VICE PRESIDENT FOR RESEARCH

THE UNIVERSITY OF TEXAS AT AUSTIN

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February 15, 2007

Mr. Allan C. Shipp, MHA
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Mr. Shipp:

This is a follow-up to the two telephone conference calls of January 30 and February 8 between your office and the Office of Environmental Health & Safety (EHS) at The University of Texas at Austin (University). As per the National Institute of Health request, I am enclosing a packet of information related to the lab incident that occurred on April 12, 2006 in Dr. Robert Krug's BSL3.

In addition to the specific information you requested, the University has taken several proactive steps to improve the education of researchers in the area of recombinant DNA research. Additionally, a rapid response team has been assembled, an improved incident reporting form has been created, and Standard Operating Procedures are being enhanced (See Appendix 6 of the enclosed packet.). The information on biosafety procedures also appears on the web sites of the Office of Environmental Health and Safety (http://www.utexas.edu/safety/ehs/) and the Office of Research Support and Compliance (http://www.utexas.edu/research/rsc/index.html). With these improvements, the University has taken a significant step forward in assuring biosafety on this campus.

The University appreciates your review of our research oversight and remains committed to the highest standards of safe research. I would like to invite you and Dr. Kathryn L. Harris to visit our campus during this academic year to provide on-site training for our faculty and members of the Institutional Biosafety Committee.

Please do not hesitate to contact Erle Janssen, the Director of EHS, or myself should you need further information.

Sincerely yours,

Juan M. Sanchez, Ph.D.
Vice President for Research

Gerald R. Harkins
Associate Vice President for
Campus Safety and Security

JMS/ll
Enclosures
cc: Vice President Patricia Clubb
Dr. Erle Janssen
Dr. Lisa Leiden

NIH Documentation Request

1) Written description of the agent (including genetic insert)

2) Centrifuge make and model #

3) Photographs of the damaged safety cup or centrifuge materials

4) BSL3 biosafety SOP's (including centrifuge safety)

5) Biosafety training materials and documentation of training (including training records for Rei-Lin)

6) Occupational health requirements (including mention of how those requirements are communicated to workers in the BL3 facility)

7) Video recording of the incident

8) USDA permit and documentation

9) Copies of correspondence with local or state health departments or other local, state or federal agencies concerning this incident

10) Incident reporting SOP and form

11) IBC minutes:
   a) For the meeting at which the IBC initially approved Dr. Krug 's research
   b) For the meeting at which the incident report would have been reviewed by the committee.

12) Additional Documents

Responses to the NIH Documentation Request

1.) Written Description of the Agent (including genetic insert):

HA: A/Udorn/72
NA: A/Udorn/72
PB1: A/Udorn/72
PB2: A/Udorn/72
PA: A/Udorn/72
NP: A/Udorn/72
M: A/Udorn/72
NS: H5N1 A/Hong Kong/483/97

No viruses were used in the creation of this recombinant virus. The recombinant virus was generated using DNA plasmids. The DNA plasmid for the NS gene of H5N1 A/Hong Kong/483/97 was obtained from Not public information at the Not public information after receiving an import license from USDA. The DNA plasmids for the A/Udorn/72 genes were obtained from Dr. Robert A. Lamb at Northwestern University.

2) Centrifuge Make and Model #

From the Researcher (ersonal Infi):

"In the beginning, we bought the Beckman Allegra X-12 centrifuge and SX4750 rotor (it contains 4 buckets) with its safety caps for BSL-3. We found that this centrifuge needed 220-volt power (there was no 220v output in BSL-3). So a Beckman Allegra 6R centrifuge with GH 3.8A rotor (it contains 4 buckets and uses 110V power) was put into the BSL-3 actually. But those safety caps for SX4750 rotor were still used for GH 3.8A rotor."

The Beckman Allegra 6R centrifuge with GH 3.8A rotor was used with the SX4750 cups.

3) Photographs of the damaged safety cup or centrifuge materials:

No photographs were taken of the damaged safety cup or centrifuge materials. The damaged safety cup and centrifuge materials were disinfected, transferred to a biohazard container, autoclaved and disposed.

4) BSL3 biosafety Standard Operating Procedures (SOP) (including centrifuge safety):

See Appendix 1

5) Biosafety training materials and documentation of training (including training records for Personal Info):

See Appendix 2

6) Occupational health requirements (including mention of how those requirements are communicated to workers in the BSL3 facility):

The researchers are informed of the following occupational health requirements during their initial BSL3 training. Researchers that are not compliant may have their access withdrawn by the lab director.

The occupational health requirements for workers are as follows:

Antiviral (Tamiflu) Prescription:

Each researcher is required to obtain a prescription for Tamiflu. The researcher fills out a medical evaluation that given to an university/EHS contracted occupational health physician. The physician reviews the medical evaluation to determine if any follow-up is needed and issues a prescription. The researcher fills the prescription and stores the prescription in a lockbox in the anteroom of the BSL3 lab. The lab director periodically inspects the lockbox to ensure the prescriptions are available and not expired. In the event of an accident or suspected exposure, the researcher notifies the lab director. The director notifies the occupational health physician prior to the researcher starting the prescription.

Annual Flu Vaccine:

Each researcher is required to obtain the annual influenza vaccine at the beginning of the flu season. The researchers can get their shot at University Health Services or their physician.

Baseline Serum:

Each researcher is required to have a baseline serum taken. The lab director provides the researcher with a form that is taken to University Health Services. Blood serums are stored there.

7) Video recording of the incident:

Video recordings of this incident are not available. Video recordings are automatically deleted after 90 days.

8) USDA permit and documentation:

See Appendix 3
Permit and email correspondence with USDA and the CDC.

9) Copies of correspondence with local or state health departments or other local, state or federal agencies concerning this incident:

See Appendix 4

The local public health authority (Austin-Travis County Health Department) was notified of the event several days after the incident had occurred. This was a telephone notification, and no notes were recorded.

