# IBC APPLICATION:
# APPLICANT'S GUIDE TO COMMON AREAS FOR IMPROVEMENT

**This guide is designed to assist principal investigators and laboratory personnel in the accurate and satisfactory completion of the Institutional Biosafety Committee Application (IBCA).** Highlighting issues commonly found by committee members during the IBC review process, this guide includes specific tips for providing accurate and informative responses.

For questions, please contact IBCstaff@umich.edu.

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# IBCA SECTION: LAB PERSONNEL & LAB SPACES

## 1. ISSUE: NO LAB PERSONNEL LISTED

SUGGESTIONS FOR IMPROVEMENT: List all people who will be working in the BSL2 lab. If the only person working in the lab is the person currently listed, let us know when you return the application.

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## 2. ISSUE: NO BSL2 SPACE LISTED

SUGGESTIONS FOR IMPROVEMENT: If you are performing BSL2 work, please list the laboratory spaces where you will perform this work.

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## 3. ISSUE: BSL2 ROOMS DON'T MATCH YOUR BIOSAFETY INSPECTION REPORT

SUGGESTIONS FOR IMPROVEMENT: Confirm that the BSL2 rooms listed on your application match the rooms listed on your most recent Biosafety Inspection Report. If you have a BSL2 room listed on your IBC application that has not been inspected by EHS Biosafety within the past 12 months, you will need to schedule a biosafety inspection. Contact EHS to schedule this inspection. ULAM vivarium rooms and rooms used only for storage or BSL1 work do not need a biosafety inspection.

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# IBCA SECTION 1. NIH GUIDELINES

## 4. ISSUE: NIH GUIDELINES (EXEMPT) ANSWERS ARE INCORRECT

SUGGESTIONS FOR IMPROVEMENT: For Question 1-1.2, choose "Yes" if you are using one of the listed host-vector systems: Escherichia coli K-12, Saccharomyces cerevisiae, Saccharomyces uvarum, Kluyveromyces lactis, Bacillus subtilis or Bacillus licheniformis.

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## 5. ISSUE: NIH GUIDELINES (NON-EXEMPT) ANSWERS ARE INCORRECT

SUGGESTIONS FOR IMPROVEMENT: For Question 1-2.1, examples of Risk Group 2 (RG2) agents include pathogenic bacteria, human adenoviruses, HSV, and 3rd generation (and higher) HIV-based lentivirus vectors.

For Question 1-2.3, choose “Yes” if you are using a retroviral or lentiviral vector, since the viral genome is cloned into a plasmid that is grown in a prokaryote (bacterium). This may also apply to adenovirus vectors, depending on how they are produced.

For Question 1-2.17, this includes most use of baculovirus and adeno-associated virus vectors (AAV), depending on the experiments being conducted.

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## 6. ISSUE: NIH GUIDELINES (ANIMALS) ANSWERS ARE INCORRECT

SUGGESTIONS FOR IMPROVEMENT: For Question 1-3.3, answer “Yes" if you administer Risk Group 2 (RG2) agents to animals (e.g., pathogenic bacteria, human adenoviruses, HSV, or 3rd generation (and higher) HIV-based lentivirus vectors).

For Question 1-3.5, answer “Yes" if you are administering recombinant DNA or synthetic nucleic acids by means such as adeno-associated virus (AAV), plasmids, or cells containing rDNA.

For Question 1-3.18, this includes use of BSL2 agents and/or transgenic animals requiring ABSL2 containment.

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# IBCA SECTION 2. RECOMBINANT DNA

## 7. ISSUE: INADEQUATE INFORMATION ABOUT CLONED OR TARGETED GENES

SUGGESTIONS FOR IMPROVEMENT: For Question 2-2.1, if you are working with many genes and cannot list them all individually, you can group them into sets. When using gene sets, use a descriptive name and give examples of specific genes in the set in Subquestion 1. Only group genes together that have similar properties or functions. Genes that control cell growth, division, or apoptosis should be grouped separately from those that do not control these processes.

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# IBCA SECTION 3. VECTORS

## 8. ISSUE: WORKING WITH E. COLI THAT IS NOT A K-12 DERIVATIVE

SUGGESTIONS FOR IMPROVEMENT: If you are working with E. coli plasmid vectors, please be sure to verify whether your strain is an E. coli K-12 derivative. List any non-K-12 strains separately using the "Other host" option.

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## 9. ISSUE: NOT ENOUGH INFORMATION ABOUT LENTIVIRUS VECTORS

SUGGESTIONS FOR IMPROVEMENT: Provide additional detail in Question 3-7.5. Even if your virus is replication defective, it is still an infectious particle that can elicit an immune response. Please consider this and the questions below when writing your answer.

- For part A, would there be any adverse effects in a person of knockdown or expression of the genes you are working with?
- For part B, what would be the effect of the lentivirus vector itself on the host genome (e.g., the effects of vector integration into the genome)?

