



Biosafety Committee

WAYNE STATE UNIVERSITY shRNA CORE FACILITY PROPOSALS

Procedures for Submission and Approval

If you are planning to work with shRNA clones received from the Core Facility, please note there is a special review process for this type of work.

Click the upcoming [IBC Meeting Schedule](#) (click on highlighted text to be forwarded to the OEHS/IBC website) to view 2011 dates.

Submit applicable forms to the Biological Safety Officer, Office of Environmental Health and Safety, campus address: 5425 Woodward Avenue, Suite 300. Contact the WSU Biosafety Officer at 577-1200 for more information.

Institutional Biosafety Committee (IBC) Review Process Questions and Answers

1. Will the IBC require that the PI file a protocol application and safety procedures with the committee before receiving the clones?
Yes, the PI should submit an IBC Biological Agents User Application (BAUA) form, lab and procedure-specific standard operating procedures (SOPs), and a Lentivirus Questionnaire for IBC review and approval prior to receiving material from the Core Facility. IBC approvals are good for three years, at which point, if the project is ongoing, a new IBC application and SOP would need to be submitted for IBC review and approval.
2. Is it sufficient that the Core keep a distribution log and notify the Biosafety Officer / IBC as clones are distributed?
No, the Core must receive a copy of the PI's IBC approval letter before clones are distributed.
3. Should the Core Facility establish BSL2/ BSL2+ protocols, approved by the Biosafety Officer/IBC, for routine use of these reagents on campus? The Core would use these protocols for ITS OWN research activities and would provide sample BAUAs and SOPs to investigators who receive clones from the Core.
Yes, a Core Facility BAUA and SOP were approved by the IBC on 5/29/09 (IBC # 05-50-09). This approval is set to expire on 5/29/12, at which time a new BAUA and SOP must be submitted to the IBC. A PI who wishes to request one or more shRNA constructs (bacterial clones or lentiviral vectors, some of which exhibit possible oncogenic properties), available either as bacterial DNA stocks or as packaged lentivirus preparations, will need to submit a BAUA and lab- and protocol-specific SOPs to the IBC, as noted above. The IBC requires a PI to provide a concise but detailed research summary describing potential biohazards. PI's should avoid general descriptions of the projects or reagents and should supply specific information about the potential biohazards of the reagents and experiments.

3. What types of experiments would require up-grading from the BSL2 to BSL2+ biosafety level?
The IBC recommends that procedures using material from the Core Facility involving lentiviral vectors be performed using BSL2+ practices. BSL2 practices will be acceptable if the PI only intends to use an shRNA construct in plasmid form.

**BSL2+ (expanded) Practices to be used in BSL2 Facilities
Wayne State University Office of Environmental Health and Safety,
as Recommended by the National Institutes of Health**

BSL2+ practices include:

1. restricted lab access to essential staff* only when experiments are in progress
2. infectious waste is decontaminated prior to removal for off-site disposal
3. lab door is kept closed when experiments are in progress
4. needles and syringes or other sharp instruments should be restricted except if there is no other alternative
5. all open manipulations of infectious agents are to be done in a biosafety cabinet
6. suggest using plastic backed sorbent pads in biosafety cabinet, if feasible
7. spill procedures are developed and posted in lab
8. protective lab clothing (i.e., solid front wrap-around gowns) is worn when in the lab
9. sealed rotors or sealed bucket covers must be employed when centrifuging biohazardous material

*Essential staff are those that are listed as part of the project. Only essential staff personnel are allowed in the lab when experiments with BSL2+ agents are in progress.

Reference: CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (2009)

4. Under what conditions should serum surveillance of viral infection (i.e., by commercial p24 ELISA assay) be used to monitor laboratory workers? NIH does not require this for BL2 level lentiviral work and it is up to the local IBC to decide if it is required for BL2+ work.

The IBC will recommend such monitoring on a case-by-case basis, as part of the application review process.

5. Once initial approval is given by the IBC, does the PI need to resubmit a whole new BAUA and SOP and go through the full IBC review and approval process if he/she wants to work with new shRNA constructs?

Not necessarily. The first step when requesting new shRNA constructs (clones) is to submit an IBC Protocol Amendment/Update form. This document is reviewed by the IBC Chair and Biosafety Officer. If there are no additional safety issues that warrant full IBC review, the addition of the new constructs will be approved administratively by the IBC Chair. If, however, the new constructs create a new safety hazard (e.g., initially using only plasmids but now want to use lentiviral vectors; use of clones exhibiting possible oncogenic properties) or if new experimental procedures are introduced that create new hazards (e.g., initial project included only in vitro experiments but now want to perform in vivo work - this modification creates new hazards such as animal injections and viral shedding), a recommendation would be made to submit a new BAUA and SOPs for full IBC review.

6. How should shRNA constructs be removed/ transported from the Core Facility to my lab?

All bacterial stocks or lentiviral preparations must be transported in "secondary" containment. The conical tubes or cryovials holding your constructs will need to be placed in a covered/ sealed container (example: a Tupperware container with snap lid) that can hold the materials in an upright position and prevent spillage if dropped.