

## Chapter 2 IBC Review and Approval Process

The Institutional Biosafety Committee (IBC) reviews all funded and unfunded research involving the use of recombinant DNA, microbial pathogens and mammalian cell lines. All proposals presented from the laboratory of a Principal Investigator (as defined in Chapter 1 and below) shall be treated as if they belong to that Principal Investigator.

For the purposes of this proposal review format, a Principal Investigator (PI) shall be regarded as the ultimate, single point of accountability and responsibility for a given laboratory. A Principal Investigator is defined as, i) a rank of faculty member, ii) who has assigned laboratory space and iii) who is ultimately responsible for the work carried out in such space.

The review format consists of a Memorandum of Understanding and Agreement (MUA) form on which the PI must describe the nature of the research and include the following information:

- what procedures are being carried out;
- what biosafety practices are employed;
- where each aspect of the work is being done; and
- and, who are the researchers, lab workers and collaborators.

The PI must complete an MUA form for all research funded or unfunded. The PI must also obtain IBC approval before changing any variable which may increase the biosafety precautions necessary for the research. The IBC signature is required on Sponsored Projects Proposal Routing Sheets. Any IBC member may sign the Routing Sheet.

As a working principle, PIs must decide if a new agent or protocol poses any new or increased risk from those indicated in the currently approved proposal. If there are new or increased risks (or if there is any doubt or question), approval must be sought prior to implementing the change. Approval must be sought and obtained from the IBC prior to the initiation of work involving any of the following:

- new organisms such as viruses, bacteria, or fungi
- any agent listed on the CDC Final Rule: "Additional requirements for facilities transferring or receiving select infectious agents" (See Appendix 5)
- new vector systems (including plasmids)
- work with non-human systems being changed into work in human systems
- work with new cell lines
- changes in constructs or systems that result in significantly higher titers
- enhanced replication or infectivity
- expression of toxic products
- cloning and expression of more than two-thirds of a whole genome
- new or altered procedures that pose increased risk of aerosol or other type of exposure

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The IBC reviews MUAs monthly during the academic year. After Committee review and approval the PI is sent a letter of approval and a copy of the signed MUA form. These documents should be kept on file with the research proposal in case a granting agency requests information about the IBC review. Occasionally, the IBC has questions about MUAs and will request additional information from the researcher prior to approving the MUA. Refer to the flow chart.

MUA forms are available from the IBC Office (Life Sciences South Room 333, P.O. Box 210106, phone: 621-3441) as well as in most departmental offices. The MUA is available on-line at the IBC homepage (<http://128.196.124.153/biosafetyfolder/home.html>). A user name and password are required to access the MUA page and can be obtained by calling 621-5279.

## Quiz

1. The letters IBC stand for the Institutional Biosafety Committee.
  - True.
  - False.
2. According to the IBC definition of a Principal Investigator, the person must:
  - Be a faculty member.
  - Has been assigned laboratory space.
  - Ultimate responsibility for work carried out in the assigned laboratory space.
  - All of the above.
3. It is not necessary for Principal Investigators to complete a Memorandum of Understanding and Agreement form if the proposal is not funded.
  - True.
  - False.
4. The Memorandum of Understanding and Agreement form (MUA) includes all of the following except.
  - Description of the project.
  - Biosafety containment (physical and biological) and biosafety practices used to reduce risk of laboratory acquired infections.
  - Breakdown of all funding sources and amounts.
  - Acknowledgment of Principal Investigators biosafety responsibilities.
5. An electronic MUA form available at <http://mua.ibc.arizona.edu/> must be submitted to the Institutional Biosafety Committee staff prior to submitting a Sponsored Projects Routing Sheet for signature under the DNA/Microbial Pathogens section.
  - True.
  - False.
6. The IBC is responsible for reviewing all research involving the use of:
  - Microbial Pathogens.
  - Recombinant DNA.
  - All cell lines.
  - Microbial Pathogens and Recombinant DNA.
7. The IBC reviews U of A courses involving recombinant DNA, microbial pathogens (including human blood, fluids, tissues, or bone), and field trips.
  - True

- False
- 8.** The form used by the IBC for reviewing U of A courses involving recombinant DNA, microbial pathogens (including human blood, fluids, tissues, or bone), and field trips is called:
- Memorandum of Understanding and Agreement Form
  - Teaching Lab and Field Course Biosafety Review Form
  - Field Course Risk Assessment Form
  - None of the above.
- 9.** Among the reasons why an existing MUA approval must be resubmitted to the IBC for review include:
- Considering use of a new organism such as a virus, bacteria or fungi.
  - Considering use of a new vector system (including plasmids).
  - Considering use of human systems from non-human systems.
  - All of the above.
- 10.** Once the IBC approves an MUA, the following documents are sent to the Principal Investigator.
- Electronic confirmation to Principal Investigator.
  - Original of signed IBC Approval Letter listing proposal name, Principal Investigator, sponsor and date of approval.
  - Signed copy of MUA.
  - All of the above.