**IBC Protocol Amendment Form (Substantive)**

*This form is to amend funding, personnel, laboratory research, and/or procedures, oversight, or materials on active IBC protocols. If you only need to amend funding, investigators, or locations, please follow the instructions for a brief amendment.*

**To complete a substantive amendment, please:**

1. Complete the form below.
2. Using track changes (or yellow highlight if you cannot use track changes), please amend your approved protocol.
3. Submit the amendment form and your track-changed protocol via email to [IBC@marian.edu](mailto:IBC@marian.edu).
4. Please contact [IBC@marian.edu](mailto:IBC@marian.edu) if you have any questions.

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| --- | --- | --- |
|  | | |
| **Principal Investigator:** | **Appointment:** | |
| **Office Address:** *Include building and room #* | **College/Program:** | |
| **Department:**(if applicable)**:** | **Section** (if applicable)**:** | |
| **E-Mail:** | **Phone:** |  |
| **Title of Protocol**: | | |
| **IBC Protocol Number**: | | |
| **SUMMARIZE THE PROPOSED RESEARCH**  **Please provide a brief summary paragraph(s) of the research protocol including goals, biological agents used, and procedures conducted both *in vivo* and *in vitro*.  Please specify what proposed research activities or materials are changing in your amendment. In particular, describe any recombinant approach used or use of any biohazardous or infectious agent.** | | |

**Sec. I-E. Funding (please list only those grants that support work covered on this protocol)**

Internal Funding

External Funding: Agency:

Grant Number:

VA Funding:

Grant Number:

**Sec. I-F. Investigators (List ALL personnel involved in this project)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | ***IBC USE ONLY*** | | | | | | | | | | | | |
| ***Last Name, First Name  <E-mail Address>*** | | ***Title/Job Description*** | |  | | ***Lab Safety Basics*** | | ***Lab Chemical Safety*** | | ***OSHA BBP*** | | ***rDNA Research*** | | ***Animal Biosafety*** | ***Other*** |
| ***Example:***  Doe, Jane <[jdoe@marian.edu](mailto:jdoe@marian.edu)> | Associate Professor / PI / Performs all experiments, Oversees Lab | | **Required:**  **Complete:** | |  | |  | |  | |  | |  | |  |
|  |  | | **Required:**  **Complete:** | |  | |  | |  | |  | |  | |  |
|  |  | | **Required:**  **Complete:** | |  | |  | |  | |  | |  | |  |

*\*Note: To add additional lines to the table, please click the “+” sign on the left hand side of the last row. \**

**Investigator Acknowledgement:** By checking this box, the PI is ensuring that all personnel listed on this protocol have access to the protocol, read it, agree to participate in said research activities, and will complete all necessary training requirements.

**Sec. I-G. Research Location(s)** Please list the building, room numbers, research activities performed in that space, and the highest biosafety level for that space and research activity. Please specify where all biological material is being used or stored.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Building*** | ***Room #*** | ***Research Activities Performed*** | ***Biosafety Level*** |
| ***Example*:**  MH | MH151 | Transformation; plate assays | BL-1 |
| ***Example*:**  MH | MH151A | Cell Culture | BL-2 |
|  |  |  |  |
|  |  |  |  |

\**Note: Please include Core Facility locations in the table.*

*\*Note: To add additional lines to the table, please click the “+” sign on the left hand side of the last row.\**

**Section III. Experiments Covered by the NIH Guidelines**

*Please choose ALL appropriate sections of the* [*NIH Guidelines*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) *that apply to the proposed research*

**III-A: Experiments that require IBC, RAC review, and NIH Director approval before initiation**.

III-A-1-a: The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally, if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.

**III-B: Experiments that require NIH/OBA and IBC approval before initiation.**

III-B-1: Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight.

III-B-2: Experiments that have been approved as Major Actions under Sec. III-A-1-a of NIH Guidelines.

**III-C: Experiments that require IBC/IRB approvals and RAC review before research participant enrollment.**

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.

*Note: No research participant shall be enrolled until the RAC review process has been completed (Appendix M-I-B, NIH Guidelines)*

*Note: Complete Section VIII of this form.*

**III-D: Experiments that require IBC approval before initiation.**

III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or restricted agents as host-vector systems.

III-D-2: Experiments in which DNA from RG2, RG3, RG4, or restricted agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems.

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.

III-D-4: Experiments:

Involving whole animals in which the animal’s genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or DNA derived therefrom, into the germ- line (transgenic animals),

Experiments involving viable recombinant or synthetic nucleic acid molecule-modified

microorganisms tested on whole animals

Appendix Q: Experiments involving large animals

*Note: Experiments involving the generation of transgenic rodents that require BL-1 containment are described under Sec. III-E-3. The purchase/transfer of transgenic rodents is exempt from the NIH Guidelines under Sec. III-F (see Appendix C-VII)*

III-D-5: Experiments involving whole plants

III-D-6: Experiments involving more than 10 liters of culture (in one container).

III-D-7: Experiments involving influenza viruses.

**III-E: Experiments that require IBC notice simultaneous with initiation.**

III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.

III-E-2: Experiments involving whole plants.

III-E-3: Experiments involving transgenic rodents: involving the generation 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. Only experiments that require BL1 containment are covered under this section; experiments that require BL2 or higher containment fall under section III-D-4 above.

General III-E: Experiments that do not fall under any of the previous sections of the guidelines or under an exception listed in section III-F of the NIH guidelines.

*Note: Only experiments that require BL-1 containment are covered under Sec III-E-3.*

**III-F: Experiments that are exempt from the NIH Guidelines.**

III-F-1: Uses synthetic nucleic acids that:

* 1. Can neither 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 that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.

III-F-2: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated to render them capable of penetrating cellular membranes.

III-F-3: Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

III-F-4: Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or closely related strain of the same species), or when transferred to another host by well-established physiological means.

III-F-5: Those 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).

III-F-6: 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.

III-F-7: Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. (You MUST check one of the Appendix C exemptions below)

Appendix C-I: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture.

Host-Vector System Exemptions:

Appendix C-II: Escherichia coli K-12 Host-Vector Systems.

Appendix C-III: Saccharomyces Host-Vector Systems.

Appendix C-IV: Kluyveromyces Host-Vector Systems.

Appendix C-V: Bacillus subtilis OR Bacillus licheniformis Host-Vector Systems.

Appendix C-VI: Extrachromosomal Elements of Gram Positive Organisms.

Transgenic Rodent Exemptions:

Appendix C-VII: The purchase or transfer of transgenic rodents at BSL-1.

Appendix C-VIII: Generation of BL1 transgenic rodents via breeding.