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# University of Missouri - Kansas City

# Institutional Biosafety Committee

**Recombinant DNA and Biohazardous Materials Application Form**

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|  | New Submission |  |  | Resubmission |  | 3-year Renewal |  |

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|  | Amendment |  |  | Continuation |  | Previous IBC # |  |

**General Information**

(To be completed for all recombinant and biohazardous materials use and experimentation)

Note: All investigators and participating personnel must have documentation showing participation in the approved Biosafety Training provided by Biosafety Officers of UMKC and affiliated institutions.

*General Biosafety training is required for all participants and valid for three years. Specialized training is required on an annual basis for those individuals who work in a BSL-3 lab and/or handle Select Agents.*

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| Project Title |
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| Principal Investigator: Name | Degree | Position/Title and Institution(UMKC, CMH, TMC, St. Luke) |
|  |  |  |
| Address | Phone | Email |
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| Location(s) of Research - Bldg/Rm(s) | IRB, IACUC, or Other Protocol #s (for reference) |
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Secondary or Co-Investigators

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| --- | --- | --- | --- | --- |
| Name | Degree | Institutional Position/Title | Institution(UMKC, CMH,TMC, St. Luke) | Address, Phone, Email |
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Research Personnel

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Institutional Position/Title | Institution(UMKC, CMH,TMC, St. Luke) | Role in ResearchProtocol *(i.e., identify shippers)* | Address, Phone, Email |
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| Is this Project Funded?  |  | Yes |  | No |  |
| Name of Funding Agency? |  |
| The title of the Funding Project? |  |

The signature certifies that the PI understands and accepts the following obligations in this study:

* I recognize that as the PI it is my responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform with the IBC approved protocol and the provisions of the *NIH Guidelines for Research Involving Recombinant DNA*, the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* manual, and the *Select Agent Rule* where appropriate. All regulations are available online at <http://www.umkc.edu/ors/ibc/>.
* I will inform the IBC of any unanticipated biosafety related problems encountered while doing the research.
* I will notify the IBC of any change in a BSL-1 protocol.
* I will not initiate any change in a BSL-2 or BSL-3 protocol without prior IBC approval.
* I will maintain all required research records on file and I recognize that representatives of the IBC are authorized to inspect these records.
* I accept responsibility for the safe conduct of the experiments to be conducted and will see that all associated personnel are trained in the safe laboratory practices required for this work. CITI IBC training courses will be completed by the PI, co-PI(s) and all listed researchers as required (see below).
* I will oversee the development and implementation of standard biosafety operating procedures for the laboratory.
* I understand that IBC approval is valid for 1 year and an annual IBC update is required in order to maintain approved status.
* I accept responsibility that all personnel working in my laboratory will be trained to report any biological spill to me and that any spills involving the contamination of personnel and/or the environment that has the potential to cause illness or may cause sufficient concern to the public will be reported to the IBC within the regulatory deadlines specified.
* I will instruct employees to report to me, or in my absence to Environmental Health and Safety, any infection where a potential exists that the infection may have been occupationally acquired.
* I understand that failure to comply with all NIH regulations, IBC requirements/policies, and the provisions of the protocol as approved by the IBC may result in suspension or termination of my research project.

For protocols involving the **use of Select Agents** (as defined in 42 CFR Part 73):

* I will comply with the requirements for the reporting and securing of select agents that fall within the bounds of 42 CFR Part 73.

For protocols using **animals in research**:

* I will contact the IACUC staff and develop standard operating procedures (SOPs) and an IACUC protocol to address relevant operational biocontainment and safety issues for the use of these agents in animals, prior to their introduction into animals. IBC protocol approval is required prior to IACUC protocol approval.

For protocols **requiring the purchase or transfer of tangible research materials** including, but not limited to, animals, reagents, plasmids, vectors and cell lines.

* Where an MTA is not established through the purchase, I understand the requirements and will submit a Material Transfer Agreement (MTA) request to the Office of Technology Transfer and Commercialization for UMKC, or by use of MTAShare for CMH, or \_\_\_\_\_\_\_\_\_\_ at St. Luke’s Hospital
* I will complete an MTA for the materials listed in the application prior to obtaining the materials
* I acknowledge that compliance to renew the MTA(s) or to comply with MTA-specified termination conditions at the end of the MTA approval period are the responsibility of the PI and will undertake these activities when needed.

