

Guide: How to fill out the IBC registration form

This form should be completed for ALL research (funded or non-funded) involving:

1. **Recombinant DNA** - Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, and the molecules that result from them.
2. **Pathogens** – Can cause disease in healthy human adults
3. **Select Agents** – On the select agents list at www.selectagents.gov

If mammalian cells or body fluids (fixed or not) are used but **no agents listed above** are used then work must be done at biosafety level 2 (BSL2), however, you **need NOT complete the registration form**.

The form is to be submitted along with the research description form. The PI who is ultimately responsible for the lab must submit all documents by email (see form for address). Sending forms from an email account constitutes a signature from that person. For assistance contact the Office of Laboratory Safety (OLS), Ross 627, 4-2630.

INSTRUCTIONS FOR SECTION 1

PI responsible for the lab space and ultimately responsible for safety and must actually submit the proposal to the IBC via email.

Primary researcher for the project (often same as submitter)

Name of PI for this project: John Doe

Name of responsible PI for lab (submitter): Jane Doe Dept: Mic

Title of proposal (grant name if funded): Gene expression study of

Seeking (or have) external funding for work? Y N Source: NIH

Title of other grant(s) if more than one: NA

Period: 4/08 to 4/11 Location for proposed work (rooms): Ross 6

Submission type: new IBC project periodic review amendment to exist

Reviews are done at least annually. If changes are needed: open the original electronic copy, make the changes and send it to OLS via email with an explanation of the changes.

An amendment must be submitted when a significant change is made to research. **“Significant”** would include: a change in research class; change in biosafety level; new select agent; new pathogen; major modification of a unique, non-commercial expression vector; any change in an expression vector resulting in increased levels of transgene expression; large changes in the nature of an inserted gene (ie: oncogene, virulence, origin or replication).

To submit: make changes to the original form (track changes) and attach to an email. In the email:

1. Write a brief **synopsis** outlining the original work approved by the committee.
2. Explain the **changes** (ie: changes in the insert, vector or host and how this will affect risk)

INSTRUCTIONS FOR SECTION 2a

#	DNA source(s): organism, gene name	Nature of sequence(s) (ie: coding, regulatory)	Vector(s): type, name	List All hosts and/or infectious agents	Risk group (RG) ³
1	rat - NeuroD6 (Next1) mouse - ME1 (HEB) mouse - ME2 (E2-2)	coding	pc DNA6 or pBud CE4.1 plasmid	E. coli	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
2					<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3

For multiple items within a column for the same line, add new lines within the box

Use a different line for each host vector system. Also there may be more than one host per line (ie: E.Coli for replication and mouse cells for expression OR rDNA host and live animal)

Select the highest number risk group of all agents on the line assuming agents are full genome. Human pathogens are 2 or higher.

INSTRUCTIONS FOR SECTION 2a cont.

Structure of sequence(s) (coding, regulatory)	Vector(s): type, name	List All hosts and/or infectious agents	Risk group (RG) ³
		A. caninum	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3

If a pathogen is used without rDNA work then simply put the agent in the "host(s) / infectious agent(s)" column.

AND

Structure of sequence(s) (coding, regulatory)	Vector(s): type, name	List All hosts and/or infectious agents	Risk group (RG) ³
		dog (live), A. caninum	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3

If a host is involved, enter the host information as well. Put (live) next to the host if it is a whole, live, animal (higher eukaryote).

INSTRUCTIONS FOR SECTION 2d

<input type="checkbox"/>	III-D	IBC [†]	rDNA transferred to or from: whole animals, whole plants (high risk work) animals, experiments involving >10 Liters of culture, agents listed in Risk of Infective Eukaryotic Viruses in Cell Culture.
<input checked="" type="checkbox"/>	III-E	IBC [‡] - most common	rDNA involving: eukaryotic viruses (not more than 2/3 genome) in cell culture (high risk work) and associated small animals, arthropods, or generation of transgenic animals (BSL1), any work not covered in the other categories (most non-pathogenic).



Each line represents NIH classes of research decreasing in risk as you go down the column (III-A is highest risk).

Categories IIIA-IIIIC are self-explanatory. In general choose III-D if any agent in Table 1 is a pathogen. Also, work with whole animals, large quantities (>=10 liters) or high risk whole plants falls in this class. For research not applying to any other class choose III-E. This class is a **catchall for most non-pathogen work** and is the most common. Also, lower risk whole plant use and associated small animals are III-E. Infectious eukaryotic viruses are Pathogens and thus III-D. However, if the DNA used is less than **2/3 of the genome** (with no helper viruses) then they are considered defective and fall into III-E.

INSTRUCTIONS FOR SECTION 3

Y	N	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Is there any reason to believe any of the following things would be different in your work? (ie: virulence, pathogenicity, infectious dose, environmental stability, host range, etc.)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	NA (not a pathogen) Are there biological barrier options available (ie: attenuated agents, etc.)?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	NA (no rDNA) Will the insertion encode for an oncogene, integrate into the genome, or otherwise affect the host? (ie: competent viruses?)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	NA (not a pathogen) Is an effective prophylaxis and/or treatment available?

Each line addresses measures or characteristics of the research that could **increase or decrease** the risk of the original agents. For instance the source DNA may increase the virulence of the host and raise the risk whereas attenuating an agent can lower the risk.

INSTRUCTIONS FOR SECTION 4

	Biosafety level (BSL)				Animal biosafety level (ABSL)				
1	<input type="checkbox"/> 1	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> enhanced	<input type="checkbox"/> NA	<input type="checkbox"/> 1	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 3	14-3
2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> enhanced	<input type="checkbox"/> NA	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	
3	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> enhanced	<input type="checkbox"/> NA	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	

All biological work on campus must meet the **minimum** requirements of BSL1. Check the animal biosafety level only if whole, live, vertebrates are used.

Each line corresponds to the lines in Table 1. Risk groups (RG) are for agents, while biosafety levels are for facilities and they will usually be the same (ie RG2 = BSL2) **UNLESS**...the risk assessment in section 3 has lowered or raised the risk level. The containment level must match the new risk. Also, work with mammalian cells must be conducted at BSL2 or higher. The "enhanced" box is for work with pathogens, such as HIV, that are concentrated (much higher than regular clinical samples), this work is done with higher containment practices.