

## IS MY RESEARCH EXEMPT FROM ANNUAL REVIEW BY THE IBC?

*Please submit your form to [IBC@ttuhsc.edu](mailto:IBC@ttuhsc.edu), Research Integrity Office, Lubbock.*

All recombinant DNA research at NIH-funded institutions must be performed according to the **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** (the [NIH Guidelines](#)). The Guidelines' purpose is to protect researchers and the environment from exposure to or release of harmful agents produced by recombinant DNA research. The Guidelines specify the kinds of experiments subject to annual review by the **Institutional Biosafety Committee (IBC)**. The Guidelines also identify some experiments as **EXEMPT** from annual review because they pose no significant risk to personnel or the environment when performed with good microbiological technique and lab hygiene. The IBC reviews DURC and all other research involving hazardous biological, hazardous chemical agents, and toxins; hereafter referred to as hazardous materials. Any faculty member at TTUHSC who oversees a research lab will be required to have an **approved** protocol from the TTUHSC IBC. The approved protocol serves as a broad inventory of all hazardous agents in the lab, approved laboratory personnel and provides a general scope of the activities taking place in the research lab.

### DEFINITIONS:

Risk Group 1: Agents not associated with disease in healthy adult humans.

Risk Group 2: Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.

Risk Group 3: Agents associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available (i.e. high individual risk but low community risk).

Risk Group 4: Agents likely to cause serious or lethal human disease for which preventive therapeutic interventions are not usually available (i.e. high individual risk and high community risk).

After each question, if your research is determined **NONEXEMPT** by this Questionnaire, please fill out the **IBC Amendment form in iRIS** (with proper BSOP form attached) and submit it for review by the IBC.

To determine if your research is **EXEMPT** from registering an agent upon annual review with the IBC according to the NIH Guidelines, please answer the following questions:

#### 1. Will you introduce recombinant or synthetic DNA into live animals or human subjects?

YES       NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

#### 2. Will you use transgenic animals **other than** transgenic mice or rats?

YES       NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

3. Will you generate transgenic mice or rats, or use transgenic mice or rats harboring more than 2/3 of the genome of viruses or organisms belonging to Risk Groups 2, 3, or 4 (as defined at the end of this Questionnaire)?

YES  NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

4. Will you work with nucleic acids from Risk Group 3 or 4 agents or restricted organisms, or with nucleic acids that code for biosynthesis of molecules toxic to vertebrates?

YES  NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

5. Will recombinant or synthetic nucleic acids be deliberately introduced into any living cells or be modified to make them capable of penetrating into cells (e.g. as for transformation or transfection)?

YES  NO

If you answered "NO", skip all remaining questions and submit your Questionnaire. If you answered "YES", please complete questions 6-9.

6. Will recombinant or synthetic DNA be propagated or expressed using host-vector systems **other than** *Escherichia coli* K-12, *Saccharomyces*, *Bacillus subtilis* or *Bacillus licheniformis*, be shared between microorganisms of different species or strains that do not naturally exchange DNA, or be introduced into cultured eukaryotic cells **other than** existing cell lines?

YES  NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

7. Will *E. coli* K-12 hosts contain conjugation-proficient plasmids or generalized transducing phages?

YES  NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

8. Will cell culture experiments use infectious viruses (DNA or RNA), defective viruses in the presence of helper virus, or eukaryotic viral genome segments comprising more than 1/2 of the full viral genome?

YES  NO

If you answered "YES", **STOP** here. Your research is **NONEXEMPT**.

