Institutional Biosafety Committee (IBC) Policy For Principal Investigator On A Biosafety Protocol

1.0 Purpose: The purpose of this University of Wisconsin-Madison Institutional Biosafety Committee (IBC) policy is to define roles, responsibilities for a Principal Investigator (PI) on a biosafety protocol.

2.0 Policy:

The IBC defines a PI for biological safety protocols as University of Wisconsin-Madison tenure track faculty or academic staff that have been granted Permanent PI Status.

Circumstances may occur where a non-tenure track researcher or researcher from an external entity may request to be a PI for the purposes of the biological safety protocol. This is requested of the IBC by filling out the attached form and submitting it to the IBC. These requests are subject to IBC approval. These persons may include (but are not limited to):

1. Emeritus faculty authorized to continue to participate in research or academic staff including but not limited to titles: Scientist, Research Instructor, Lecturer, Faculty Associate, etc. Such individuals must have the approval of the dean or director to serve as PI on the biosafety protocol.

2. Employees of external agencies with which UW-Madison has a formal agreement to provide biosafety/IBC services.

The completion and approval of the form by the IBC pertains solely to the ability to serve as Principal Investigator on a biosafety protocol. Although the same form may be used to apply for PI status on Institutional Review Board (IRB), Animal Care and Use Committee (ACUC), and Stem Cell Research Oversight (SCRO) protocols, approval of PI status on a biosafety protocol by the IBC does not confer PI status for IRB, ACUC, and/or SCRO protocols; approval for these must be granted by the relevant oversight committee(s).

Submission of the form to the IBC does not replace the formal campus designation process to serve as a Principal Investigator on an extramural grant proposal, nor does it confer any of the benefits of campus-designated PI status.

3.0 Roles and Responsibilities:

Roles and responsibilities of PIs are defined by the UW-Madison IBC, NIH Guidelines, and other applicable regulations or local, state, and federal guidelines. The PI shall sign and adhere to the assurance statement for their research conducted within the UW-Madison IBC’s oversight.

4.0 Definitions:

Principal Investigator (PI): The term Principal Investigator identifies the individual who is responsible for a research project. This responsibility includes leadership of the scientific/technical aspects, training of laboratory personnel and adherence to NIH Guidelines,
UW-Madison IBC policies, and rules and regulations of all applicable governing entities. The PI must understand, adhere to, and sign the UW-Madison IBC assurance statement.

5.0 Related Documents/Resources:
- U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current version.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) - Biosafety in Microbiological and Biomedical Laboratories (BMBL), current version.

6.0 Document Revision:

<table>
<thead>
<tr>
<th>Revision Number</th>
<th>Revision Date</th>
<th>Description of Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11/04/2015</td>
<td>Clarification regarding PI status solely for biosafety protocol and not otherwise, updated formatting.</td>
</tr>
<tr>
<td>2</td>
<td>06/01/2016</td>
<td>Clarification regarding emeritus status, updated references, updated formatting</td>
</tr>
<tr>
<td>3</td>
<td>06/01/2018</td>
<td>Reorganized sections; removal of unnecessary section; updated application form; modified the wording of the policy</td>
</tr>
</tbody>
</table>

Original signed & dated Policies are retained by the Office of Biological Safety

Signature
Professor Kristen Bernard, IBC Chair

Date
06/18/2018
Request for Principal Investigator (PI) Status

This form is to be used by individuals with a UW-Madison appointment or affiliation with a non-UW entity to request principal investigator (PI) status for research protocols. This includes IRB (human subjects), IACUC (animal), SCRO (embryo and stem cell), and Biosafety. This form is not to be used to request permanent or limited PI status for grant purposes.

NAME: _______________________________________
TITLE: ________________________________________

1. Please select the group(s) for which you would like to be PI: [ ] IRB [ ] IACUC [ ] BIOSAFETY [ ] SCRO

2. Select the appointment type for which you are requesting PI status:
[ ] Academic Staff: Circle one- employed / visiting
[ ] Limited Appointee
[ ] Visiting Faculty
[ ] Emeritus (with departmental or center authorization to continue participation in research, additional documentation may be uploaded when you upload this form)
[ ] Other [ ________________________________________________ ]

2. DEPARTMENT/CENTER:

3. HIGHEST DEGREE EARNED: ____________________ YEAR: ____________________

4. JUSTIFICATION:
   From the list below, please indicate why you are an appropriate candidate to serve as a PI for the type of research you have requested.
   ___ Experience serving as a Co-Investigator, collaborator or scientist on a previous protocol with [ ] IRB, [ ] IACUC, [ ] Biosafety, [ ] SCRO
       Please explain:
   ___ Served as a PI on a previous UW-Madison protocol with [ ] IRB, [ ] IACUC, [ ] Biosafety, [ ] SCRO
       Please explain:
   ___ Demonstrated ability to carry out the responsibilities of a PI, including meeting administrative management of studies with [ ] IRB, [ ] IACUC, [ ] Biosafety, [ ] SCRO
       Please explain:
   ___ Other [ ________________________________________________ ]
       Please explain:

   Provide additional information about your experience and qualifications to help support this request.
The completion and approval of this form pertains solely to your request to serve as Principal Investigator for the Research Oversight Committee(s) selected.

Applicant Title__________________________________________

Applicant Signature______________________________________ Date____________________________

Department or Center Director/ Chair/ Dean Approval

By signing this form as a department or center director, chair, or dean, you are certifying this individual has the necessary qualifications to serve as PI.

Please note: Your signature authorizes this individual to request PI status for all groups selected in question 1. If that is not your intent, please state your recommendations and/or limitations below.

Title__________________________________________ (department or center director/chair/dean)

Print Name: _______________________________________

Signature__________________________________________ Date____________________________

___ Are there any recommendations or limitations (such as the individual should only be permitted to serve as PI on minimal risk studies).

Yes No

If yes, please explain:

Please select the group(s) for which this person can be a PI: [ ] IRB [ ] IACUC [ ] BIOSAFETY [ ] SCRO
University of Wisconsin-Madison
IBC Approval for Principal Investigator (PI)
On a Biological Safety Protocol

The completion and approval of this form pertains solely to your ability to serve as Principal Investigator on a biosafety protocol. Submission of this form to the Institutional Biosafety Committee (IBC) does not replace the formal campus designation process to serve as a Principal Investigator on an extramural grant proposal, nor does it grant you any of the benefits of campus-designated PI status.

PI Name:
Title:

IBC Decision:
Date:
Contingencies:

Justification:

Signature IBC Chair _______________________________ Date ___________________

Copyright © 2013 UW-Madison Institutional Biosafety Committee