the required work practices and primary/secondary barriers to ensure the safe conduct of the research. Questions can be directed to the Biological Safety Officer at 913-588-5206 or ibc@kumc.edu.

I certify that, to the best of my knowledge, the information provided in this registration form is complete and accurate. I am familiar with, and agree to abide by the provisions in the NIH Guidelines and Biosafety in Microbiological and Biomedical Laboratories (BMBL 5th Edition) as well as the requirements established by the KUMC Institutional Biosafety Committee. I accept responsibility for the work conducted on this project and will ensure that laboratory personnel are appropriately trained to perform all work activities safely.

[ ]  **PRINCIPAL INVESTIGATOR AGREEMENT**

**DATE:**

**\*SUBMIT COMPLETED FORM TO** **ibc@kumc.edu****\***

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| 1. **RESEARCH PERSONNEL WORKING ON PROJECT**
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| **NAME** | **POSITION** |
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All research personnel must complete the following laboratory safety training courses **ANNUALLY** before participating in laboratory research. Training is accessed via [SABA](https://kumc.sabacloud.com/Saba/Web_spf/NA7P1PRD102/app/dashboard).

[Biosafety](https://kumc.sabacloud.com/Saba/Web_spf/NA7P1PRD102/common/ledetail/EHS_BIOSAFETY_TRAINING)

[Bloodborne Pathogens](https://kumc.sabacloud.com/Saba/Web_spf/NA7P1PRD102/common/ledetail/EHS_BLOOD_PATH__RECUR)

[Personal Protective Equipment](https://kumc.sabacloud.com/Saba/Web_spf/NA7P1PRD102/common/ledetail/EHS_PERS_PROTECT_EQUIP)

[Hazard Communication and RCRA Chemical Safety](https://kumc.sabacloud.com/Saba/Web_spf/NA7P1PRD102/common/ledetail/EHS_HAZARD_COMM_AND_RCRA)

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| 1. **PROJECT LOCATIONS (INCLUDES USE AND STORAGE OF MATERIALS)**
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| **BUILDING** | **ROOM** |
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| 1. **MATERIAL USAGE SUMMARY**
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|[ ]  **Recombinant/Synthetic Nucleic Acid Molecules**[ ]  *Introduced into Non-Pathogenic E. coli – Complete Sections 8, 9 and 10*[ ]  *Introduced into Prokaryotic Hosts other than E. coli* – *Complete Sections 8, 9 and 11*[ ]  *Introduced into Lower Eukaryotic Hosts – Complete Sections 8, 9 and 12*[ ]  *Introduced into Cell Culture – Complete Sections 8, 9 and 13**\*Use of viral vector (e.g. lentivirus, adenovirus) also requires completion of* [*viral vector registration form*](https://www.kumc.edu/documents/compliance/safety/Viral%20Vector%20Registration%20Form.docx) |
|[ ]  **Whole Animals**[ ]  *Recombinant/Synthetic DNA in Animals and Transgenic Animal Experiments* – *Complete Sections 8, 9, 14 and 15*[ ]  *Human-Derived Materials Introduced into Animals* – *Complete Section 16*[ ]  *Animal-Derived Materials Introduced into Animals* – *Complete Section 17*[ ]  *Infectious Agents Introduced into Animals* – *Complete Section 18*[ ]  *Toxins or Select Agents Introduced into Animals* – *Complete Section 19* |
|[ ]  **Infectious Agents*** *Microbial Agents Pathogenic to Humans, Animals or Plants - Complete Section 18*