On January 19, 2007, the CDC Select Agent Program requested information on the incident. A response was sent on January 22, 2007.

10) Incident reporting SOP and form (as was in use at the time of the event):

While there is an internal incident reporting form, there was no external incident reporting SOP or form at the time of the incident. A form has been developed (see Appendix F) and an SOP is in development.

11) IBC minutes:
a) For the meeting at which the IBC initially approved Dr. Krug 's research:
b) For the meeting at which the incident report would have been reviewed by the committee:

See Appendix 5

At the November 15, 2005 IBC meeting, the Board initially approved Dr. Krug's Protocol 2004-10-0175 for work with rDNA agents. Dr. Krug's accompanying biosafety Protocol 2005-03-0128 was subsequently approved by the Director of Environmental Health and Safety on 7/3/05. The incident report was reviewed by the IBC on April 17, 2006.

12) Additional Documents:

See Appendix 6

In addition to the information you requested, the university has determined four institutional changes will be made to improve the safety and the conduct of research using recombinant DNA, particularly as they pertain to the process of incident reporting:

1. *Incident Report Form and SOP* [Appendix 6].
2. A *rapid response team* will be created, composed of the following individuals: Director of Environmental Health and Safety; the Chair of the Institutional Biosafety Committee, Director of Research Support and Compliance, the Biosafety Specialist and the researcher whose lab is involved. The incident report form shall be completed by this team with reports to be sent to the Vice President for Research and NIH. The team is expected to meet within 24 hours of the event documented.
3. *Training for researchers*. Training programs on rDNA research, biosafety and use of infectious agents will be installed on the university's compliance website and required in order for an rDNA protocol to be approved by the IBC. This training will provide an example of the incident report form and how it is to be completed.
4. *Centrifuge Safety Form*. All centrifuges will be required to post the new Centrifuge Safety Form.

Appendix 1

BSL3 Biosafety Standard Operating Procedures:

1) BSL3 Chemical Hygiene Plan

2) Biohazard Sign for Krug Lab

3) Krug Lab Entry/Exit Procedures

4) BSL3 Emergency Algorithm

5) Krug Response Protocol

6) Lab Safety Manual *with Centrifuge References*

BioSafety Level 3 Facility

Chemical Hygiene Plan

Table of Contents:

Important Numbers:

Contact	Campus #	Home	Mobile	e-mail
Univ. Texas Environmental Health and Safety	1-3511	Personal Info	Personal Info	ehs@www.utexas.edu
Erle Janssen University Biosafety Officer	1-3511			ehs@www.utexas.edu
Dennis Nolan BSL3 Director	2-4999			dnolan@austin.utexas.edu
Bill Cassady Building Supervisor	2-2727			billc@mail.utexas.edu

Room A (Ellington)	Contact	Campus #	Mobile	Home	
	Amos Yan, Researcher	1-6445	Personal Info		ayan@mail.utexas.edu
	Angel Syrett Researcher	1-6445			angelita@mail.utexas.edu
	Na Li (Lina) Researcher	1-6445			lina0505@mail.utexas.edu
	Ted (Chi-Tai) Chu Researcher	1-6445			chuctt@mail.utexas.edu
	Dr. Andrew Ellington Principal Investigator	2-3424			andy.ellington@mail.utexas.edu

Room B (Krug)	Contact	Campus #	Mobile	Home	
	Rei-Lin Kuo, Researcher	2-5566	Personal Info		rlkuo@mail.utexas.edu
	Karen Twu Researcher	2-5566			ytwu@mail.utexas.edu
	Dr. Bob Krug Principal Investigator	2-5563			rkrug@mail.utexas.edu

Room C (unoccupied)	Contact	Campus #	Mobile	Home	

Introduction:

Principles of Biosafety

Containment is the means by which researchers manage infectious agents and toxins in the laboratory in order to control or eliminate exposure to laboratory workers, other people and the environment. Biosafety level 3 (BSL3) containment protocols are designed to protect against airborne and high risk contact agents, especially those associated with diseases or toxins affecting humans.

Primary containment of work in the Level Three laboratory is the first step in managing and controlling substances. At this stage, the researcher must minimize exposure to the self. Primary containment is accomplished by sterile and careful microbiological technique in conjunction with the use of a Biological Safety Cabinet (sterile hood) and appropriate Personal Protective Equipment (PPE). Vaccination, when available, against infectious agents may provide added protection to the individual working in the BSL 3.

Secondary containment, or minimizing contamination of other people and the environment, is provided by the facility and its design. The air handling in a BSL3 laboratory provides negative air flow into the facility, thereby preventing agent-exposed air from escaping the laboratory. All air in the facility is HEPA filtered before exhaust. The facility design however is only as effective as the adherence to operational procedures.

Evaluation of all risks involved in working with each agent will determine the appropriate combination of elements necessary in each laboratory project. This evaluation will be performed by each individual investigator with approval reserved for Environmental Health and Safety Officers.

Definition of BSL3 Agents

BSL3 agents, for the purposes of this protocol, include all biological and toxic materials isolated into our facility for heightened safety and security reasons. The "CDC Biosafety in the Microbiological and Biomedical Laboratories" is used as the guide for the classification of agents in this facility. The agents in this facility may not be strictly categorized as BSL3 by the CDC or NIH, but, due their possible effects on humans and the recombinant nature of the work in these labs, they will be treated with full BSL3 status in this facility.

General Overview of BSL3 Operations:

Access to Facilities

Access to BSL3 laboratories is restricted at all times. Only personnel who have been fully trained will be issued keys and codes for the facility (see below "Training").

All other accessors, including observers, facilities maintenance, vendor maintenance of equipment, etc. will be informed of the risks involved with access to this facility and must have approval of the lab director in advance. Additionally, visitors must be accompanied by trained personnel who logs the entry into the sign-in sheet. Emergency access will be granted only by approval of the University Biosafety Officer. The University Biosafety Officer Erle Janssen or his designate can be reached at **471-3511** or after hours paged at Personal Info

Personnel may also be required to provide baseline serum samples before they may begin work in the BSL3. If vaccines against an agent are available they may be required for work with that agent unless justification can be produced for the IBC and written excuse from this requirement obtained from the IBC.