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## 10. ISSUE: NOT ENOUGH INFORMATION ABOUT AAV VECTORS

SUGGESTIONS FOR IMPROVEMENT: Provide additional detail in Question 3-8.4. Be sure your response addresses parts A, B, and C of this question, and consider the following when answering:

- Is there is any expectation of replication-competent virus?
- AAV can integrate into the genome through DNA breaks, and with integration there is always a chance of mutagenesis of an endogenous gene that could lead to deleterious outcomes.

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## 11. ISSUE: DID NOT ADEQUATELY ARTICULATE RISK

SUGGESTIONS FOR IMPROVEMENT: The IBC is aware of the risks associated with recombinant DNA research and wants to ensure that the PI is aware of potential risks and can articulate these risks to their lab personnel.

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### 12. ISSUE: WORK WITH VECTORLESS SYSTEMS PROPOSED AT BSL2

SUGGESTIONS FOR IMPROVEMENT: For Question 3-12.1, work with vectorless systems can be performed at BSL1. If there is a specific reason that BSL2 is more appropriate, please add an explanation to your research goals in Section 2, Question 2.1.

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## IBCA SECTION 4. INFECTIOUS AGENTS & BIOLOGICAL TOXINS

### 13. ISSUE: ADDITIONAL INFORMATION NEEDED ABOUT WORK WITH CTB

SUGGESTIONS FOR IMPROVEMENT: For Question 4.3, include that cholera toxin subunit B will be prepared in a fume hood. If you are administering CTB to animals, include that double gloves will be used when administering to animals.

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### 14. ISSUE: WORK WITH INFECTIOUS AGENT INCORRECTLY MAKRED INACTIVE

SUGGESTIONS FOR IMPROVEMENT: For Question 4-1.1, Subquestion 7, if you are currently working with an infectious agent, or planning to soon, please answer "Yes" to this question and answer the follow-up questions. Only answer “No” if the agent is in long-term storage.

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## IBCA SECTION 5. HUMAN-DERIVED SUBSTANCES

### 15. ISSUE: WORK WITH HUMAN CELL LINES PROPOSED AT BSL1

SUGGESTIONS FOR IMPROVEMENT: For Question 5-1.1, human cell lines, even in the absence of overt contamination, may contain adventitious viruses and/or other opportunistic pathogens or zoonotic agents. Since it is extremely difficult to screen for every pathogen, all human cell lines require BSL2.

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## IBCA SECTION 6. ANIMALS

### 16. ISSUE: BIOHAZARD LISTED ON YOUR IACUC PROTOCOL BUT NOT ON IBCA

SUGGESTIONS FOR IMPROVEMENT: Review the hazards list(s) for your IACUC protocol(s) and confirm that all IBC-relevant substances listed are also listed in Section 6-1 of your IBC application.

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### 17. ISSUE: ADMINISTRATION OF HUMAN CELLS TO ANIMALS AT ABSL1

SUGGESTIONS FOR IMPROVEMENT: For Question 6-1.1, Subquestion 3, animals administered human-derived substances should be housed at ABSL2 for the duration of the experiment. It is possible to receive permission to perform these experiments at ABSL1, but that process is separate from the IBC application and is done after your IBC application is approved.

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## IBCA SECTION: RISK MITIGATION PRACTICES

### 18. ISSUE: MISSING DISSECTION AS AN AEROSOL-GENERATION PROCEDURE

SUGGESTIONS FOR IMPROVEMENT: For Risk Mitigation Question 1, check the box for "dissection" if you will be performing dissection or necropsy of animals administered BSL2 substances, as this is an aerosol generating procedure.

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### 19. ISSUE: INADEQUATE DESCRIPTION OF SHARPS USE

SUGGESTIONS FOR IMPROVEMENT: For Risk Mitigation Question 4, describe how you will handle any sharps used with BSL2 substances (e.g., lab personnel will wear double gloves and dispose of sharps in appropriate containers). Also indicate which BSL2 substances are used with sharps.

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## 20. ISSUE: MISSING OR INADEQUATE DESCRIPTION OF BSL2 TRANSPORT

SUGGESTIONS FOR IMPROVEMENT: For Risk Mitigation Question 5, if you are transporting BSL2 materials between lab spaces or to animal housing areas, please respond "Yes" to this question. BSL2 materials should be transported be in a closed container within a leak-proof secondary container with a lid and a biohazard label.

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## 21. ISSUE: INCORRECT SELECTIONS FOR WASTE DISPOSAL

SUGGESTIONS FOR IMPROVEMENT: For Risk Mitigation Question 6, select “Vendor/EHS pickup” if your building offers vendor-provided bins for disposal of solid biohazardous waste. In areas with this service, labs should not autoclave their own waste. Select “Chemical inactivation” if bleach is used for tissue culture media prior to disposal.

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