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| Signature of PI |  | Date |

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| Signature of Department Head |  | Date |

**If the PI is a Department Head, the second signature should be provided by a supervising administrator.**

The signed application form can be submitted by mail to the IBC at the following address:

IBC Manager, ORS Compliance Office

5319 Rockhill Road, Kansas City MO 64110

Alternatively, the signed application form can be scanned, converted into a pdf file and emailed to umkcIBC@umkc.edu

The completed application form may also be printed into a pdf file and valid electronic signatures of PI and Department Head can be added prior to emailing to umkcIBC@umkc.edu

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| For IBC Office Use OnlyThe Institutional Biosafety Committee has reviewed the proposed project and has found it to be in compliance with the *NIH Guidelines*, the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* manual, and the *Select Agent Rule* requirement for research involving biohazardous materials. |
| Biosafety Officer Signature |  |
| Approved Biosafety Level |  |
| Date |  |
| IBC Protocol Approval Date |  |
| 3 Year Expiration Date |  |
| IBC Chair Signature |  |

**Check each use to select the proper form(s) to complete for your protocol.**

*Every* entry should be marked, either as 'Yes' or 'No'.

Clarification

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| **Yes** | **No** | **Type of Biohazardous Material** | **Appendix to be Completed** |
|  |  | Recombinant or Synthetic Nucleic Acid Molecules (Exempt and Non-Exempt) | A-1 |
|  |  | Biosafety Level 2 Infectious Agents, Select Agents, and Biological Toxins | A-2 |
|  |  | Biosafety Level 3 Infectious Agents, Select Agents, and Biological Toxins | A-2 + A-3 |
|  |  | Blood Borne Pathogens, Human Blood, Fluids, Tissues, Human Origin Cell Lines, and other Potentially Infectious Material (OPIM) | A-4 |
|  |  | Human Gene Transfer | A-1 |
|  |  | USDA and CDC Regulated Agents | A-2 / A-3 |
|  |  | Dual Use Research concerns | Attach explanation |
|  |  | Purchase or transfer of tangible research materials including, but not limited to animals, reagents, plasmids, vectors and cell lines | Contact your institutions technology transfer office |

**Scientific Summary and Rationale**

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| Provide a concise description of the work proposed with enough detail for the IBC to evaluate the safety protocols.**Do not copy grant application section.** Explain only experiments that will be performed under *this* protocol.It is not necessary to supply kit manuals; if they are useful for the committee, give a link to the on-line version.If more space is needed, the text box will expand indefinitely; or attach the information. |
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**IBC Protocol Training Requirements**

UMKC has contracted with **CITI**, the Collaborative Institutional Training Initiative, at <http://www.citiprogram.org> to provide training courses in Biosafety and Recombinant Research in order to comply with federal training requirements.

Principal Investigators (PI), co-PIs and all researchers on IBC protocols as well as IBC members, BSOs and other University staff involved in or acting in support of research involving biosafety issues are required to complete selected courses and course modules, as appropriate for the type of research covered by this IBC protocol.

* *New* IBC protocols and 3-year renewal submissions will be approved by the IBC only *after* all listed persons have completed required CITI courses.
* In the case of changes in listed research personnel, required courses must be completed by new researchers before they begin research covered by this protocol.
* Annual renewals within the 3 year authorization period of a protocol require completion of the 'Biosafety Refresher Course' (and possibly 'OSHA Bloodborne Pathogens') by all listed personnel.

**Mark** in the listing of course titles below those courses that are **required** based on the content of the IBC protocol and the required appendices, if any. Reminders that specific CITI courses are required under specified conditions are provided throughout the protocol application forms, including appendices.

The basis for course requirements are specified below.

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| **Required** | **CITI course title** (with module numbers) | Course modules | Basis of requirement |
| **X** | Basic Introduction to Biosafety | 1, 5 | Each person listed on this form |
|  | Training for Investigators, Staff and Students Handling Biohazards | 1-9 | Appendix A-1 (non-exempt), A-2, A-3 and/or A-4 |
|  | Biosafety Refresher Course for Investigators, Staff and Students Handling Biohazards | 5-9 | Annual renewal of IBC protocol with Appendix A-1 (non-exempt), A-2, A-3 and/or A-4 |
|  | OSHA Bloodborne Pathogens | 10 | Appendix A-3 and/or A-4Annual renewal with Appendix A-4 |
|  | NIH Recombinant DNA (rDNA) Guidelines | 11 | Appendix A-1 (non-exempt; PI if exempt) |
|  | Human Gene Transfer Trials | 12 | Appendix A-1 with NGL Section III-C |
|  | Dual Use Research of Concern (DURC) | 16 | All new / renewal applications (PI only) |
|  | Select Agents, Biosecurity and Bioterrorism | 13 | Appendix A-3 |
|  | Shipping and Transport of Regulated Biological Materials | 14 | Any protocol that involves shipping by listed researchers of biohazards |
|  | Animal Biosafety | 15 | Any protocol that uses small mammals |

Note: any researcher can enroll in any CITI Biosafety courses beyond those required.

