**Email the completed form to: Dr. Judette Haddad, Regulatory Compliance Coordinator, Office of Research Administration**, **at Email:** **haddad@oakland.edu**

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| Applicant Information |
| Applicant: |  | **Title:**  |  |
| Email: |  | **Department:** |  |
| Office (Rm & Bldg.): |  | **Extension:** |   |
| Lab (Rm & Bldg.):  |  | **Date:** |  |

Please complete the following questionnaire to determine if your project is exempt according to the NIH Guidelines for Recombinant DNA (rDNA). Once exempt status is verified by the Biosafety Officer you will receive a confirmation letter from the Office of Research Administration. An amended form MUST be provided for project changes altering your original responses to the below questionnaire.

Risk Assessment: Please review NIH Guidelines to determine if any of the materials used in your study fall into a “Risk Group” ([Appendix B](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276291)) or is identified as a [Select Agent](http://www.selectagents.gov/SelectAgentsandToxinsList.html). It should be noted that work with RG2 or select agents is NOT exempt.

Please check any of the below boxes which may apply to your project.

[ ] I will generates more than 10 liters of culture.

[ ] The viral construct is from DNA a risk group 3, 4 or a select agent

[ ] I will generates toxic products or oncogenes lethal for vertebrates

[ ] Will contains viral DNA from more than 2/3 of any eukaryotic viral genome

[ ] Involves the transfer of rDNA into human subjects

[ ] Involves the generation of transgenic animals or plants

**If you checked any of the above boxes, your project is NOT exempt**. Please submit an IBC application in RAM. If you are amending an IBC application please contact Dr. Judette Haddad at extension 4898 or email haddad@oakland.edu.

If you checked none of the above boxes, please continue completing this form. In most cases, exemptions for rDNA work fall under Section III-F of the NIH Guidelines. IBC registration would not be required, but review and assessment by the Biosafety Officer and the Office of Research Administration would still be required. All exempted work must still be conducted at Biosafety Level 1 containment.

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| **Project Title:**  |

| Recombinant Vector (Bacterial Plasmid, Naked DNA/RNA,) | Promoter Tropism | Proposed Insert or Gene | Insert Function (Ex: structural protein, oncogene, transporter, etc.) | Vendor | Cat # | Purpose | Briefly describe risks to researchers if exposed to viral vector, gene(s), and/or construct(s): |
| --- | --- | --- | --- | --- | --- | --- | --- |
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| Please place a check mark next to any of the Section III- Exemptions which apply to your project. A check mark below will qualify your project for review as exempt. |
| Exempt Experiments – NIH Guidelines Section III-F |
| 1. | **Section III-F-1.** Those 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. | [ ]  |
| 2. | **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. | [ ]  |
| 3. | **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. | [ ]  |
| 4. | **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. | [ ]  |
| 5. | **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). | [ ]  |
| 6. | **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. 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. | [ ]  |
| 7. | **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. | [ ]  |
| 8. | **Section III-F-8.** Those 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. | [ ]  |

Note- Knock-Out Animals: Knock-Out (gene silencing, gene ablation, etc.) rodents are exempt from the NIH Guidelines as long as the method to generate the knock-out animal does not leave any “new” genetic material behind in the genome after the procedure. If DNA from the molecule used to create the knock-out is permanently inserted into the genome, the experiment will require review and approval by the IBC.

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| Investigator Assurance |
| By submitting this Exempt rDNA Registration Form to the Oakland University IBC, I certify the following:* All work identified on this application will be conducted at a minimum BSL-1 containment.
* I will promptly notify the IBC of any changes to this project by amending this form.
 |
| Principal Investigator Signature: |  | Date: |  |

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| --- |
| IBC / Research Office Use Only |
| IBC Approval #: Date: | Approval Status: [ ] Exempt [ ] Deemed Not Exempt | [ ] Requires IBC Review  |
|  |  |  |

**Email completed form to: Dr. Judette Haddad, Regulatory Compliance Coordinator, Office of Research Administration, at Email: haddad@oakland.edu**

**APPENDIX C. EXEMPTIONS UNDER SECTION III-F-8**

Section III-F-8 states that exempt from these *NIH Guidelines* are "those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *NIH Director--Specific Responsibilities*), 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 Sections III-F-8*, for other classes of experiments which are exempt from the *NIH Guidelines*." The following classes of experiments are exempt under Section III-F-8:

**Appendix C-I. Recombinant or Synthetic Nucleic Acid Molecules in Tissue Culture**

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-IX-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.

**Appendix C-I-A. Exceptions**

The following categories are not exempt from the *NIH Guidelines*: (i) experiments described in Section III-B which require NIH/OBA and Institutional Biosafety Committee approval before initiation, (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard*, and Sections V-G and V-L, *Footnotes and References of Sections I through IV*) or cells known to be infected with these agents, (iii) experiments involving the deliberate introduction of genes coding for the biosynthesis of molecules that are toxic for vertebrates (see Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*), and (iv) whole plants regenerated from plant cells and tissue cultures are covered by the exemption provided they remain axenic cultures even though they differentiate into embryonic tissue and regenerate into plantlets.

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

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-IX-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 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.

**Appendix C-II-A. Exceptions**

The following categories are not exempt from the *NIH Guidelines*: (i) experiments described in Section III-B which require NIH/OBA and Institutional Biosafety Committee approval before initiation, (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, *Classification of Human*

*Etiologic Agents on the Basis of Hazard*, and Sections V-G and V-L, *Footnotes and References of Sections I*

*through IV*) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-D-2 with prior Institutional Biosafety Committee review and approval, (iii) large-scale experiments (e.g., more than 10 liters of culture), and (iv) experiments involving the cloning of toxin molecule genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*).

**Appendix C-III.** *Saccharomyces* **Host-Vector Systems**

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.

**Appendix C-III-A. Exceptions**

The following categories are not exempt from the *NIH Guidelines*: (i) experiments described in Section III-B which require NIH/OBA and Institutional Biosafety Committee approval before initiation, (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard*, and Sections V-G and V-L, *Footnotes and References of Sections I through IV*) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-D-2 with prior Institutional Biosafety Committee review and approval, (iii) large-scale experiments (e.g., more than 10 liters of culture), and (iv) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*).

**Appendix C-IV.** *Kluyveromyces* **Host-Vector Systems**

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.

**Appendix C-IV-A Exceptions**

The following categories are not exempt from the *NIH Guidelines*: (i) experiments described in Section III-B, which require NIH/OBA and Institutional Biosafety Committee approval before initiation; (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard*, and Sections V-G and V-L, *Footnotes and References of Sections I through IV*) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-D-2 with prior Institutional Biosafety Committee review and approval; (iii) large-scale experiments (e.g., more than 10 liters of culture), and (v) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see

Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*).

**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 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.

**Appendix C-V-A. Exceptions**

The following categories are not exempt from the *NIH Guidelines*: (i) experiments described in Section III-B which require NIH/OBA and Institutional Biosafety Committee approval before initiation, (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard*, and Sections V-G and V-L, *Footnotes and References of Sections I through IV*) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-D-2 with prior Institutional Biosafety Committee review and approval, (iii) large-scale experiments (e.g., more than 10 liters of culture), and (iv) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*).