**CLEVELAND STATE UNIVERSITY IBC APPLICATION**

**INSTRUCTIONS:**

* Please download the newest version of the IBC application forms before preparing any new submission, resubmission, continuing renewal, or amendment. The form may have been updated since your last application. A version number can be found in the lower-left corner of each form.
* Sections 1,2,3, and 5 must be filled out completely in all applications.
* The nature of the proposed research using recombinant or synthetic nucleic acids dictates which information in Section 4 is required. The questions in Section 1F may help one determine which parts of Section 4 must be completed.
* Certain research using recombinant or synthetic nucleic acids is exempt from IBC review. Summaries of some common exemptions can be found on the [CSU IBC webpage](https://www.csuohio.edu/sprs/ibc).
* An [example of a completed IBC application](https://www.csuohio.edu/sites/default/files/IBC%20application%20examples.docx) is available for download from the CSU webpage. It may help demonstrate the level of detail required for each section.
* *If you are unsure whether you need to complete a full application, you may complete Section 1 and send that to the IBC chair as a presubmission inquiry.*

In many versions of Microsoft Word, the Enter/Return key will not make a line break in form fields like those in this document. Instead, use Shift+Enter (Windows) or Shift+Return (Mac).

**SECTION 1: General information.**

**1A. Project Title**
Click or tap here to enter text.

**1B. Principle Investigator**
Click or tap here to enter text.

**1C. Application Date**Click or tap to enter a date.

**1D. Is this a new submission, resubmission, continuing renewal, or amendment?** *New submissions are applications that have not been previously submitted. Resubmissions involve applications that have been previously rejected or returned for revision. Continuing renewals update the project details to allow the project to continue beyond the prior approval period. Amendments update the project when there are changes in personnel or experimental details before a renewal is required*Click to choose a submission type.

**If a resubmission, continuing renewal, or amendment, briefly summarize any changes since the last submission.***Example: “This amendment includes changes to the study team members, proposed risk group, viral vectors being used, and list of recombinant materials.”*Click or tap here to enter text.

**If a continuing renewal or amendment, please note date and approval number for last submission.**Click or tap here to enter approval date. Click or tap here to enter approval number.

**1E. What is the expected duration of the research project or grant-supported funding period following this submission?** *IBC approvals are for three years. Projects longer than three years will require a renewal prior to the start of the fourth year.*Click or tap here to enter text.

**1F. Please answer the following questions regarding areas of the research project *that involve recombinant materials/transgenic organisms.***

**Does the study involve human subjects (e.g., gene transfer/therapy, vaccine study, etc.)?** *If yes, provide IRB approval number.*Select Yes or No Click or tap here to enter approval number.

**Does the study involve live vertebrate animals?** *If yes, provide IACUC approval number.*Select Yes or No Click or tap here to enter approval number.

**Does the study involve known pathogens?** *If yes, section 4A is required.*Select Yes or No

**Does the study involve creation of an organism that harbors and/or expresses a known pathogenic agent, toxin, prion, oncogene, etc.?** *If yes, section 4A is required.*Select Yes or No

**Does the study involve using a virus/viral vector?** *If yes, section 4B is required.*Select Yes or No

**Does the study involve cell culture?** *If yes, sections 4C and 4D are required.*Select Yes or No

**Does the study involve bacterial strains other than *E. coli* K-12 derivatives (*e.g.*, BL21)?** *If yes, sections 4C and 4D are required.*Select Yes or No

**Does the study involve CRISPR mediated gene editing with gRNA and nuclease encoded on the same plasmid, vector, or delivery vehicle?** *If yes, section 4E is required.*Select Yes or No

**Does the study involve working with compacted DNA/nanoparticles?** *If yes, section 4F is required.*Select Yes or No

**Does the study involve non-pathogenic invertebrates or fungi?** *If yes, please contact the IBC before completing your application.*Select Yes or No

**Does the study involve transgenic plants?** *If yes, please contact the IBC before completing your application.*Select Yes or No