Training

All personnel must complete all the following training requirements before full access is granted to the BSL3 laboratory:

1). A copy of these Protocols, a copy of "Biosafety in Microbiological and Biomedical Laboratories" and Materials Safety Data Sheets (MSDS) for all BSL3 and extreme toxin agents present in the laboratory will be provided. The contents of the texts must be understood and agreed to. The last page of this Protocol will be an agreement to adhere to all rules and regulations as set forth.

2). Personnel must complete a Biosafety training course provided by Erle Janssen, the University Biosafety Officer, or his designate. Class time and information can be found at the University Office of Environmental Health and Safety site:

http://www.utexas.edu/safety/ehs/train/index.html

3). At the end of the study and classroom training, an interview will be given by the Lab Director and/or University Biosafety Officer to verify comprehension of the material.

4). More specific training will be performed by the supervisor of the BSL3 project or the Lab Director. The trainee will be partnered with this person at all times when working in the BSL3 facility until the supervisor is satisfied with the trainee's techniques and practical knowledge of the BSL3 safety practices. At no time will a trainee be granted access to the facility on a solo basis until the supervisor, the lab director, and the University Biosafety Officer have given approval by signature for this privilege on the Protocols Agreement form.

The most important element of protection is strict adherence to standards of microbiological practices and techniques. Personnel working with potential hazards must be trained and proficient in the practice and techniques required for handling these hazards safely. Each project must be directed by a faculty member or staff member who understands the potential hazards and is responsible for the training of research personnel.

Personal Protective Equipment (PPE)

Personal protective equipment is the first line of protection for BSL3 researchers. PPE in the UT Austin MBB BSL3 include;

1. A Biological Safety Cabinet (BSC)
2. Gloves (double gloving may be necessary with some agents)
3. Surgical-style full frontal coverage gown (back closure water repellent) or Tyvek-repellent full suits.
4. N-95 Racal Respirators (**P100 respirator for B. anthracis strains other than Sterne).
5. PAPR's

These respirator requirements have been reviewed for appropriate selection by the Environmental Health and Safety Office. No personal protective equipment from the BSL2 labs will be worn in the BSL3. These are to be kept separate at all times. Each project may also require more specific PPE.

Biological Safety Cabinets (BSC)

The BSL3 in MBB 3.230 are Type II-B2. All BSL3 agents will be manipulated in Biological Safety Cabinets. No containers exposed to BSL3 agents will be opened except in the BSC. Exposed containers will be sealed and autoclaved or chemically inactivated/disinfected before opening or before leaving the BSC.

Rules and guidelines for BSC use:

1. Before each session, workers should check the gauges for appropriate functioning. The gauges should register around 0.25 on the meter, although they may fluctuate between 0.25 – 0.75.

2. Gloves must be worn at all times in the BSC. When working with BSL3 agents, remove gloves before removing your hands from the cabinet.

3. The BSC must be kept meticulously clean. Use solution appropriate for the work being performed in that BSC both at the time you sit down and as necessary throughout the session. Wipe down each item before placing it in the hood.

4. Minimize the amount of material in the cabinet. Each item added to the hood decreases the hood's protective capability by interrupting the protective air flow barrier.

5. Be sure to minimize actions that might disrupt the protective airflow. Do not block any air intake grills in the BSC. Do not move arms in and out of the cabinet unnecessarily. Move slowly and methodically through the air barrier to reduce disruption of the flow.

6. It is advisable that work in the BSC should be performed as a continuum from clean to contaminated with waste containers at the very end. This prevents cross contamination.

7. All BSL3 waste generated in the BSC will be sealed in autoclavable waste containers and decontaminated externally with the appropriate sterilizing agent before removal from BSC.

8. If equipment such as sonicators or stirrers which may disrupt air flow are used, place them in the back 1/3 of the cabinet to reduce the effect.

9. The use of a vacuum in the BSL3 BSC should be done with great care. Avoid the use of a vacuum pump if possible. There is no building vacuum system, therefore the vacuum pump is located under the BSC. The pump has a secondary trap and a HEPA filter. This requires inspection with each use. The trap should have the appropriate chemical sterilizing agent specific to each agent. This is to be added to the vacuum trap before work begins each time you enter the lab. At the end of each research session, the vacuum trap must be very carefully disconnected from the pump and moved into the BSC. Additional steps such as agitation of the contents to assure complete exposure to chemical sterilizing agents and incubation time to allow for complete sterilization can occur. Contents must then be disposed of as appropriate for the agent sterilized and the agents used to accomplish this. Disconnecting flask stoppers and hoses from the flask will inevitably lead to a spill. Disconnect only from the pump and move flask and tubing into the hood for decontamination.

10. When finished in the BSC, all materials and sealed disposal containers will be wiped down with appropriate sterilizing agents before removal from the cabinet. Materials and wastes will be stored or disposed of appropriately in the BSL3. All surfaces should be meticulously cleaned with sterilizing agents specific to the BSL3 agents present.

Operation of the BSL3:

General Rules and Guidelines for BSL3 Activity

1. Signs on the doors of each lab indicate the types of hazard, names of personnel responsible for this space and phone numbers, and requirements for entry into the area.

2. All personnel entering the facility must check the air pressure gauges for the facility and the BSC in their lab each time of entry. Acceptable parameters are indicated on the gauges by red needles. All personnel should also check for BSC certification before use. Negative air pressure indicators should be checked and logged before entering any of the sub-rooms.

3. All PPE worn in BSL2 will remain in BSL2. All PPE worn in BSL3 will remain in BSL3.

4. Any alarm will be treated as a facility failure. All personnel will secure current work, decontaminate appropriately, and exit the facility until it can be determined what has prompted the alarm.

