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POLICY

It is the policy of Johns Hopkins to conduct all research involving recombinant DNA molecules within the Federal guidelines established by the National Institutes of Health (NIH).

The Johns Hopkins Institutional Biosafety Committee, a subcommittee of the Joint Committee for Health, Safety and Environment, shall monitor the conduct of all research involving recombinant DNA molecules.

Each principal investigator or laboratory supervisor must identify all recombinant DNA materials and register the research protocol with the Biosafety Officer, Division of Health, Safety and Environment (HSE) by completing the Johns Hopkins Registration of Recombinant DNA Form (enclosed).

All changes in requirements appearing in the NIH Guide for Grants or Contracts, all directives from the U.S. Office of Biotechnology DNA Activities (OBA), and all revised NIH guidelines shall automatically be incorporated into this Johns Hopkins Policy on Recombinant DNA Research.

REFERENCE

NIH Guidelines for Research Involving Recombinant DNA Molecules, Office of Recombinant DNA Activities, Building 31, Room 4B11, National Institutes of Health, Bethesda, MD 20892. Jan 24, 2002

RESPONSIBILITIES

Principal Investigator/Lab Managers	Identify recombinant DNA materials. Prior to initiating the research, register all protocols involving recombinant DNA materials with HSE.
Health, Safety and Environment	Receive research protocols involving recombinant DNA and facilitate review by the Institutional Biosafety Committee. Maintain a registry of research protocols involving recombinant DNA.
Institutional Biosafety Committee	Review and as indicated approve all research protocols involving recombinant DNA.

REVIEW CYCLE

Annually

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Registration of Research with RECOMBINANT DNA
http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

Rev 05/06

RETURN ORIGINAL FORM TO: Biosafety Officer
2024 E. Monument Street, Room B-200
Baltimore, MD 21205-2223, SOM
410-955-5918
(Fax) 410-955-5929

JHU IBC# _____ DATE _____ BIOSAFETY LEVEL _____ ACTION _____ <i>HSE Use Only. Do not write in this space.</i>

<i>Principal Investigator (must be faculty, see * below):</i>		<i>JHU-Badge/ID Number**:</i>
<i>Academic Title:</i>	<i>Email Address:</i>	
<i>Department:</i>	<i>Division:</i>	
<i>Office Address:</i>	<i>Lab Address:</i>	
<i>Office Phone:</i>	<i>Office Fax:</i>	
<i>Project Title:</i>		
<i>Project Start Date:</i>	<i>Project Duration:</i>	
<i>Name and Source of Material:</i>		<i>Repository:</i> <input type="checkbox"/> Yes <input type="checkbox"/> No
<i>Strain, Genotype, Catalog Number, or CAS Number:</i>		<i>Freezer Serial No:</i> _____
<i>Type(s):</i> <input type="checkbox"/> Toxin <input type="checkbox"/> Pathogen <input type="checkbox"/> Oncogenic Material <input type="checkbox"/> Human Material		<i>Location:</i>

***Work involving the use or possession of INFECTIOUS AGENTS, PATHOGENS, VIRAL VECTORS, BIOLOGICAL TOXINS, or HUMAN TISSUES requires a current Registration Number or a new Registration of Research with Human Tissue, Infectious Agents, Pathogens or Toxins Form for this material.

- Will this project at any time involve shipping infectious materials over public thoroughfares? Yes No
- Specify gene sequence to be inserted into the recombinant. _____
- Identify vector(s), specific phage, plasmid or virus. For novel and viral constructs attach vector map, do not attach gene sequence.
- Host or Environment: _____ (see #11 below)
- Is Volume Large Scale, > 10 Liters Culture? Yes No
- If virus source, is it more than 2/3 of the viral genome? Yes No
- Is a helper virus, packaging system, complementary cell used? Yes No
- Are intact animals exposed to the recombinant? Yes No
- Are mammalian cells exposed to the recombinant? Yes No
- Are Human Subjects exposed to the recombinant? Yes No

For submissions involving Human Gene Therapy, please contact ibc@jhu.edu for additional information.

- Please check the relevant situation(s) that apply to your project. For "Yes", indicate the Biosafety Level.

Host / Environment			Biosafety Level	
a. E. coli K12	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-1	<input type="checkbox"/> BSL-2
b. Other Bacteria	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-1	<input type="checkbox"/> BSL-2
c. Non-pathogen	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-1	
d. Pathogen	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-2	<input type="checkbox"/> BSL-3
e. Toxin gene	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-2	<input type="checkbox"/> BSL-3
f. Drug resistance Gene	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-2	<input type="checkbox"/> BSL-3
g. Yeast / YAC	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-1	<input type="checkbox"/> BSL-2

Tissue Culture Cells Yes No

a. R-DNA / plasmids	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-2	
b. Segment of virus	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-2	<input type="checkbox"/> BSL-3
c. Virus vector	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> BSL-2	<input type="checkbox"/> BSL-3
d. If virus vector:	<input type="checkbox"/> Adeno	<input type="checkbox"/> Retro	<input type="checkbox"/> Vaccinia	<input type="checkbox"/> Sindbis <input type="checkbox"/> Other Virus _____
e. Defective viral vector	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
f. Replication competent viral vector	<input type="checkbox"/> Yes	<input type="checkbox"/> No		

*Post-doctoral fellows, research associates, & instructors require co-signature of Department Chair and Laboratory Sponsor.
**JHU Badge/ID number is the number on your ID card. Contact the Biosafety Office if you are unsure of your ID number.