*\*Use of human pathogen (e.g. S. aureus, B. burgdorferi, Hepatitis B virus) also requires completion of* [*pathogen registration form*](https://www.kumc.edu/documents/compliance/safety/Pathogen%20Registration%20Form.docx) |
|[ ]  **Human-Derived Materials*** *Blood, Unfixed Tissue, Cell Lines, Stem Cells, etc.* – *Complete Section 16*
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|[ ]  **Animal-Derived Materials** * *Non-Primate and Non-Human Primate Blood, Unfixed Tissue, Primary Cell Culture, etc. – Complete Section 17*
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|[ ]  **Toxins / Select Agents*** *Biological Toxins or Federally Regulated Select Agents/Toxins* – *Complete Section 19*
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|[ ]  **Dangerous Substances and/or Drugs*** *use and/or storage of chemicals, biologics and/or drugs that may be hazardous* – *Complete Section 20*
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| **4-A) *Will biological materials and/or packages containing dry ice be shipped from KUMC*?** | [ ]  Yes [ ]  No |
| **4-A-i) *If Yes, what classification(s) of materials do you ship?****NOTE:* [*Training*](https://kumc.sabacloud.com/Saba/Web_spf/NA7P1PRD102/app/me/learningeventdetail;spf-url=common%2Fledetail%2Fcours000000000006880%3FfromAutoSuggest%3Dtrue) *is required every two years for compliance with International Air Transport Association (IATA) and U.S. Department of Transportation (DOT) regulations when shipping these material* | [ ]  Dry ice [ ]  Category A[ ]  Category B[ ]  Exempt Specimens  |

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| 1. **PROJECT SUMMARY - *Provide a brief project overview:***
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| 1. **EXPERIMENTAL DESIGN - *Briefly describe the experimental investigations in non-technical terms****.* ***Do not cut and paste from a grant application. Highlight the recombinant DNA methodology, including any transgenic animal work and/or the use of microbial agents, cell culture experiments, etc:***
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| 1. **RISK ASSESSMENT AND CONTROL - *Identify protocol-specific risks, including consideration of potentially infectious materials, sharps and aerosol generating procedures. Identify risk mitigation measures that will be used (e.g. engineering controls, PPE, waste disposal, decontamination of work surfaces, storage conditions, etc.). Describe post-exposure procedures in the event of an accidental exposure. Reference:*** [***BMBL 6th Edition***](https://www.cdc.gov/labs/BMBL.html)***:***
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| 1. **EXPERIMENTS COVERED BY THE *NIH GUIDELINES* SECTIONS III-A – III-E**
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| **Reference:** [***NIH Guidelines***](https://osp.od.nih.gov/biotechnology/nih-guidelines/) |
| **8-A) *Do any experiments involve disease-causing microorganisms acquiring a drug resistance trait that could compromise the ability to control disease or alter the host range, transmissibility or virulence of a microorganism?*** | [ ]  Yes[ ]  No |
| **8-B) *Do any experiments involve the deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 ng/kg body weight?*** | [ ]  Yes[ ]  No |
| **8-C) *Do any experiments involve the deliberate transfer of recombinant or synthetic nucleic acid molecules into human research participants (human gene therapy studies)?*** | [ ]  Yes[ ]  No |
| **8-D) *Do any experiments involve the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2, 3 or 4 Agents or Restricted Agents?*** | [ ]  Yes[ ]  No |
| **8-E) *Do any experiments involve the cloning of DNA from Risk Group 2, 3 or 4 Agents or Restricted Agents into non-pathogenic prokaryotic or lower eukaryotic host-vector systems?*** | [ ]  Yes[ ]  No |
| **8-F) *Do any experiments involve the use of infectious or defective DNA or RNA viruses in tissue culture systems (this includes the use of a packaging cell line(s) to generate viral particles for transduction)?*** | [ ]  Yes[ ]  No |
| **8-G) *Do any experiments involve whole animals in which the animal’s genome has been altered by the stable introduction of recombinant or synthetic nucleic acid molecules into the germ-line (generation of transgenic animals) OR by knock-out of indigenous genes?*** | [ ]  Yes[ ]  No |
| **8-H) *Do any experiments involve plants containing recombinant or synthetic nucleic acid molecules, including propagating such plants?*** | [ ]  Yes[ ]  No |
| **8-J) *Do any experiments involve growing cultures of organisms containing recombinant or synthetic nucleic acid molecules in excess of 10 liters in a single growth vessel?*** | [ ]  Yes[ ]  No |
| **8-K) *Do any experiments involve influenza viruses generated by recombinant or synthetic methods?*** | [ ]  Yes[ ]  No |
| **8-L) *Do you conduct experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes?*** | [ ]  Yes[ ]  No |