**SECTION 2: Personnel and Funding**

**2A: Study team information (include PI):** *If personnel have changed since the last approval, please list all members of the current study team.*

|  |  |  |
| --- | --- | --- |
| **NAME** | **ROLE** | **EMERGENCY CONTACT(Name and Phone Number)** |
| Click here to enter name. | Click here to enter role. | Click here to enter contact info. |
| Click here to enter name. | Click here to enter role. | Click here to enter contact info. |
| Click here to enter name. | Click here to enter role. | Click here to enter contact info. |
| Click here to enter name. | Click here to enter role. | Click here to enter contact info. |
| Click here to enter name. | Click here to enter role. | Click here to enter contact info. |

*Please note any additional team members on a separate page and indicate the number of continuation pages used in the field below.* [*A formatted continuation page can be downloaded from the SPRS webpage.*](https://www.csuohio.edu/sites/default/files/IBC%20application%20s2a%20continuation%20page.docx)Click here to enter the number of Section 2A Continuation Pages included with this application.

**2B. Laboratory safety training**

\*All laboratory personnel should receive lab safety training either online or in person. Persons interested in the online training provided by Environmental Health and Safety can enroll at the following link:
<https://www.csuohio.edu/ehs/online-safety-training-sign>

\*Training for specialized techniques involving Recombinant DNA may be done in the lab.
**Please briefly summarize training that has been conducted for all lab members as well as any specialized training provided as needed:**
Click or tap here to enter text.

**2C. Please provide the following information regarding project funding:**

**Agency or Source Name(s):**
Click or tap here to enter text.

**Agency or Source Grant/Contract/Protocol #(s):**
Click or tap here to enter text.

**SECTION 3. Study Description/Plan**

**3A. What is the nature of this recombinant experiment? (select all that apply):**[ ]  Creation of transgenic animals
[ ]  Purchase or transfer of transgenic animals
[ ]  Viral infection and/or viral vectors
[ ]  Gene therapy
[ ]  Use of modified cells in animals

**Will any of the following be introduced into a living cell? (select all that apply):**[ ]  sh/si/dsRNA
[ ]  Toxin genes
[ ]  Oncogenes
[ ]  Vaccine
[ ]  Synthetic oligonucleotides or morpholinos
[ ]  Compacted DNA/nanoparticles
[ ]  Other

**\*\*If other, please explain.**Click or tap here to enter text.

**3B. Describe the purpose of the proposed experiments in 3 or 4 sentences, using language that can be understood by a non-scientist:**Click or tap here to enter text.

**3C. Briefly summarize the broad goals of the study and how the proposed recombinant nucleic acid research fits in your overall project:**Click or tap here to enter text.

**3D. Detail the recombinant and biosafety portions of your experiments in a step-by-step fashion. Indicate if you are generating or purchasing viral particles. Please detail safety measures used including Personal Protective Equipment (PPE), physical containment (biosafety cabinet), decontamination, and disposal of waste (If using bleach to decontaminate liquid media or surfaces, include bleach percentage and, if appropriate, minimum time between addition of bleach and disposal):**Click or tap here to enter text.

**3E. Indicate the laboratory facilities (building and room number) where work will be conducted.**Click or tap here to enter text.

**3F. What is the proposed Risk Group/Biosafety Level (BSL)/Animal Biosafety Level (ABSL) for this project:**Choose a Risk Group Choose a Biosafety Level Choose an Animal Biosafety Level

For more info on Risk Groups/BSLs/ABSLs please refer to the [CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL)](https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf) pages 12, 68, 71, and 147.

More information can also be found in the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)

Reference Appendix B for an extensive list of Risk Groups for various agents.

**3G. Will BSL/ABSL levels increase or decrease during the course of research?** *For example, do you propose to move animals from ABSL 2 to ABSL 1 after testing for viral shedding?*Select Yes or No

**If YES, please describe which components of the proposed research will be affected and whether any testing will be done before changing biosafety levels:**
Click or tap here to enter text.

