For IBC Use **#IBC-Exempt-_____**

Date received _____

Reviewer(s) _____

☐ Approved – date _____

☐ Must be re-submitted for IBC Review

College of Charleston Institutional Biosafety Committee

Recombinant and Synthetic Nucleic Acid Research and Classroom Laboratory

EXEMPTION REQUEST FORM

Principal Investigator _____ Department _____

Email _____ Phone _____

Title of Project (one project per form)

Funding Source _____

IACUC Protocol # (if applicable) _____

If you have questions about this form, contact the Chair of the IBC (see IBC Members List on the IBC webpage) or email callahane@cofc.edu.

Email completed application as a pdf attachment to compliance@cofc.edu with subject "IBC Application".

The following categories are not exempt from the *NIH Guidelines*:

- Experiments described in *Section III-B* which require NIH OSP and Institutional Biosafety Committee approval before initiation,
- Experiments involving DNA from Risk Groups 3, 4, or restricted organisms or cells known to be infected with these agents. This level of research is not permitted at the College of Charleston.
- Large-scale experiments (e.g., more than 10 liters of culture),
- Experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates, and
- Whole plants regenerated from plant cells and tissue cultures that do not remain axenic cultures.

If your experiment falls within any of the categories above, review by the IBC is required before the protocol is implemented. Contact callahane@cofc.edu or the Chair of the IBC.

To determine if your experiment/protocol is exempt under NIH guidelines, check all exemption categories that apply.

☐ **Section III-F-1**. Those synthetic nucleic acids that
(i) 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 nor contain elements known to interact with either DNA or RNA polymerase), and
(ii) are not designed to integrate into DNA, and
(iii) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.

☐ **Section III-F-2.** Those 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.

☐ **Section 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.

☐ **Section 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 a closely related strain of the same species), or when transferred to another host by well-established physiological means.

☐ **Section 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).

☐ **Section 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. See *Appendices A-I through A-VI*, for a list of natural exchangers that are exempt.

☐ **Section 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.

Section III-F-8. Those that do not present a significant risk to health or the environment according to the categories below (*Appendix C*)

☐ **Appendix C-II.** *Escherichia coli K-12* **Host-Vector Systems -** Experiments which use *Escherichia coli* K-12 host-vector systems are exempt 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 shall be used as vectors. However, experiments involving the insertion into *Escherichia coli* K-12 of DNA from prokaryotes that exchange genetic information 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.

☐ **Appendix C-III.** *Saccharomyces* **Host-Vector Systems -** Experiments involving *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems.

☐ **Appendix C-IV.** *Kluyveromyces* **Host-Vector Systems -** Experiments involving *Kluyveromyces lactis* host-vector systems are exempt provided laboratory-adapted strains are used (i.e. strains that have been adapted to growth under optimal or defined laboratory conditions).

☐ **Appendix C-V.** *Bacillus subtilis* **or** *Bacillus licheniformis* **Host-Vector Systems -** 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.

NOTE: For the exempt laboratory experiments outlined above in ***Appendices C-I through C-V****, Biosafety Level (BL) 1 physical containment conditions are recommended.*

☐ **Appendix C-VI. Extrachromosomal Elements of Gram Positive Organisms -** Recombinant or synthetic nucleic acid molecules derived entirely from extrachromosomal elements of the organisms listed below (including shuttle vectors constructed from vectors described above), propagated and maintained in organisms listed below:

Bacillus amyloliquefaciens	*Bacillus thuringiensis*	*Streptococcus cremoris*
Bacillus amylosacchariticus	*Clostridium acetobutylicum*	*Streptococcus dorans*
Bacillus anthracis	*Lactobacillus casei*	*Streptococcus equisimilis*
Bacillus aterrimus	*Listeria grayi*	*Streptococcus faecalis*
Bacillus brevis	*Listeria monocytogenes*	*Streptococcus ferus*
Bacillus cereus	*Listeria murrayi*	*Streptococcus lactis*
Bacillus globigii	*Pediococcus acidilactici*	*Streptococcus ferns*
Bacillus licheniformis	*Pediococcus damnosus*	*Streptococcus mitior*
Bacillus megaterium	*Pediococcus pentosaceus*	*Streptococcus mutans*
Bacillus natto	*Staphylococcus aureus*	*Streptococcus pneumoniae*
Bacillus niger	*Staphylococcus carnosus*	*Streptococcus pyogenes*
Bacillus pumilus	*Staphylococcus epidermidis*	*Streptococcus salivarius*
Bacillus sphaericus	*Streptococcus agalactiae*	*Streptococcus sanguis*
Bacillus stearothermophilus	*Streptococcus anginosus*	*Streptococcus sobrinus*
Bacillus subtilis	*Streptococcus avium*	*Streptococcus thermophilus*

☐ **Appendix C-VII. The Purchase or Transfer of Transgenic Rodents -** The purchase or transfer of transgenic rodents for experiments that require BL1 containment are exempt from the *NIH Guidelines*.

☐ **Appendix C-VIII. Generation of BL1 Transgenic Rodents via Breeding -** 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:

(i) both parental rodents can be housed under BL1 containment; and

(ii) neither parental transgenic rodent contains the following genetic modifications: (a) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (b) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and

(iii) 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.

NOTE: *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.*

Provide a brief description of the goals of the project and briefly explain why you believe your experiments fall with the exemption category checked above.