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| 1. **EXEMPT EXPERIMENTS PER *NIH GUIDELINES* SECTION III-F**
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| **Reference:** [***NIH Guidelines***](https://osp.od.nih.gov/biotechnology/nih-guidelines/) |
| **9-A) *Do you conduct experiments with synthetic nucleic acids that (1) cannot replicate nor generate nucleic acids that can replicate in any living cell, and (2) are not designed to integrate into DNA, and (3) do not produce a toxin lethal for vertebrates at an LD50 of less than 100 ng/kg body weight?*** | [ ]  Yes[ ]  No |
| **9-B) *Do you conduct experiments with nucleic acids that are not in organisms, cells or viruses and that have not been modified or manipulated to render them capable of penetrating cell membranes?*** | [ ]  Yes[ ]  No |
| **9-C) *Do you conduct experiments consisting solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature?*** | [ ]  Yes[ ]  No |
| **9-D) *Do you conduct experiments 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?*** | [ ]  Yes[ ]  No |
| **9-E) *Do you conduct experiments 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)?*** | [ ]  Yes[ ]  No |
| **9-F) *Do you conduct experiments 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 (See*** [***Appendices A-I through A-VI***](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948372)***, Exemptions under Section III-F-6 - Sublists of Natural Exchangers, for a list of natural exchangers that are exempt)?*** | [ ]  Yes[ ]  No |
| **9-G) *Do you conduct experiments with genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA?*** | [ ]  Yes[ ]  No |
| **9-H) *Do you conduct experiments that do not present a significant risk to health or the environment (See*** [***Appendix C***](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948398)***, Exemptions under Section III-F-8, for classes of experiments that are exempt)?*** | [ ]  Yes[ ]  No |

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| 1. **RECOMBINANT/SYNTHETIC NUCLEIC ACIDS IN *E. coli***
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*This section pertains to the use of recombinant or synthetic nucleic acid molecules in well-characterized, non-pathogenic strains of E. coli, such as K-12, DH5-alpha or BL21*.

**10-A) *List E. coli host strains to be used***:

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**10-B) *List gene(s) encoded by inserted nucleic acid sequences***:

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**10-C) *List species/biological origin of inserted nucleic acid sequences***:

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| **10-D) *Will inserted gene(s) be expressed?*** | [ ]  Yes [ ]  No |

**10-D-i) *If Yes, describe all pertinent biological activities of the gene products (e.g. toxicity, ability to alter cell cycle, oncogenic potential, physiological activity, normal function, etc.)*:**

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**10-E) *List vectors to be used***:

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**10-F) *List antibiotic resistance genes contained on these vectors***:

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| **10-G) *Do experiments involve the transfer of antibiotic resistance gene(s) in addition to those contained in the vectors?*** | [ ]  Yes [ ]  No |

**10-G-i) *If Yes, list the antibiotic resistance gene(s)*:**

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| 1. **RECOMBINANT/SYNTHETIC NUCLEIC ACIDS IN OTHER PROKARYOTES**
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*This section pertains to the use of recombinant or synthetic nucleic acid molecules in bacterial hosts other than non-pathogenic lab strains of E. coli*.

**11-A) *List bacterial hosts to be used***:

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**11-B) *List gene(s) encoded by inserted nucleic acid sequences***:

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**11-C) *List species/biological origin of inserted nucleic acid sequences***:

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| **11-D) *Will inserted gene(s) be expressed?*** | [ ]  Yes [ ]  No |

**11-D-i) *If Yes, describe all pertinent biological activities of the gene products (e.g. toxicity, ability to alter cell cycle, oncogenic potential, physiological activity, normal function, etc.)*:**

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**11-E) *List vectors to be used*:**

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**11-F) *List antibiotic resistance genes contained on these vectors*:**

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| **11-G) *Are any hosts human or animal pathogens?*** | [ ]  Yes [ ]  No |

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| **11-G-i) *If Yes, are any of the antibiotics listed above used to treat disease in humans or animals?*** | [ ]  Yes [ ]  No |

**11-G-ii) *If Yes, list antibiotics that can be used to treat an infection from the specific strain being used, taking into consideration the inserted and naturally occurring drug resistance genes*:**

