

Dear Investigator,

This letter is sent on the occasion of your yearly laboratory assessment to suggest that you review the status of your research program with respect to the Institutional Biosafety Committee (IBC). If your research is taking a new direction, it may be an excellent time to submit a new application to Environmental Health and Safety (EHS) for consideration by our Committee.

The IBC aspires to serve the Wake Forest University research community by supporting its work, and by avoiding any unnecessary barriers to its conduct. This committee of volunteers works very hard to promote a safe environment for members of your research group, and to fulfill oversight requirements that are a necessary prerequisite for the institution to continue to receive federal research funding. IBC members understand that the conduct of biomedical research involves a tremendous amount of paperwork. Our EH&S colleagues have worked to provide additional investigator support for the process of IBC application and approval, with the goals of easing administrative burden, promoting IBC communication and compliance, and improving biosafety for your research team.

A variety of resources are readily available to assist investigators through the application process:

- IBC Protocol Analyst, [Eric Steelman](#) can provide onsite assistance for the initial application and facilitate the review process.
- Both Bernie Menuey and Eric Steelman can be reached through 6-9375.
- The primary link for the IBC as well as Environmental Health and Safety information can be accessed via [Biosafety Program of EH&S](#)
- Links that may be useful to you:
 - [NIH Recombinant DNA Guidelines](#)
 - [ABSA Risk Group Classifications](#)
 - [Bill of Lading](#) (internal document for transport of samples between campuses)
- Additional forms, program descriptions, etc. can be accessed through the primary webpage of [Environmental Health and Safety website](#)

Our committee has full meetings quarterly, dates are posted [<http://www.wakehealth.edu/EHS/EHS-Primary-Programs/IBC-Meeting-Schedule.htm>]. We ask that investigators submit new applications for review one month in advance of an IBC meeting to allow time for administrative review, followed by committee member review. Within 3 weeks following submission, the EHS team and the IBC reviewers will perform their review and submit any additional investigator questions to be answered before your application is considered at a meeting. If your application involves recombinant DNA or expedited review, we can review that protocol at a called meeting. We understand that there are occasions when rapid IBC application review and approval are necessary to secure grant funding, and the IBC will make every effort to assist in these special circumstances. We ask that investigators plan ahead for IBC approval of new research, and remind you that final approval of protocols by the Institutional Animal Care and Use Committee (IACUC) requires prior IBC approval.

It is in the interest of all involved that IBC applications be reviewed and approved expediently, and we would like to provide some insight into what IBC reviewers are looking for particularly. It is very helpful

for biosafety application reviewers to read a general overview of the research program under consideration (Application Section 2) that is perhaps 2-3 paragraphs long, and provides context for the review. "Our lab/research group is interested in understanding. . ." Comment on what sort of general approaches/techniques are used in your research is also helpful in this summary. "Our research involves work with human subjects/transgenic mice/molecular biology and tissue culture techniques/x-ray crystallography/electrophysiology techniques. . ." We encourage you to make sure that your application is complete, with all sections filled out. Pay special attention to room numbers and storage locations, and waste disposal estimates, this information is often left out leading to needless application review delays. We understand that estimates of waste generation are approximate, they allow application reviewers to determine if your group generates very large volumes of waste that may require special EHS management. For questions about how to complete the application, contact Protocol Analyst Eric Steelman.

Investigators practiced at reviewing biosafety applications look for specific areas of concern, and having these clearly addressed is extremely helpful. If a research program poses any potential biosafety risk to the non-research community, it is of special interest. If your research group studies an infectious pathogen using a "model strain" or "laboratory strain", is that strain actually attenuated to be completely non-pathogenic, or can it still cause disease? If a pathogen under investigation presents a special risk to particular groups of people, are any of those people members of your research group? (This is of special importance if pregnancy confers special disease risk.)

Recombinant DNA and viral vectors: If a gene is being transferred by viral vector, is that gene a known oncogene, or not? Alternatively, is it associated with any human disease? If a research program involves any virus-mediated gene transfer, it is important to describe the vector system carefully, and we encourage you to briefly outline the safety features of the vector system. Bear in mind that not all committee reviewers have a background in molecular virology. Will the gene transfer vector be a lentivirus/adenovirus/ adeno-associated. . . virus vector? Is the lentivirus system a highly-developed, commercially available system or a system that was developed by a colleague's lab some time ago? Is it a first, second, or third generation lentivirus system? Resources regarding lentivirus systems:

[NIH OBA Guidance on the use of Lentiviral vectors](http://www.nih.gov/oba/guidance-on-the-use-of-lentiviral-vectors)

http://www.fda.gov/ohrms/dockets/ac/01/slides/3794s2_02_takefman/index.htm

Emergency Plans for Accidental Spills or Exposures: EHS offers some basic templates for investigator use, but these plans should be tailored for your research program. This very important section often lacks the detail that committee reviewers would like to see.

The IBC and EHS team seeks to advance the important work that you do to generate new knowledge and promote human health. We hope that these suggestions will be useful, as we work together to provide a safe environment for all members of your research team and for our community.

Sincerely,

Timothy R. Peters, MD
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Chair, Institutional Biosafety Committee

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Vice-Chair, Institutional Biosafety Committee

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