

**University of Wisconsin-Madison Institutional Biosafety Committee**  
**Minutes of Regular Meeting – Closed Session**

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**Date** 7 December 2005

**Present** Albertini, Garcia-Rivera, Jaeschke, Klein, P. Lambert, Malkovsky, Paskewitz, Schultz-Cherry, Sorsa, Splitter, Welter, West, Woods

**Consultants** Berger, Griffiths, Kenney, M. Lambert, Wunder

**Call to Order** The meeting was called to order by Professor Paskewitz, Chair, at WARF Office Building room 132 at 1:35 p.m.

**Announcements** The IBC meeting is open to the public.

**Closed Session** A motion was adopted unanimously to move into closed session to discuss research protocols containing proprietary information, pursuant to Wisconsin Statutes sections 19.85(1)(d) and 19.85(1)(e).

**Review of Minutes** The minutes of the 2 November 2005 IBC meeting – closed session were adopted unanimously.

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**Record:** 10040  
**IBC NUMBER:** SC03-076R, amendment (revised)  
**NAME:** Yoshihiro Kawaoka, Professor  
**DEPT:** Pathobiological Sciences, SVM  
**PROTOCOL TITLE:** *Genetic engineering of influenza virus*  
**REVIEWERS:**  
Primary: P. Lambert  
Secondary: G. Splitter  
**MOTION:** Approve, with requirements  
**MADE BY:** P. Lambert  
**SECONDED BY:** G. Splitter  
**COMMITTEE ACTION:** Adopted unanimously by voice vote  
**PROJECT LEVEL:** 3, 3(RG3), 3-N, 2, 2(RG2,PIM), 2-N, INA, HBP  
**REFERENCE:** III-D  
**NOTES:**

- This protocol amendment was reviewed by the IBC at the 11/2/05 meeting and action was tabled pending receipt of information regarding details of procedures. Dr. Kawaoka responded by providing a revised protocol and BSL-3 manual, and a response to the points of the IBC memo. The materials distributed to the IBC included these documents and the IBC memo. The changes to the manual and protocol satisfy the IBC's request for more detailed information.
- A custom-built negative pressure primary containment barrier will be used to house non-human primates as recommended by CDC guidelines for laboratory work with noncontemporary human influenza viruses. This HEPA-filtered structure will enclose the cage rack as well as personnel when they work with these animals. Personnel will still need to wear full PPE. The benefit of the enclosure is offset by some logistical difficulties and the

PI prefers not to use it for other animals. Furthermore, the suite's redundant system HEPA filtration provides a strong containment measure.

- The IBC discussed the control on work with these high risk agents. Animal care is provided by the research personnel, access to agents is restricted and training is held to a high standard since they are part of the select agent program. Personnel will gain initial experience in handling rhesus macaques while working with a low risk agent. Out of concerns about the difficult nature of these animals, the IBC requires that personnel not work alone while conducting procedures with these animals.
- The revisions included a slight change concerning treatment of floor drains. The options are to treat the drain routinely with disinfectant or to cap it.
- The BSL-3 manual has sections dealing with 1) HPAI isolated in 1997 or earlier (excluding elements derived from the 1918 strain) and full length Ebola DNA; and 2) contemporary HPAI and avian-like viruses, recombinant influenza expressing 1918 genes, and SARS coronavirus. The difference between these sections is that precautions are enhanced for the latter. Included in the 2<sup>nd</sup> section is a description for work with large animals such as NHP. The HPAI strains isolated in 1997 should be included with the contemporary strains.
- The following points are some of the significant enhancements to be used:
  - A primary negative pressure barrier (HEPA filtered) for macaques
  - PAPRs and N100 respirators instead of N95s are required
  - Eye protection (face shield or goggles) is required.
  - Use of Tamiflu is strongly encouraged when working with agents and required for procedures in which significant aerosol production is likely and which involve large animals.
  - Personnel receive the annual influenza virus vaccine, which should provide some protection against the 1918 virus, but not H5 strains.
- Under the non-enhanced procedures, eye protection is available and required for specific but not all situations. The IBC, however, requires eye protection to be used at all times in the BSL-3 facility. The Safety Department can provide guidance on the appropriate type of eye protection to be worn for various situations.
- Justification was provided for use of EtOH for surface disinfection. The protocol has been changed to indicate saturation when using EtOH. Bleach and phenolic disinfectants are also available and are used for cleaning the floor.
- Detailed procedures for following up an incident are described. Clarification was sought from CDC concerning their wording in the interim guidance regarding baseline serum collection and storage but disagreement within the CDC is apparent. Information from baseline sera with regard to the 1918 virus would be limited due to confounding with circulating strains and annual influenza vaccinations. The serum banking process that is available through the Occupational Health Program protects an individual's privacy. Dr. Kawaoka opposes baseline serum storage and the IBC concurred. Serum testing will be done in the event of a possible exposure, with detection based on PCR with specific viral primers.
- The IBC's recommendation regarding developing informed consent for use of Tamiflu in conjunction with consultation with a physician was not included in the revision. The described procedure, having an antiviral drug available for certain circumstances, is in accord with CDC's guidance. The IBC wants Dr. Kawaoka to develop an informed consent process for discretionary use of antiviral drugs; also available are medical assessment and counseling.
- The protocol was approved with requirements concerning the following points:
  - Eye protection must be worn at all times in the BSL-3 facility.
  - Floor drains must be capped if they cannot be reached to add disinfectant.