**IBC Services SUBMISSION REQUIREMENTS**

**Part B: Review of Non-Clinical Project**

Use this checklist to assemble a request for local Institutional Biosafety Committee (IBC) review of a specific non-clinical project. “Non-clinical” means biological materials will not be deliberately introduced into humans, and no human research subjects will be used.

Submission of a separate form (IBC Services Submission Form Part A) is required for IBC Services to establish the local IBC. We encourage new institutions to submit Part A and B simultaneously, but this is not required. For an institution with an existing IBC administered by IBC Services it is not necessary to submit Part A for a new project--only Part B is required. For questions, please contact IBC Services.

Please submit documents electronically via email at IBCServices@wcgclinical.com.

PART B: PROJECT DOCUMENTS REQUIRED FOR SUBMISSION

[ ]  IBC Services Submission Form Part B: Non-Clinical Project Information

[ ]  Full Curriculum Vitae (CV) for the Principal Investigator *(current within the last 3 years and must include publications and/or research experience)*

[ ]  Biographical sketch for the Principal Investigator (if available)

**B1. PROJECT IDENTIFICATION**

Project Number:

Project Title:

Does the research include recombinant or synthetic nucleic acid molecules (rDNA)? [ ]  Yes [ ]  No

Does the research include biological agents (cells, bacteria, viruses, fungi, prions, etc.)? [ ]  Yes [ ]  No

Does the research include the use human cells or cell lines? [ ]  Yes [ ]  No

Does the research include biological toxins? [ ]  Yes [ ]  No

Does the research include select agents? [ ]  Yes [ ]  No

Does the research include the use of animals? [ ]  Yes [ ]  No

Does the research include the use of plants? [ ]  Yes [ ]  No

Is the research already in progress? [ ]  Yes [ ]  No

What is the proposed highest level of containment? [ ]  BSL1 [ ]  BSL 2 [ ]  BSL3

Has this project ever been reviewed by an Institutional Biosafety Committee (IBC)?[ ]  Yes\* [ ]  No

*\*If yes, please explain:*

Do you have a specific calendar requirement for completion of IBC review? [ ]  Yes\* [ ]  No

*\*If yes, date:*   *explain:*

**B2. PRINCIPAL INVESTIGATOR INFORMATION**

This person holds overall responsibility for the conduct of the project.

Name:

Address:

City: State:  Zip code:

Phone:  Fax:  Email:

**B3. PRINCIPAL INVESTIGATOR REPRESENTATIVE**

***The Principal Investigator Representative is the person designated as the primary contact for IBC review.***

Name:

Position Title:

Role in project (describe):

Phone:  FAX:  Email:

**B4. PROJECT RESEARCH LOCATION(S)**

List all facilities where biological materials and/or recombinant materials will be present for this project.

**Main Facility Name:**

Address: [ ]  **same as PI address or:**

Address:

City: State:  Zip code:

**Type of facility:** *(specify such as laboratory, vivarium, etc.)*:

**What study activities involving biologicals will be done at this location?**

[ ]  receiving or shipping biological materials and/or recombinant materials

[ ]  storage of biological materials and/or recombinant materials

[ ]  bench research

[ ]  animal work

[ ]  Other *(specify)*:

**Additional Facility:**

Address:

City: State:  Zip code:

**Type of facility:** *(specify such as laboratory, vivarium, etc.)*:

**What study activities involving biologicals will be done at this location?**

[ ]  receiving or shipping biological materials and/or recombinant materials

[ ]  storage of biological materials and/or recombinant materials

[ ]  bench research

[ ]  animal work

[ ]  Other *(specify)*:

**To list more sites, please attach additional sheets.**

Does any listed facility have an IBC registered with NIH OSP? [ ]  Yes [ ]  No

Does any listed facility have an IACUC? [ ]  Yes [ ]  No

**B5. BILLING INFORMATION FOR THIS PROJECT**

This submission constitutes a request from the Research Institution or Principal Investigator for IBC review of the research. As instructed, IBC Services will directly bill third parties for project fees, when we are authorized to do so; otherwise, payment responsibility remains with the Research Institution. IBC Services bills for each project separately upon IBC meeting and then annually until project closure is accepted.

Party to be billed:

Address:  Mail Stop/Cost Center:

City:  State:  Zip code:

Country:

Phone:  FAX:  Email:

“ATTENTION”:

Describe any special billing instructions: (for example reference numbers, purchase order number or tracking number)

**B6. PERSON COMPLETING THIS FORM**

Name:

Title: Phone:  Date:

**B7. PRINCIPAL INVESTIGATOR OR PROJECT MANAGER ACKNOWLEDGEMENT**

“On behalf of the institution, the Principal Investigator is responsible for full compliance with the NIH Guidelines\* in the conduct of recombinant or synthetic nucleic acid molecule research.” [NIH Guidelines IV-B-7]

As Principal Investigator I agree to adhere to the *NIH Guideli*nes and acknowledge that under the *NIH Guidelines* I am responsible to:

1. Not initiate or modify research until all requirements of the *NIH Guidelines* are met;
2. Be adequately trained in good microbiological techniques;
3. Be responsible for training the staff, supervising their activities, and overseeing biosafety procedures for their research;
4. Instruct and train the research staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
5. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested;
6. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed;
7. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken;
8. Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecules;
9. Ensure the integrity of the physical and biological containment of recombinant or synthetic nucleic acid molecules;
10. Comply with shipping requirements recombinant or synthetic nucleic acid molecules (and other hazardous materials);
11. Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC, NIH OSP, and other appropriate authorities (where applicable) within the timeframe as set forth in the *NIH Guidelines*;
12. Remain in communication with the IBC throughout the conduct of the project;
13. Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination;
14. Submit any subsequent changes in the research to the IBC for review and approval or disapproval.

Signature of Principal Investigator Date

\*“NIH Guidelines for Research Involving Recombinant Or Synthetic Nucleic Acid Molecules” or as revised or substituted.