



November 23, 2005

Matthew Fox and Jim O'Halloran, Co-Chairs
Northeast District Council
1407½ - NE 56th Street
Seattle, WA 98105

Dear Matt and Jim,

I am responding to your October 17th letter on behalf of President Emmert.

Your letter supports and advocates for independent regulation of Seattle biosafety laboratories and informing the public of incidents that occur at these facilities. The model you recommend for independent regulation is the "Cambridge Bio-Safety Committee" that is part of the Department of Public Health in Cambridge.

First let me say that the University Administration shares your concerns about assuring the health and safety of our neighbors, faculty, researchers, staff, and students. Through a number of mechanisms we are currently providing a high level of protection. I would like to highlight some of these protections and our relationship with Public Health - Seattle and King County because this type of regulation and protection was not present in Massachusetts when the Cambridge model was created.

- The University of Washington and Public Health currently work together on public health protection.

The University works closely with Public Health - Seattle and King County on several issues and projects. For example, the UW Hall Health Center is a sentinel site for them in watching for any increases in certain diseases and syndromes. We jointly worked with their epidemiologist in developing the University of Washington SARS policy. They have advised our campus Advisory Committee on Communicable Disease regarding requirements for international students and immunizations. We forward information on reportable diseases that are seen in our clinics, and often work in concert with Public Health on campus issues dealing with diseases in our campus population, such as chickenpox, whooping cough, and tuberculosis. The local epidemiologist has met with us as we explore necessary protective strategies and requirements for infectious disease research. We are currently working with them on developing quarantine plans and strategies for pandemic flu. In addition, our faculty at the School of Public Health and Community Medicine train the practitioners in the public health system, work closely with them at the local, state, and federal levels and are considered leaders in epidemiological studies. Some of the research around which you have expressed concern is actually linked with the advancement of public health protections.

- We appropriately inform Public Health of reportable diseases at the University of Washington.

If any of our work with certain reportable research agents were to be associated with any illnesses, we would not only report to the local public health department but also to federal health and law enforcement authorities. That requirement is mandated by law for work with select agents, such as tularemia. Should any workplace incidents be a public health threat because of communicability to the general public, University officials would not only immediately notify the authorities but also work closely with them as they determine what information should be released and what actions would be appropriate.

For your information, there have been cases of tularemia in community members seen in our hospitals, unrelated to any workplace exposures, as this is a disease found naturally. This information is not released to the public because it is private health care information, which is protected by federal law.

I point these facts out for three reasons: first, the University does inform public health of any reportable diseases it encounters. Secondly, patient information is private and unless there is a threat to the public's health, such information is not released by the public health department, except as cumulative data. The University cannot release patient data. And lastly, the University clearly seeks every opportunity to work with Public Health to carefully plan for any disease contingencies, particularly anything related to the research work we do. We are partners with them in public health protection.

- Proposed research with infectious agents is carefully reviewed at the University of Washington.

The University operates under very strict guidelines from the National Institutes of Health as it conducts its research. While Institutional Biosafety committees were historically established to assure the careful review of recombinant DNA projects, the University has a history of expanding that mandate to include the careful review of research proposals involving infectious agents as well as recombinant DNA. Research proposed for select agents or toxins are all reviewed by oversight bodies mandated by the federal government. Such requirements did not exist thirty years ago when the Cambridge Committee, to which you refer, was formed. At the University, depending on the type of research being proposed, reviews will not only involve the Institutional Biosafety Committee (IBC), but also the Institutional Animal Care and Use Committee (IUCAC) and the Human Subjects Review Committee. Researchers must indicate what and how they will protect themselves and others, as they conduct their research, and they are not approved to go forward with their research until all plans, facilities, and practices are in place. For example, certain aspects of proposed research for the 1918 influenza studies planned at the UW have not been approved by the IBC since appropriate facilities that offer the necessary level of protection are not available. The committees do not "rubber stamp" research, but rather carefully review and often demand specific protections and processes be put in place, and they even deny research when such protections are not possible.

A member of Public Health - Seattle and King County currently serves as a member of our IBC. In addition, we now have three public members serving on the committee, who do not have any self-interest in the research. The membership of the IBC must be sent to the Office of

Biotechnology Research and must meet federal requirements. Our IBC does meet these federal requirements, and exceeds them with respect to public membership. Any researcher who serves on the committee and whose work is to be reviewed by the committee is recused from the discussions and cannot vote. In addition, the meetings are open to the public.

Information on the University's biosafety program can be found on the EH&S website, www.ehs.washington.edu.

Your letter references the Cambridge committee, and the type of oversight you believe they provide is exactly the charge given to the UW Institutional Biosafety Committee. Based on a discussion I have had with Sam Lipson, Director of the Cambridge Committee, it appears that what they have in place at this time would not provide any significant improvement in oversight, requirements, and expectations than those that currently exist at the University. It is very important to note that the guidelines, oversight, restrictions and mandates under which research laboratories conduct their work are very extensive, and creating an additional committee, such as the Cambridge committee at the UW, would probably be redundant and not provide any additional protection to the public.

While the University Administration does not believe another committee is necessary, they have asked that I continue to recruit for an additional public member for appointment to the UW IBC. If some of the Northeast District Council members would be interested in such a position, they could send a letter of interest and resume directly to me for completion of an application/ screening and interview process.

While I appreciate your concerns, I sincerely believe that the University of Washington, through its committee processes, as well as through ongoing work by biosafety experts, industrial hygienists, and occupational health nurses in the Environmental Health and Safety Department has an oversight process that protects the public.

I hope this answers most of your questions and I thank you for calling my attention to your concerns and your suggestion. Please feel free to contact me at 206-616-4146 if you have additional questions.

Sincerely,

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cc: President Mark Emmert, UW President
Weldon Ihrig, UW Vice President
Theresa Doherty, UW Assistant Vice President
Greg Nickels, Seattle Mayor
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