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| **11-H) *Do experiments involve the transfer of antibiotic resistance gene(s) in addition to those contained in the vectors?*** | [ ]  Yes [ ]  No |

**11-H-i) *If Yes, list the antibiotic resistance gene(s)*:**

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| 1. **RECOMBINANT/SYNTHETIC NUCLEIC ACIDS IN LOWER EUKARYOTES**
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*This section pertains to the use of recombinant or synthetic nucleic acid molecules in lower eukaryotic hosts, such as fungus/yeast, protozoa or plants.*

**12-A) *List hosts to be used***:

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**12-B)** ***List gene(s) encoded by inserted nucleic acid sequences***:

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**12-C)** ***List species/biological origin of inserted nucleic acid sequences***:

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| **12-D) *Will inserted gene(s) be expressed?*** | [ ]  Yes [ ]  No |

**12-D-i) *If Yes, describe all pertinent biological activities of the gene products (e.g. toxicity, ability to alter cell cycle, oncogenic potential, physiological activity, normal function, etc.)*:**

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**12-E) *List vectors to be used*:**

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| 1. **RECOMBINANT/SYNTHETIC NUCLEIC ACIDS IN CELL CULTURE**
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*This section pertains to the use of recombinant or synthetic nucleic acid molecules in cell culture, including viral vectors and other genetically modified viruses*.

**13-A) *List tissue culture cell line(s) to be used***:

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**13-B)** ***List species from which cell culture was derived***:

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**13-C)** ***List gene(s) encoded by inserted nucleic acid sequences***:

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**13-D)** ***List species/biological origin of inserted nucleic acid sequences***:

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| **13-E) *Will inserted gene(s) be expressed?*** | [ ]  Yes [ ]  No |

**13-E-i) *If Yes, describe all pertinent biological activities of the gene products (e.g. toxicity, ability to alter cell cycle, oncogenic potential, physiological activity, normal function, etc.)*:**

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**13-F) *List vectors to be used*:**

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| **13-G) *Do any vectors contain inserted nucleic acid sequences that retain more than 2/3 of the genome of any eukaryotic virus?*** | [ ]  Yes[ ]  No |

**13-G-i) *If Yes, list the name of the virus*:**

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| **13-H*) Is a packaging cell line used?*** | [ ]  Yes [ ]  No |

**13-H-i) *If Yes, list the packaging cell line name*:**

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**13-H-ii) *If Yes, list the virus that is produced*:**

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| **13-J*) Is a defective virus used in the presence of a helper virus?*** | [ ]  Yes [ ]  No |

**13-J-i) *If Yes, list the helper virus*:**

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| 1. **RECOMBINANT/SYNTHETIC NUCLEIC ACIDS IN ANIMALS**
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*Sections 14 and 15 pertain to recombinant or synthetic nucleic acid molecules (modified microbial agents, plasmids or cells) in animals, including the generation, breeding, purchase/transfer or use of transgenic animals.*

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| **14-A) *Will animals be used as a host for recombinant microbial agents or plasmids (e.g. viral vector)?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

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| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |

**14-A-i) *If Yes, briefly describe the procedure. Provide relevant information (e.g. name of vector, name/biological origin of inserted gene, anticipated effect of inserted DNA, name of microbial agent)*:**

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| **14-B) *Will animals be used as a host for recombinant eukaryotic cells?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

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| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |
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**14-B-i) *If Yes, briefly describe the procedure. Provide relevant information (e.g. name/species of cells, name of vector, name/biological origin of inserted gene)*:**

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| 1. **TRANSGENIC ANIMAL EXPERIMENTS COVERED BY THE *NIH GUIDELINES***
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| **Reference:** [**FAQs for Research on Genetically Modified (Transgenic) Animals**](https://osp.od.nih.gov/biotechnology/faqs-on-genetically-modified-transgenic-animals-and-the-use-of-recombinant-or-synthetic-nucleic-acid-molecules-in-animals/) |
| **15-A) *Do experiments with whole animals require housing or containment at Animal Biosafety Level 1 (ABSL-1)?*** | [ ]  Yes [ ]  No |

*If Yes, answer questions 15-A-i through 15-A-xi to inform the IBC of the transgenic animal work that will be conducted at ABSL-1*:

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| **15-A-i) *Are you generating transgenic or knocked-out rodents?*** | [ ]  Yes [ ]  No |
| **15-A-ii) *Are you generating transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-A-iii) *Are you breeding transgenic or knocked-out rodents from one strain for the purpose of maintaining a transgenic rodent colony?*** | [ ]  Yes [ ]  No |
| **15-A-iv) *Are you breeding transgenic or knocked-out rodents from two different strains (or breeding a transgenic rodent with a non-transgenic rodent) to create a new strain of transgenic rodent that is under the NIH Guidelines*** [***Appendix C-VIII***](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948412) ***exemption?*** | [ ]  Yes [ ]  No |
| **15-A-v) *Are you breeding transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-A-vi) *Are you purchasing or transferring transgenic or knocked-out rodents?*** | [ ]  Yes [ ]  No |
| **15-A-vii) *Are you purchasing or transferring transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-A-viii) *Are you conducting experiments with transgenic or knocked-out rodents?*** | [ ]  Yes [ ]  No |
| **15-A-ix) *Are you conducting experiments with transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-A-x) *Do experiments involve introducing nucleic acid sequences that contain less than 2/3 of the genome of any eukaryotic virus into a non-human vertebrate or invertebrate?*** | [ ]  Yes [ ]  No |
| **15-A-xi) *Do experiments involve propagating whole animals containing viral vector sequences that will not lead to direct or indirect transmissible infection in other whole animals?*** | [ ]  Yes [ ]  No |

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| **Reference:** [**FAQs for Research on Genetically Modified (Transgenic) Animals**](https://osp.od.nih.gov/biotechnology/faqs-on-genetically-modified-transgenic-animals-and-the-use-of-recombinant-or-synthetic-nucleic-acid-molecules-in-animals/) |
| 15-B) Do experiments with whole animals require housing or containment at Animal Biosafety Level 2 (ABSL-2) or higher? | [ ]  Yes [ ]  No |

*If Yes, answer questions 15-B-i through 15-B-xi to inform the IBC of the transgenic animal work that will be conducted at ABSL-2 or higher*:

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| --- | --- |
| **15-B-i) *Are you generating transgenic or knocked-out rodents?*** | [ ]  Yes [ ]  No |
| **15-B-ii) *Are you generating transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-B-iii) *Are you breeding transgenic or knocked-out rodents from one strain for the purpose of maintaining a transgenic rodent colony?*** | [ ]  Yes [ ]  No |
| **15-B-iv) *Are you breeding transgenic or knocked-out rodents from two different strains (or breeding a transgenic rodent with a non-transgenic rodent) to create a new strain of transgenic rodent that is under the NIH Guidelines*** [***Appendix C-VIII***](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948412) ***exemption?*** | [ ]  Yes [ ]  No |
| **15-B-v) *Are you breeding transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-B-vi) *Are you purchasing or transferring transgenic or knocked-out rodents?*** | [ ]  Yes [ ]  No |
| **15-B-vii) *Are you purchasing or transferring transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-B-viii) *Are you conducting experiments with transgenic or knocked-out rodents?*** | [ ]  Yes [ ]  No |
| **15-B-ix) *Are you conducting experiments with transgenic or knocked-out animals other than rodents?*** | [ ]  Yes [ ]  No |
| **15-B-x) *Do experiments involve introducing nucleic acid sequences that contain less than 2/3 of the genome of any eukaryotic virus into a non-human vertebrate or invertebrate?*** | [ ]  Yes [ ]  No |
| **15-B-xi) *Do experiments involve propagating whole animals containing viral vector sequences that will not lead to direct or indirect transmissible infection in other whole animals?*** | [ ]  Yes [ ]  No |

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| 1. **HUMAN-DERIVED MATERIALS**
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*This section pertains to the use, manipulation and storage of human samples, including but not limited to, blood, serum, bodily fluids, unfixed tissue, cell culture, identifiable cells/tissues, stem cells or fetal tissue.*

**16-A) *List human-derived materials to be used*:**

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**16-B) *Where are the human-derived materials obtained from*?**

