

UNIVERSITY OF MIAMI INSTITUTIONAL BIOSAFETY COMMITTEE

EXEMPTION REQUEST FORM

Principal Investigator: Department
Phone: Email:
Title of Project:
Funding Source:
IACUC # (if applicable):

The NIH guidelines for research involving recombinant DNA molecules (NIH Guidelines) can be found on the web at http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

Are the animals/experiments outlined in this form part of a preexisting IBC protocol? Yes No
If yes, please submit the IBC addendum form rather than this form

Do your animal experiments include DNA recombinant techniques? Yes No
If yes, please submit the IBC long form rather than this form

This study **ONLY** involves recombinant DNA molecules that (please check those below that apply):

For synthetic nucleic acids, those 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. (See Section III-F-1)

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. (See Section III-F-2)

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

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. (See Section III-F-4)

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). (See Section III-F-5)

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 Section III-F-6)

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

Those that do not present a significant risk to health or the environment as determined by the NIH Director (See Section III-F-8)

If your study **does not** meet any of the exemption criteria listed above, your application will require full review by the Institutional Biosafety Committee (IBC). Please visit our website and fill out the appropriate form for IBC review.
<http://www.miami.edu/rdna/>

If your study does qualify for an exemption, please complete questions 1&2 below. If you are only requesting transgenic animals please complete questions 1 &3 below. Email this form to MRamirez@med.miami.edu or Ekapsali@med.miami.edu for IBC review.

1. Provide a brief description of the research objectives:

--

2. Please provide the following information:

<i>Source(s) of DNA</i>	<i>Host(s)</i>	<i>Vector(s)</i>	<i>Experimental Use *</i>

*Please describe the intended application of the rDNA molecule. If your intent is to express a certain gene (protein), please indicate which gene. Refer to Appendix A in the NIH guidelines for examples. http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

3. For pre-existing transgenics for use and/or breeding please provide the following information:

<i>Origin/lab</i>	<i>Name of transgenic animal</i>	<i>Commercial source/stock #(s)</i>	<i>Reference/publication</i>