**SECTION 4. Recombinant Nucleic Acid/Recombinant Material Details.**

**4A. If Recombinant experiments involve working with a pathogen, please list the names. Note that Baculovirus experiments that involve a pathogen are NOT exempt from the NIH Guidelines for Research Involving Recombinant DNA Molecules.**
Click or tap here to enter text.

**4B. If Recombinant experiments involve working with viruses, select all that apply.** *A map for each vector is required. This may be submitted as a separate file (e.g., graphic map cut and pasted into a Word document) or a web link or vendor AND product number that leads directly to information/maps for the vector/system used. The IBC may reject applications lacking documentation of the viral elements present in the vectors used.*

[ ]  Adenovirus
[ ]  Baculovirus
[ ]  Lentivirus 3 plasmids
[ ]  Lentivirus 4 or more plasmids
[ ]  Retrovirus
[ ]  AAV
[ ]  Other

**If other, please specify**
Click or tap here to enter text.

**Will more than 2/3 of a viral genome be used?**Select Yes or No

**Will a helper virus be used? If using a helper plasmid, please answer no.**Select Yes or No

**Will a virus be used as a vector to introduce a foreign gene?**Select Yes or No

**If yes, please list the vector(s) name(s):**
Click or tap here to enter text.

**4C. If Recombinant experiments involve cell lines or bacterial strains other than *E. coli K-12*, please provide cell information, if applicable. Include packaging cell lines in this list.**

|  |  |  |
| --- | --- | --- |
| **Type of cell/cell line (including species):** | **Origin/Source of cells (including name of supplier):** | **IRB approval number (if necessary):** |
| Click here to enter text. | Click here to enter text. | Click here to enter IRB #. |
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*Please note any additional cell lines on a separate page and indicate the number of continuation pages used in the field below.* [*A formatted continuation page can be downloaded from the SPRS webpage.*](https://www.csuohio.edu/sites/default/files/IBC%20application%20s4c%20continuation%20page.docx)Click here to enter the number of Section 4C Continuation Pages included with this application.

**4D. Will the research project involve more than 10 Liters of culture at any time?**Select Yes or No

**4E. For CRISPR experiments, please answer the following:**

**If gRNA and nuclease are encoded on the same plasmid, vector, or delivery vehicle, can this vector transfect or infect a human cell?**Select Yes or No

**Does this research involve the creation of a gene drive experiment?** *If yes, please explain.*Select Yes or No
Click or tap here to enter text.

[*More information on gene drive experiments*](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6069294/)*.*

**Will the gene editing technology be used to target embryos or germ line cells?** *If yes, please explain.*Select Yes or No
Click or tap here to enter text.

**4F. If Recombinant experiments involve working with compacted DNA/nanoparticles, please specify the type of nanoparticle being used and safety procedures to minimize risk of exposure:**
Click or tap here to enter text.

**SECTION 5: Sources and nature of recombinant materials:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of gene/protein** | **Species of origin** | **Will a foreign gene be expressed?** | **Activity/function of gene (tissue inhibitor, marker gene)** |
| Click here to enter text. | Click here to enter text. | Select Yes or No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Select Yes or No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Select Yes or No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Select Yes or No | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Select Yes or No | Click here to enter text. |

*Please note any additional recombinant materials on a separate page and indicate the number of continuation pages used in the field below.* [*A formatted continuation page can be downloaded from the SPRS webpage.*](https://www.csuohio.edu/sites/default/files/IBC%20application%20s5%20continuation%20page.docx)Click here to enter the number of Section 5 Continuation Pages included with this application.

**Resources:**

[CSU IBC forms, instructions, and biosafety requirements & exemptions on the SPRS website](https://www.csuohio.edu/sprs/ibc)

[NIH Guidelines April 2019](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)
[Biosafety in Microbiological and Biomedical Labs 6th Ed.](https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf)