



SOP Title	Submission and Approval of the Biosafety Agent Registration Application				
Date Last Revised	05/01/2018	Date Created	06/2011	Revision #	2.0
SOP Number	2	Required by:	<input type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input type="checkbox"/> OLAW		
Applicability	<input type="checkbox"/> RGC Internal		<input checked="" type="checkbox"/> Researcher		<input checked="" type="checkbox"/> Institutional
Subgroup	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input checked="" type="checkbox"/> IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process for submitting new projects to the Institutional Biosafety Committee (IBC).

2.0 GENERAL INFORMATION AND SCOPE

This SOP applies to any researcher at NKU submitting a research or classroom protocol to the Institutional Biosafety Committee (IBC). The IBC recognizes that research takes place without exterior funding sources. Therefore, applications must also be filed to seek approval for all [non-IBC exempt](#) relevant activities conducted without a specific sponsor.

All application materials will be available on the NKU Office of Research, Grants and Contracts Institutional Biosafety Committee (IBC) webpage and should be downloaded and completed by the Principal Investigator (PI) or administrative head.

The IBC actively encourages any submitting PI/administrative head to seek input from the IBC Administrator or the IBC Chair/Biological Safety Officer (BS) to prevent undue delays prior to submission. The IBC seeks to minimize time and effort required by the PI/administrative head to successfully acquire permission for the underlying activities.

All applicants requesting the use of Select Agents will be directed to [NKU Safety and Emergency Management](#).

Approved BAR applications are valid for no more than three years. After three years, a new application (three year renewal) is required if the researcher wishes to continue a study.

3.0 PROCEDURES

A. SUBMISSION OF THE BIOSAFETY AGENT REGISTRATION (BAR) APPLICATION

- Complete the Biosafety Agent Registration (BAR) application
 - In the BAR, the PI will verify:
 - the completion of required trainings
 - the review of NKU IBC internal regulations and procedures
- Submit, to the IBC Administrator (biosafety@nku.edu):
 - The completed BAR
 - The PI's current Curriculum Vitae (CV)

- The IBC Addition of Personnel form (if applicable)

B. REVIEW AND APPROVAL OF THE BAR APPLICATION

After receiving the electronic copy of the BAR with the appropriate attachments, the IBC Administrator will facilitate review of the application between the reviewers and the PI.

If revisions are required, reviewers will communicate this with the IBC Administrator who facilitates all communication with the PI.

SCORING OF APPLICATIONS

Applications will be scored as follows:

1. Approve – allows the PI to begin immediately with experiments
2. Reject – the researcher may not proceed with the experiment
3. Revisions Required – the PI must respond to IBC required revisions to the IBC. Final approval from the IBC is required prior to starting the experiments.

LEVELS OF REVIEW

- **LEVEL 1 – Exempt (from full IBC review) Experiments**

Review Type: Must be reviewed and determined by the IBC Chair who will, as needed, consult with committee members or obtain outside input.

Method of Review: The PI must contact the IBC Chair for this determination. A BAR form is not required.

Examples:

- a. Normal cloning in standard prokaryotic host-vector systems
- b. All Cell-free recombinant DNA works
- c. Bio 150, 151 class activities
- d. The purchase or transport of nonhazardous transgenic animals onto campus

Resources: [Exempt from NIH Guidelines](#)

- **LEVEL 2 – Low risk experiments - Recombinant DNA work involving non-pathogenic BSL 1 agents outside of standard host-vector systems.**

Review Type: Review by the full NKU Institutional Biosafety Committee either by a convened meeting or designated reviewer.

Method of Review: Biosafety Agent Registration form

- **LEVEL 3 – Moderate Risk Experiments**

Review Type: Review by the full NKU Institutional Biosafety Committee either by a convened meeting or designated reviewer.

Method of Review: Biosafety Agent Registration form

Examples:

- a. Introduction of recombinant DNA into BSL2 (or above) agents
- b. Introduction of recombinant DNA from BSL2 (or above) agents into non-pathogenic host-vector systems
- c. Experiments done with infectious microorganisms of humans, animals and plants
- d. Use of recombinant DNA in animals
- e. Creation of transgenic animals

Resources: [Transgenic Animals and Recombinant DNA Guidelines](#), [Animal Experiments Covered under NIH Guidelines](#)

- **LEVEL 4 – Use of Recombinant DNA in Humans (Gene Therapy Research)**
Contact IBC Chair
- **LEVEL 5 – High Experiments that Require NIH and IBC Approval Before Initiation**
Contact IBC Chair

Funded Research

When required by funders, applications must be filed when grant proposal applications are filed with the NKU Office of Research, Grants, and Contracts.

4.0 REFERENCES

[Transgenic Animals and Recombinant DNA Guidelines](#)
[Animal Experiments Covered under NIH Guidelines](#)

5.0 FORMS OR ATTACHMENTS

NKU IBC Biosafety Agent Registration

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
IBC Chair	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IACUC Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	