5. Hands will be washed before gloving and beginning work, when work is complete, and before touching any door handle or exiting the facility.

6. Eating, drinking, smoking, and applying any cosmetics is strictly forbidden.

7. Mouth pipetting is prohibited. A variety of mechanical pipettors are provided.

8. All efforts to reduce the production of aerosols will be made. This effort will include, but is not limited to vortexing in sealed containers, using sealed rotors for centrifugation and working only in the biological safety cabinet as well as other project specific techniques.

9. No glass or sharps will be used in the BSL3 laboratories unless no alternative is available. Disposal of these items must be arranged through the University Safety Office or the Lab Director.

10. All procedures with concentrated toxins or open cultures will be performed in the BSC or in sealed containers.

11. Biological Safety Cabinets will be inspected and certified annually. This will be arranged by William Cassady, the building supervisor. Access will be granted for this purpose under access protocols of this manual.

12. Solid waste materials exiting BSL3 facilities must be autoclaved at greater than 121°C for at least 45 min. Liquid wastes must be disinfected and disposed of accordingly for that agent. (see 'Treatment of Biohazard Waste' below)

13. Animals, plants and other materials not directly involved in the research will not be permitted in that area.

Entry to BSL3 (General):

1. Entry to the BSL3 facility from the general hallway will be by keypad access only. The codes will be issued only to those researchers who have completed training and approved by the necessary authorities. This code will be changed regularly.

2. The primary (hallway) door is secured with an NX8E alarm system. Upon initial entry, check to see if the alarm has been armed. Disarm the alarm by entering the given security code. You will have 30 seconds to disarm the alarm.

3. When entering the BSL3, be aware of the air pressure gradient. A door alarm is integrated into the first, primary door which sounds if the door is left open too long (usually about 30 seconds). A secondary alarm sounds if both the primary door and the secondary door (between shower room and anteroom) are open at the same time. Make sure the door behind you is closed and secured each time you enter or leave.

4. In the primary room (shower room), BSL2 lab coats and any unnecessary materials will be shed. Lockers are available in the shower area. Any material passing through the second door may leave the facility only through the autoclave or after appropriate sterilization.

5. Entering the secondary door should be done only after carefully checking the air pressure on the magnahelic gauges to the right of the door. The pressure on the magnahelic should be within **-0.2 and –0.3** with the doors closed. An audible alarm should be going off if the readings are not with in these set limits. If this is not the case, please notify personnel who may still be in the BSL3 facility by phone and exit the facility. Notification of the University Biosafety Officer at 471-3511 or (after hours) pager #875-0911 should be done immediately.

6. On entry into the secondary anteroom, after checking that the door is securely closed, water repellent gowns with back closures or full Tyvek suits, gloves and respirators will be donned. Depending on the application, a base-layer glove may be worn as a "second skin" over which "research" gloves can be put on. These items will not be removed, except for replacement of soiled gloves, until exiting procedures are begun.

7. On entry into the laboratory itself, the door will be opened for the minimal periods only necessary for access. No research gloves will touch the door handle.

9. All equipment will be checked for airflow, temperature, seals, water (cleanliness and volume in water bath) , liquid nitrogen content with each entry into this lab. Any discrepancies and corrections will be noted in the log before leaving. Anything that needs further attention will be brought to the attention of the Lab Director as soon as possible.

Exiting BSL3

1. Remove gloves and wash hands or base layer gloves thoroughly before leaving labs A, B, or C.

2. Remove gown and hang on hook to be reused or place in an autoclavable biohazard waste bag. If a gown is to be reused, remove unlatching at the back of the neck and pulling the gown off by the front of the chest with the arms coming out last. This should result in the gown being inside-out. This minimizes any contaminated surfaces from being exposed to the outside or personnel. Gowns should be replaced often to insure no inadvertent contamination.

3. Remove respirator and goggles and remaining PPE

4. Scrub hands with bacteriostatic, virocidal, soap.

5. Nothing will leave the BSL3 facility in your hands except in appropriately sealed secondary containers that have been externally decontaminated. Everything else must leave through the autoclave or be chemically sterilized. A fax machine is provided for sending written notes out. If notes must leave, they will must be in individual zip lock bags taped shut and wiped down with appropriate sterilizing agent. Disposal of these notes must be back in the BSL3 biohazard waste for proper disposal treatment. Please keep these to the absolute minimum.
   No notebooks or other documents that you wish to use in the future outside of the BSL3 facility will exit except through the autoclave.

6. BSL3 agents or products will leave the BSL3 only in IATA or FCR approved containers for shipment of BSL3 and other infectious agents.

Room A (HIV / Select Agents / Toxins) Specific Guidelines:

All toxin and select agent work must be performed in the biosafety cabinet. To prevent aerial contamination, all toxins and agents will be be put into solution upon arrival and aliquoted into working volumes. The concentrations, volumes and locations of the stocks

must be documented. Each access of stocks will be documented in the appropriate agent log.

No toxin work above set values will be done without a partner. These maximum values are set for each agent by the University Biosafety Officer when the agent is added to the protocol. The partner is not for active participation, but as backup for unforeseen needs or circumstances and to observe and warn of possible sources of exposure to the person actively undertaking the research. He is also the person responsible for immediate response in the event that containment has been breached.

Visitors into Room A (HIV / Select Agents / Toxins) will be required to sign in on the log sheet near the door.

Room B (Influenza) Specific Guidelines:

See Appendix

Room C Specific Guidelines:

Room C is currently unoccupied

Treatment and Decontamination of Specific Agents:

Bacillus anthracis (Sterne):

1. 2.5% sodium hypochlorite (be aware that bleach is not a100% stock solution and varies concentration by manufacturer) and 0.25 N sodium hydroxide.

2. Exposure time is a minimum of 30 minutes.

Botulinum toxin:

1. 2.5% sodium hypochlorite (be aware that bleach is not a100% stock solution and varies concentration by manufacturer) and 0.25 N sodium hydroxide.

2. Exposure time is a minimum of 30 minutes.

Clostridium botulinum:

1. 2.5% sodium hypochlorite (be aware that bleach is not a100% stock solution and varies concentration by manufacturer) and 0.25 N sodium hydroxide.

2. Exposure time is a minimum of 30 minutes.

HIV:

1. Vesphene will be diluted with water at a ratio of 1 to 64
   This dilute solution does not lose its effectiveness over time as bleach does.

2. Bleach will be diluted with water at a ratio of 1:10. This dilute solution is effective for the day of preparation only. It must be prepared at the beginning of each work day in the BSL3. This solution is for cleaning surfaces only. Undiluted bleach should be used for decontamination of HIV-1 itself.

3. Exposure time to chemical sterilization is a minimum of 30 minutes.

Influenza:

1. Vesphene will be diluted with water at a ratio of 1 to 64
   This dilute solution does not lose its effectiveness over time as bleach does.

2. Bleach will be diluted with water at a ratio of 1:10. This dilute solution is effective for the day of preparation only. It must be prepared at the beginning of each work day in the BSL3. This solution is for cleaning surfaces only. Undiluted bleach should be used for decontamination of HIV-1 itself.

3. Exposure time to chemical sterilization is a minimum of 30 minutes.

Ricin A chain:

1. 2.5% sodium hypochlorite (be aware that bleach is not a100% stock solution and varies concentration by manufacturer) and 0.25 N sodium hydroxide.

2. Exposure time is a minimum of 30 minutes.

Staphylococcal enterotoxin B:

1. 2.5% sodium hypochlorite (be aware that bleach is not a100% stock solution and varies concentration by manufacturer) and 0.25 N sodium hydroxide.

2. Exposure time is a minimum of 30 minutes.

Yersinia pestis:

1. 2.5% sodium hypochlorite (be aware that bleach is not a100% stock solution and varies concentration by manufacturer) and 0.25 N sodium hydroxide.

2. Exposure time is a minimum of 30 minutes.

Treatment of Biohazard Waste

Solid Waste

1. All solid waste materials leaving the hoods should be sealed in autoclavable containers. All waste must be sealed in autoclavable biohazard bags before the waste is removed from the individual research suites.

2. Waste from the individual suites will be autoclaved in a secondary container (autoclavable tray) to prevent possible escape of contents while in autoclave for a minimum of 30 minutes. Please log all autoclave cycles on the autoclave log sheets.

3. Autoclaved waste should be sealed in a waste bag and biomedical waste box provided by the Safety Office and stored in the BSL3 closet (Room 3.234).

4. Autoclaved materials will then be disposed of by the Office of Environmental Health and Safety. Pickup can be arranged with this office by filling out the disposal form found at: http://www.utexas.edu/safety/ehs/disposal/ and faxing it to their office.

Liquid Waste

1. Liquid waste will be autoclaved for 1 hour at 121*c before being disposed of in laboratory sinks or disposal through chemical waste procedures.

2. Alternately, liquid waste may be treated at room temperature for a minimum of 1 hour minimum with appropriate sterilizing agents and then disposed of down sink drains.

Sharps

1. Sharps and glass waste should be kept at a minimum.

   Sharps waste should be disposed of in sharps containers provided by the Safety Office. When the container is full, place the whole container within an autoclave bag. Place the bag and container in the cardboard biomedical waste boxes for pick-up by the Safety Office.

Materials treated and ready for pickup may exit the BSL2 side of the autoclave and be stored in the biohazard storage facility outside the BSL3 door (MBB 3.234).

Cleaning BSL3 Spaces

1. All users should set aside time for cleaning and maintenance of the BSL3 facility.

2. Maintenance will include general cleaning of lab spaces, mopping, dusting with a damp rag, equipment maintenance etc.

3. All equipment used for cleaning of BSL3 spaces will remain in the facility at all times. Equipment will be autoclaved or thoroughly disinfected before leaving for disposal, repair or maintenance.

4. All solutions will be diluted according to directions in Decontaminating Solution Preparation section of this protocol.

Insect Control

Insect control will be maintained by the building supervisor, William Cassady. Access for insect control activities will be monitored by the laboratory supervisor. See "Access" section of this protocol.

Wash Room Use

1. The washroom is BSL3 space and should be considered as hazardous as the individual research suites..

2. The washroom is a transition area, and care must be used to move from contaminated to clean areas. Hazard tape on the floor marks areas where BSL3 PPE should not cross.

3. All materials including, but not limited to, biohazard waste, gowns, plastics and respirators must be autoclaved or chemically sterilized before leaving the BSL3 area. This applies to used and unused materials.

4. The sink area is for washing previously autoclaved or chemically sterilized materials and hands only. Exposed and untreated materials in this area are unacceptable at all times.

5. The sink is operated by foot pedals to prevent contamination by hand contact with sink surfaces. A bacteriostatic, virocidal soap will be used at this sink for hand washing.

6. All surfaces will be wiped down regularly.

Handling BSL3 Agents:

Delivery/Shipment of BSL3 Agents

Delivery of BSL3 agents to this facility will be carried out in accordance with the Code of Federal Regulations and the regulations regarding select agents set forth by the CDC. This includes, but is not limited to, placards, packing slips, Dangerous Goods Declarations, advance notice of shipment to all parties involved, and phone numbers for 24 hour contact of shipper and consignee. These shipments will be carried out by personnel who have received certification in an 8 hour course on shipping of infectious and select agents as regulated by the CDC.

The delivery will be packed or unpacked in the Level Three lab in the biological safety cabinet and externally decontaminated according to agent specific lab protocols. This packaging will be witnessed and documented by 2 or more personnel. All shipments will be priority overnight. Shipment and delivery will be made directly from the lab, not from a second party, office personnel or central receiving. The University Biosafety Officer, Erle Janssen or his appointee will be notified of BSL3 shipments not considered select agents prior to shipment. Select agent shipments will be approved in writing by Erle Janssen, the personnel who packed the shipment, the receiving lab and the biosafety officer at the receiving institution.

Storage and Usage Records of BSL3 Agents

All BSL3 agents will be stored in a locked refrigerator/freezer, drawer or liquid nitrogen storage facility appropriate to the agent. It is the responsibility of each researcher to assure security of these agents on each access and exit of the facility. The use of each agent, quantity used, purpose, date and time will be logged by the user in a log provided in the BSL3. All work in the BSL3 will be documented in the researcher's lab book immediately on leaving the lab. This provides an accurate and up to date record of activity. Notes made in the BSL3 can be faxed to the BSL2 labs.

Handling Spills

This section is a guideline for spill assessment based on volume. Concentrations of the agent must also be considered at the time of the spill. Information for comparison of toxic levels is found in the attached MSDS for each agent.

Spills of 10 milliliters or less

Within the Biosafety Cabinet

1. Spills of 10 ml or less within the BSC will be covered with absorbent material and soaked with disinfecting agent for greater than 15 minutes.

2. Gloves should be changed and cleanup continued within the confines of the cabinet.

3. All waste generated should be sealed in autoclavable containers and externally decontaminated before removal from the cabinet for disposal.

Outside of Biosafety Cabinet

1. Spills of 10 ml or less outside of the BSC should be covered with absorbent material to contain the spill. Workers should evacuate the laboratory space for 30 minutes. All work will cease immediately and the room will be sealed to all personnel for 30 minutes. This will allow complete clearance of any aerosols produced by the spill to be removed from the space.

2. Any personnel exposed to the spill should be treated according to exposure protocols for the spilled agent.

3. The University Biosafety Officer or his appointee will be notified of the spill and any exposures at this time. The Safety Office phone number is 471-3511. The after hours pager number is Personal Info

4. At the end of the 30 minute period, personnel that are gowned, gloved and properly fitted with a respirator may begin cleanup.

5. The area will be flooded with appropriate sterilizing agent and covered with absorbent materials such as paper towels or under padding. This will be left for 30 minutes before pickup of materials will begin.

6. All waste generated will be sealed in an autoclavable biohazard waste bag for disposal. All surfaces in the BSL3 laboratory will be decontaminated appropriate disinfecting agent before work continues in this space.

Spills exceeding 10 milliliters

Within the Biosafety Cabinet

1. Spills exceeding 10 ml inside the BSC will lead to evacuation of the laboratory for 30 minutes. Absorbent material should be laid on the spill and all work should cease immediately. The room will be sealed to all personnel for 30 minutes. This will allow complete clearance of any aerosols produced by the spill to be removed from the space.

2. Any personnel exposed to the spill will be treated according to exposure protocols for the agents spilled.

3. The University Biosafety Officer or his appointee will be notified of the spill and exposures at this time. Biosafety Office phone number is 471-3511. After hours pager number is Personal Info

4. Clean up will not proceed without instruction and/or supervision of the University Biosafety Officer. At the end of the 30 minute period, personnel that are gowned, gloved and properly fitted with a respirator may begin cleanup with the approval of the Biosafety Officer.

5. The spill will be flooded with appropriate disinfecting agent. This will be left for 30 minutes before pickup of materials will begin.

6. All waste generated will be sealed in an autoclavable biohazard waste bag for disposal.

7. All materials will be decontaminated with appropriate sterilizing agent and removed from BSC . The BSC will be broken down for cleaning between decks before work is continued, even if no pooling of materials is suspected in hidden spaces.

8. Work will continue only after the University Biosafety Officer or his appointee has given clearance.

Outside of the Biosafety Cabinet

1. Spills exceeding 10 ml outside the BSC will lead to evacuation of the laboratory for 30 minutes. All work will cease immediately and the room will be sealed to all personnel for 30 minutes. This will allow complete clearance of any aerosols produced by the spill to be removed from the space.

2. All other personnel within the BSL3 should be notified of the spill

3. Any personnel exposed to the spill will be treated according to exposure protocols for the agents spilled.

4. The University Biosafety Officer or his appointee, Principle Investigator and Lab Director will be notified of the spill and exposures at this time. The Office of Environmental Health and Safety phone number is 471-3511. The after hours pager number is Personal Info

5. Clean up will not proceed without supervision of the University Biosafety Officer or his appointee. At the end of the 30 minute period, personnel that are gowned, gloved and properly fitted with a respirator may begin cleanup with the approval of the Biosafety Officer.

6. The spill will be flooded with the appropriate disinfecting agent and left for 30 minutes before pickup of materials will begin.

7. All waste generated will be sealed in an autoclavable biohazard waste bag for disposal.

8. All surfaces in the BSL3 laboratory will be decontaminated with appropriate sterilizing agent and removed from BSC. The BSC will be broken down for cleaning between decks before work is continued, even if no pooling of materials is suspected in hidden spaces.

9. Work will continue only after the University Biosafety Officer or his appointee has given clearance.

If the spill is of an unknown, be sure to use disinfecting agent(s) capable of disinfecting any and all of the possible agents spilled.

Exposures

Exposure, in this manual, is defined as the inadvertent direct contact of a person with an agent that could lead to ill effects directly to the researcher or to contamination into other areas outside of the facility. These include inhalation of an agent, contact of an agent to the skin, ingestion of an agent or spill/leakage into external areas.

All exposures will be reported to the Lab Director, University Biosafety Officer and Workman's Compensation Insurance as soon as possible so that proper treatment and documentation is initiated. Exposures will be assessed on the basis of agent, type of exposure, concentration of agent and condition of personnel. Any information that can be ascertained at the time of exposure without disrupting spill and exposure procedures will be helpful.

Minor exposures include small non-barriered openings on gloves, gowns or other areas that should be covered by standard PPE, and does not require steps 8-13 below. Any perforation of skin and exposures through the nose, eyes, ear and mouth are considered serious, and all steps below must be followed. Serious medical emergencies include situations in which severe bleeding, loss of breathing, or heart failure is involved.

******In all cases of serious medical emergencies:*****

1. **Contain and stabilize the affected person and areas following standard first aid response techniques.**

2. **Call 911 immediately and the Office of Environmental Health and Safety**

3. **Proceed to decontaminate and treat as below until emergency and safety personnel arrive.**

<u>In case of any exposure:</u>

1. **Remove self or the exposed individual(s) from the laboratory to next outer laboratory space. (i.e. washroom or shower room.)**

2. **Remove any gross contamination by sweeping or blotting.**

3. **Allow any needle sticks or lacerations to bleed within reason. This will flush the wound from the inside out.**

4. **Remove contaminated clothing cautiously. Pull it away from the body. Clothing that would normally be removed over the head should be cut away. Change gloves or wash hands, if appropriate, before proceeding to next step.**

5. **Remove glasses, contact lenses, jewelry, and other small items that may also be contaminated.**

6. **Wash affected areas profusely with soap and lukewarm water (warm or hot water will increase exposure by opening pores in the skin). Start at the top with hair and face and work methodically down the body. Rinse with dilute bleach solution and rinse again with copious amounts of water. This may be done using the washroom sink, eyewash and shower with soaps provided.**

7. **Change into uncontaminated clothes, lab coats, or blankets.**

8. **Call the Environmental Health and Safety Officer after hours on call at 875-0911. Call EMS and ask for ambulance and Haz Mat Team as indicated at 9-911. These numbers are all posted on the wall next to the phone in the washroom. This should done concurrently with any of the previous steps when possible.**

9. **Secure the facility and post doors with signs indicating this closure.**

10. **NO ONE may enter the facility until authorized by the Lab Director and the University Biosafety Officer to initiate clean up.**

11. Proceed to Brackenridge Emergency Room by EMS/ Haz Mat approved method of transport with a copy of the appropriate MSDS sheets.

12. Document the circumstances of the exposure as soon as possible on the back of your laboratory protocol. Include concentration, volume and route of exposure (i.e. inhalation, needle stick, topical, ingestion etc.).

13. All other personnel present in the lab at the time of exposure must stay together in the lab until emergency personnel arrive. No one may leave facility for any reason.

14. Note information on individual toxins provided in the next section.

Specific Agents and Their ExposureTreatments

The treatment protocols for exposures to the various agents are outlined in the next pages. Please take this manual with the protocols in it to the appropriate caregivers in event of an exposure of any kind. The more information they have the better. Write down the circumstances of an exposure immediately so that no information is lost in transfer from one person to another.

Bacillus anthracis (Sterne)

Bacillus anthracis Sterne lacks the protective antigen thereby making it inactive. Although the strain in this facility does not produce clinical anthrax, it can still infect a human, and it is wise to treat it as an infectious agent. The incubation period for infectious anthrax is 1-6 days. Infection may be contracted topically causing infection, swelling and open wounds to the skin. Inhalation results in respiratory symptoms, shock and death within 24 to 36 hours of severe symptoms.

Symptoms include:

fever	malaise	fatigue	cough	chest discomfort
dyspnea	diaphoresis	stridor	cyanosis	skin lesions
swelling	severe respiratory distress			

Treatment of anthrax:

500mg i.v. Ciprofloxacin every 8-12 hours,(or 200mg Doxycycline then 100mg every 12 hours, or Penicillin 2 million units i.v. every 2 hours). Vaccination against anthrax is preferable and will be made available before work if possible.

Botulinum Toxin A

The botulinum toxin A is the purified toxin from Clostridium botulinum. Botulinum toxin A is an acetylcholinesterase inhibitor and can cause severe neuromuscular damage. Because of its severe effects, researchers working with this organism will be required to be immunized.

Symptoms include

mucous in the throat	cold-like symptoms	difficulty swallowing
dilation of pupils	weakness	paralysis
respiratory failure	affected eye movement	
difficulty with motor skills		

Treatment:

Treatment with antitoxin is effective if applied before symptoms appear. After the toxin has entered the cells and symptoms have appeared, symptoms must be treated directly.

Clostridium botulinum

Clostridium botulinum is the bacterial agent responsible for botulism. Because of its severe effects, researchers working with this organism will be required to be immunized.

Symptoms include

mucous in the throat	cold-like symptoms	difficulty swallowing
dilation of pupils	weakness	paralysis
respiratory failure	affected eye movement	
difficulty with motor skills		

Treatment:

Treatment with antitoxin is effective if applied before symptoms appear. After the toxin has entered the cells and symptoms have appeared, symptoms must be treated directly.

HIV

Needle stick or laceration: Encourage wound to bleed for a short period of time. This is the best way to cleanse the internal site. Cleanse the area with bacteriostatic, virocidal soap provided at the lab sink and shower. Stop bleeding with application of direct pressure. Proceed to Brackenridge Emergency Room for evaluation of exposure to HIV and consultation on available prophylactic therapies.

Aerosol Exposure, Splash, Eye or Mucous Membrane, Skin:
Remove personnel from area of exposure. Decontaminate exposed clothing and skin. Wash out any exposed eyes and mucous membranes with water for a minimum of 15 minutes. Proceed to Brackenridge Hospital Emergency Room for evaluation and consultation on prophylactic therapies currently available.

There are no immediate symptoms of HIV infection. Treatment should be sought immediately. The treatments available are effective when administered as soon after the exposure as possible.

Ricin A chain

The material in this lab is the A chain of Ricin. It lacks the component that allows quick entry into cells and is, therefore, not considered lethal. It remains, however, a highly toxic cytotoxin if it can enter the cell. The onset of symptoms of ricin inhalation is reported to be within 1-12 hours. For ingestion, onset is reported to be within 5 minutes to 1 hour.