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Intact Lab Animal Recipient Yes No If yes, species: _____

a. University Animal Use & Care Committee Protocol Number: _____ Approval Date: _____

b. Animal Housing (building & room no.) _____

c. R-DNA / Plasmid Yes No ABSL-1 ABSL-2

d. Transgenic Yes No ABSL-1 ABSL-2

e. Virus Vector Yes No ABSL-1 ABSL-2 ABSL-3

f. SCID / Nude Yes No ABSL-1 ABSL-2 ABSL-3

Human Subject Recipient Yes No

a. I.R.B. or RPN Protocol Number: _____ Approval Date: _____

b. R-DNA / Plasmid Yes No BSL-2

c. Pathogen Yes No BSL-2

d. Virus Vector Yes No BSL-2

Plants Yes No Insects Yes No Field Release Yes No BSL-2-P BSL-3-P

12. Reference your experiment from the NIH Recombinant DNA Guidelines (see attachment). _____
(Required)

** Recombinant DNA inserts in plasmid and phage in E. coli K12, DH5 alpha or in transgenic knockout mice, not involving a viral gene, toxin, or pathogen source, or in large-scale culture (>10L), are EXEMPT from full IBC review and can be approved administratively by the Biosafety Officer. rDNA in tissue culture is not exempt. The use of knockouts (by creating or purchase) must be registered prior to use in research.

13. Please list all professional personnel (employees, student, post doctoral, visiting investigator) involved in the project who will come into contact with recombinant materials:

<i>Name</i>	<i>Mailing Address</i>	<i>JHU-Badge/ID Number</i>

14. Prepare and attach a summary (not more than one page). Include the following information:

- a) Nature and purpose of the research.
- b) Viral vectors; name, source and key features including replication deficient or replication competent, identify marker genes and foreign insert genes.
- c) Outline of the procedure and techniques to be employed.
- d) Assessment of risks to personnel working with the agent or material.
- e) Specific practices, equipment, and facilities that will be used to protect personnel from exposure to the agent or material.
- f) Specific methods of inactivation or disposal of the agent or contaminated materials.

The registration form (summary and any attachments) must provide sufficient detail for the Institutional Biosafety Committee to understand and evaluate rDNA components of the project in order to review the registration. For attached published references, please highlight pertinent paragraphs or sentences. Submissions that lack detail or are illegible will be deferred from action and returned for revision and resubmission. The project registration must be updated annually, and must include a summary of results and changes to the project. Major changes to the project require submission of a new registration form. **Incomplete registration forms will be returned.**

As Principal Investigator, I accept responsibility for the safe conduct of work with this material. I will ensure that all personnel receive training in regard to proper safety practices and personal protective equipment needed for this work.

Signature (Principal Investigator): _____ Date: _____

*Co-Signature (Dept. Chair): _____ Date: _____

*Post-doctoral fellows, research associates, & instructors require co-signature of Department Chair and Laboratory Sponsor.

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Summary of NIH Guidelines for Research Involving rDNA April 2002

****(Reference for Item #12)**** http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

The summarized categories below are extracted from the NIH Guidelines, the full text of which is available at the hyperlink listed above. Guidelines for Research Involving Recombinant DNA Molecules are intended to prevent an accidental release of recombinant material into the environment and ensure safe work practices in the conduct of research. The JHI IBC has attempted to summarize the NIH Guidelines into a convenient format without altering the original intent. It is possible for a given project be simultaneously classified under more than one of the sections below. Consider that the NIH Guidelines have evolved in a piecemeal fashion over the past 26 years and are based on the evaluation of technology described in protocols submitted to and reviewed by the Recombinant Advisory Committee (RAC) of the Office of Biotechnology Activities (OBA) at the NIH. As such, the resulting full text of the Guidelines is lengthy and somewhat vague.

SECTION III-A: Experiments Requiring JHU-IBC Registration and Approval plus RAC Review and NIH Director Approval Before Initiation.

III-A-1-A Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control the disease agents in humans, veterinary medicine or agriculture.

SECTION III-B: Experiments Requiring JHU-IBC Registration plus NIH/ORDA Approval Before Initiation.

III-B-1 Cloning of Toxin Molecules with LD₅₀ < 100ng/kg of body weight.

SECTION III-C: Experiments Requiring JHU-IBC Registration plus IRB Approval and NIH/ORDA Registration

III-C-1 Transfer of R-DNA or DNA or RNA derived from R-DNA into human subjects.

SECTION III-D: Experiments Requiring JHU-IBC Registration and approval Before Initiation

III-D-1a Introduction of R-DNA into Risk Group 2 agents, BSL-2 or ABSL-2N. (See appendix B for listing)

III-D-1-b Introduction of R-DNA into Risk Group 3 agents, BSL-3 or ABSL-3N.

III-D-1-c Introduction of R-DNA into Risk Group 4 agents not permitted except on case-by-case basis approval from RAC and USDA permit.

III-D-2-a DNA from Risk Group 2 or 3 agents transferred into nonpathogenic prokaryotes or lower eukaryotes or exempt from the guidelines (see Section III-F).

III-D-2-b DNA from Risk Group 4 and restricted agents transferred into nonpathogenic prokaryotes or lower eukaryotes is also reviewed by NIH/ORDA and require an FDA permit.

III-D-3-a Infectious or defective [defective eukaryotic viruses contain less than 2/3 of the genome] Risk Group 2 viruses in the presence of helper or packaging system in tissue culture BSL-2 or higher at JHU-IBC discretion.

III-D-3-b Infectious or defective Risk Group 3 viruses and prions in the presence of helper functions in tissue culture.

III-D-3-d Infectious or defective restricted pox viruses in the presence of helper functions in tissue culture also reviewed by NIH/ORDA and FDA.

III-D-3-e Infectious or defective viruses in the presence of helper virus in tissue culture not covered in III-D above. IBC reserves the right to determine Risk Group Classification for novel agents.

III-D-4-a Recombinant DNA or DNA or RNA molecules derived from DNA (including the creation and use of transgenic animals) except greater than two-thirds of eukaryotic viral genome transferred to any non-human vertebrate or an invertebrate organism. Animals with sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly. BSL-1 or BSL-1N Introduction of other sequences from eukaryotic viral genomes are covered in Section III-D-4-b. R-DNA modified Risk Group 2 and higher agents in animals are covered in Section V-A, V-G and V-L.

III-D-4-b Recombinant DNA, or DNA or RNA molecules derived from DNA involving whole animals not covered in Section III-D-1, human or animal pathogen Risk Group 2 and higher as host vector systems or Section III-D-4-a. Containment determined by IBC.

III-D-5-a Recombinant techniques with exotic infectious agents with recognized potential for serious detrimental impact on ecosystems using whole plants. BSL-3P

III-D-5-b Plants with cloned genomes of readily transmissible exotic infectious agents that may reconstitute by genomic complementation.

III-D-5-c Readily transmissible exotic infectious agents such as the soybean rust fungus, maize streak or other viruses in the presence of specific arthropod vectors. BSL-4P

III-D-5-d Sequences coding vertebrate toxins introduced into plants or associated organisms, BSL-3P

III-D-5-e Microbial pathogens of insects or small animals associated with plants if the R-DNA microorganism has a recognized detrimental impact on ecosystems. BSL-3-P

III-D-6 Experiments involving more than 10 liters of culture. IBC determines containment level. (See Appendix K)

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SECTION III-E: Experiments Requiring JHU-IBC Registration Before Initiation

- III-E-1 Formation of R-DNA molecules containing nor more than two-thirds of the genome of any eukaryotic virus in tissue culture, BSL-1 with no helper virus. JHU-IBC classifies Retroviral vectors with packaging system capable of infecting human cells as BSL-2.
- III-E-2-a R-DNA modified whole plants or R-DNA modified organisms not in Section III-E-2-b. BSL-1-P
- III-E-2-b Plants modified by R-DNA that are noxious weeds or can interbreed with noxious weeds. Plants with R-DNA that is the complete genome of a non-exotic infectious agent. Plants associated with R-DNA modified non-exotic microorganisms with a recognized potential for serious impact on ecosystems. R-DNA modified arthropods or small animals associated with plants or with arthropods or small animals associated with them if the R-DNA modified microorganisms have no serious impact on ecosystems. BSL-2-P
- III-E-3 Generation of rodents with stable introduction of DNA into the animal's genome if BSL-1, otherwise Section III-D-4.

SECTION III-F: Exempt experiments Requiring JHU-IBC Registration before Initiation (BSL-1)

- III-F-1 Not in organisms or viruses.
- III-F-2 DNA segments from a single non-chromosomal or viral DNA source.
- III-F-3 DNA from prokaryotic host when propagated only in that host or transferred to another host by well established physiological means.
- III-F-4 DNA from an eukaryotic host when propagated only in that host.
- III-F-5 DNA segments from different species that exchange DNA by known physiological processes.
- III-F-6 Those that do not present a significant risk to health or the environment.
- Appendix C-1 Recombinant DNA (not-virus vector) in Tissue Culture (see C-IV for exceptions)
- Appendix C-II E. coli K-12 host-vector systems. (See C-II-A for exceptions)
- Appendix C-III Saccharomyces host-vector systems. (See C-III-A for exceptions)
- Appendix C-VI Purchase or transfer of transgenic rodents.

Please retain the last two pages of this form (Summary of Guidelines).
Do not submit it with your registration.