**Risk Assessment**

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| 1. | Indicate the risk group (or class) of all material(s) used in the experiments performed under this protocol.For a searchable database of risk groups go to <http://www.absa.org/riskgroups/index.html>). |
|  | **Risk Group 1** | Agents are *NOT* associated with disease in healthy adult humans. |
|  | **Risk Group 2** | Agents are associated with human disease that is rarely serious.There are often preventive or therapeutic interventions available. |
|  | **Risk Group 3** | Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *MAY* be available. |
|  | **Risk Group 4** | Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *NOT* *USUALLY* available. |

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| 2. | Indicate the biosafety level(s) at which recombinant DNA and/or biohazardous experiments will be performed. |
|  | **BSL-1** | Low risk agents (generally risk group 1), special containment equipment not required * Work is done on open bench tops.
* Standard microbiological practices are observed Biohazard signs should be posted.
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|  | **BSL-2** | Moderate risk agents (generally risk group 2), biosafety cabinets, restrictions to research areas. All BSL-1 containment and practices plus the following:* Laboratory access is restricted when experimental work is in progress.
* Personnel have specific training in handling of agents.
* Biological safety cabinets (BSC) or other physical containment devices are used for potential aerosol generation procedures.
* Biohazard signs must be posted.
* Specific PPE (personnel protective equipment) and entrance requirements.
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|  | **BSL-3** | High risk agents (generally risk group 3), BSL-3 containment facilities, and practices. All BSL-2 containment and practices plus the following:* Laboratory access is restricted.
* Personnel have specific training in handling of agents.
* All procedures are performed in biological safety cabinets (BSC).
* Biohazard signs must be posted.
* Written safety policies provided by the investigator defining laboratory procedures, waste disposal, disinfection and medical surveillance.
* Centrifuge safety cups must be used.
* Specific facility design parameters must be followed, including requirements for location, ventilation, room integrity and security.
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| 3. | Is the highest proposed Biosafety Level different (lower or higher) than the risk group classification for any of the described agents? (e.g. use of a single gene from a risk group 3 organism may qualify for recombinant work at BSL-1 or BSL-2). |
|  | Yes |
|  | No |
|  | If “Yes”, explain the rationale for the use of the lower/higher Biosafety Level. |
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4. Describe the potential biosafety risks of this research proposal. Address the following issues:

Note that specific *detailed answers* are requested in Appendix A-1 (SECTIONS B, C, D and E), A-2 and/or A-3, depending on the experiments proposed and the biohazardous materials and agents involved.

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| 4a. | Are agent(s) used that may be infectious to humans? |
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| 4b. | Describe the risks of accidental exposure to personnel. |
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| 4c. | Does the potential exist for airborne transmission of agent(s), i.e. sonication, homogenization, centrifugation? |
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| 4d. | Describe precautions to be taken by personnel including any personal protective equipment and/or routine monitoring. |
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| 4e. | Describe disposal of agent(s) including methods for disposal or inactivation of agent(s) and of contaminated or infectious material(s). |
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| 5. | Describe the Principal Investigator’s experience with procedures and experiments described for this application including the use of agents, organisms, viruses, vectors and/or recombinant/synthetic nucleic acid molecules materials and procedures. |
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**Dual Use Research Concerns**

**All PI’s must complete the CITI Modules “Dual Use Research of Concern (DURC)” for any new or renewal application submitted to the IBC**

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| 6. | The potential of Dual Use Research, research with an identifiable benefit but with the potential for misuse, has become a public safety concern that is being regulated at the federal level based on NSABB considerations and local oversight responsibility resides with the IBC.If any of the questions posed below for research covered by this IBC application are answered by 'Yes', please attach as a separate page your description of the Dual Use aspects of the project <https://www.phe.gov/s3/dualuse/Pages/default.aspx> |
|  | 1. Will this work create resistance to therapeutically useful antimicrobials or antivirals? (This applies to therapeutic agents used to control disease agents in humans, animals or plants)
2. Will this work enhance the virulence of a pathogen or render a non-pathogen virulent? (This applies to human, animal or plant pathogens)
3. Will this work increase the transmissibility of a pathogen? (This would include enhancing transmission within or between species, and altering vector competence to enhance disease transmission)
4. Will this work alter the host range of a pathogen?
5. Could the results of the project potentially demonstrate how to render a vaccine ineffective? (This applies to both human and animal vaccines)
6. Could this work enable the evasion of diagnostic/detection modalities? (e.g., microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods)
7. Could this work enable the weaponization of a pathogen or toxin (e.g., stabilization or synthesis of a “high-risk” agent)
 |
|  | Yes |
|  | No |
|  | In responding in a free-form attachment to a 'Yes' answer, please consider not only the Project Design issues but also Research Progress and Completion issues The IBC website at [http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-biosafety-committee-(ibc](http://ors.umkc.edu/)) Biosafety Training - Presentations provides background for these questions. |