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| **16-C-i*) Are the human-derived materials known to contain an infectious agent?*** | [ ]  Yes [ ]  No |
| **16-C-ii*) Were the human-derived materials tested for presence of SARS-CoV-2?*** | [ ]  Yes [ ]  No |

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| **16-D*) Are modified or unmodified human cells/tissues introduced into animals?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

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| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |

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| 1. **ANIMAL-DERIVED MATERIALS**
 |

*This section pertains to the use, manipulation and storage of non-primate and non-human primate samples, including but not limited to, blood, serum, bodily fluids, primary cell culture of unfixed tissue.*

**17-A) *List animal-derived materials to be used*:**

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**17-B) *List species of animal-derived materials to be used*:**

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**17-C) *Where are the animal-derived materials obtained from*?**

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| **17-D*) Are the animal-derived materials known to contain an infectious agent?*** | [ ]  Yes [ ]  No |

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| **17-E*) Are modified or unmodified animal cells/tissues introduced into animals?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

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| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |

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| 1. **INFECTIOUS AGENTS**
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*This section pertains to the use, manipulation and storage of microbial agents that are pathogenic to humans, animals or plants, and the use of infectious agents in animals.*

**18-A) *List pathogenic microbial agents to be used*:**

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| --- | --- |
| **18-B*) Is toxin produced?*** | [ ]  Yes [ ]  No |

**18-B-i) *If Yes, list the toxin(s) and indicate if work is conducted with the toxin*:**

|  |
| --- |
|  |

**18-C) *What is the largest volume that is cultured?***

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **18-D*) Are modified or unmodified infectious agents introduced into animals?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

|  |  |
| --- | --- |
| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |

|  |
| --- |
| 1. **TOXINS / SELECT AGENTS**
 |

*This section pertains to the use and/or storage of non-federally regulated biological toxins plus infectious agents and toxins regulated under the Federal Select Agent program.*

|  |  |
| --- | --- |
| **19-A*) Do experiments involve a biological toxin that is not regulated under the Federal Select Agent Program?*** | [ ]  Yes [ ]  No |

**19-A-i) *If Yes, list the name of the toxin and quantity used/stored*:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **19-B*) Do experiments involve a select agent or toxin from the*** [***Federal Select Agents and Toxins List***](https://www.selectagents.gov/SelectAgentsandToxinsList.html)***?*** | [ ]  Yes [ ]  No |

**19-B-i) *If Yes, list the name of the agent or toxin and quantity used/stored*:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **19-C*) Do experiments involve an attenuated strain of a select agent or toxin from the*** [***Select Agents and Toxins Exclusions List***](https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html)***?*** | [ ]  Yes [ ]  No |

**19-C-i) *If Yes, list the name of the agent or toxin and quantity used/stored*:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **19-D*) Do experiments involve a select toxin that is not regulated under the Federal Select Agent Program due to*** [***permissible toxin amounts***](https://www.selectagents.gov/PermissibleToxinAmounts.html)***?*** | [ ]  Yes [ ]  No |

**19-D-i) *If Yes, list the name of the toxin and quantity used/stored*:**

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| --- |
|  |

|  |  |
| --- | --- |
| **19-E*) Are any agents or toxins introduced into animals?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

|  |  |
| --- | --- |
| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |

|  |
| --- |
| **20) DANGEROUS SUBSTANCES AND/OR DRUGS** |

*This section pertains to the use and/or storage of chemicals, biologics and/or drugs that may be hazardous – carcinogens, substances with a potential to cause congenital disorders, substances causing severe side effects, noxious substances, environmental hazards, etc. (Include such drugs as Tamoxifen, Paclitaxel, Cisplatin, etc.).*

|  |  |
| --- | --- |
| **20-A*) Do experiments involve dangerous substances and/or drugs*** | [ ]  Yes [ ]  No |

**20-B) *If Yes, list the name and quantity of substance(s) used/stored*:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **20-C*) Are dangerous substances and/or drugs introduced into animals?*** | [ ]  Yes [ ]  No |

***If Yes, list the animal species and housing location*:**

|  |  |
| --- | --- |
| **ANIMAL SPECIES**  |  |
| **ANIMAL HOUSING LOCATION** |  |