Symptoms include:

cough	tightness of chest	difficulty breathing	nausea

muscle aches cyanosis internal bleeding heart failure
airway inflammation

Treatment:

Support for affected systems is the only treatment.

Staphylococcal Enterotoxin B

The material in our lab is Staphylococcal Enterotoxin B. Symptoms of exposure are related to those of toxic shock syndrome. The onset of symptoms is reported to be within 3-4 hours and lasting 3-4 days.

Symptoms include:

non-productive cough rales dyspnea headache
nausea anorexia vomiting liver enlargement
chest pain (substernal pleuritic pain mild to severe)

Supportive therapy with cool compresses, fluids, rest and narcotic antitussives have been generally adequate in previous cases.

Yersinia pestis

Yersinia pestis is the causative agent of pneumonic plague.

Symptoms include:

fever headache weakness cough watery/bloody sputum
septic shock death

Treatment:

Early treatment is essential, as several antibiotics can be effective including streptomycin, tetracycline, and chloramphenicol. Prophylactic treatment can also be administered to persons exposed to the organism.

Influenza

See Appendix

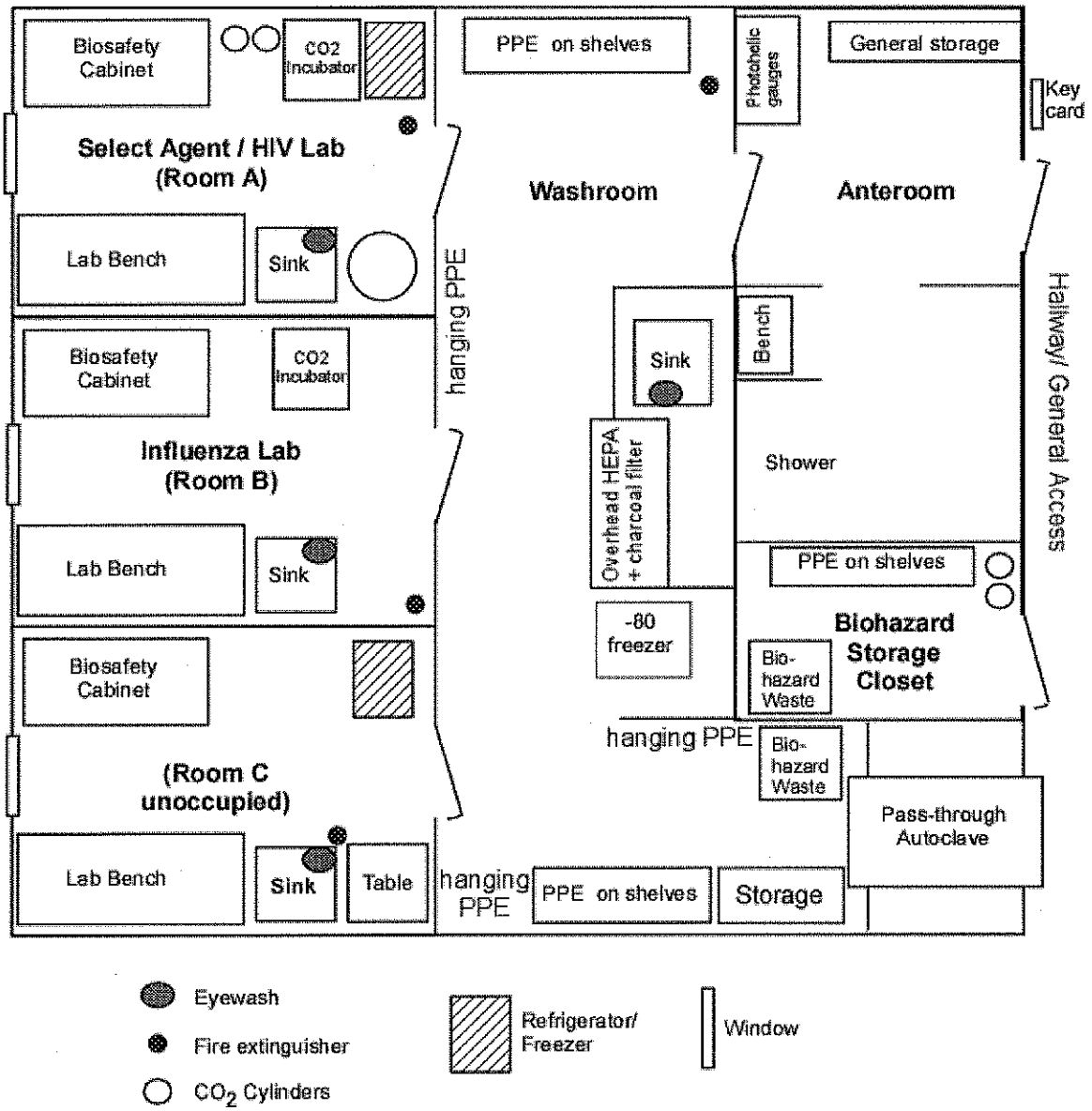
Additions to and Review of BSL3 Research

No other BSL3 Agents will be admitted to this facility without prior approval of the Institutional Biosafety Committee (IBC) and addition to this protocol of exposure. Additionally, protocols on the agent's use and its associated MSDS must be reviewed and approved by Erle Janssen.

Review of these Protocols will be made on annual basis by Laboratory Director in collaboration with the IBC and all current investigators using the facility.

Biosafety Level 3 Facility

Not public information) Room



INFLUENZA (FLU)

FACT SHEET

Influenza Symptoms, Protection, and What to Do If You Get Sick

Influenza (commonly called the "flu") is a contagious respiratory illness caused by influenza viruses. The information below describes common flu symptoms, how to protect yourself and those close to you from getting the flu, and what to do if you ge sick with flu-like symptoms.

People May Have Different Reactions to the Flu

The flu can cause mild to severe illness and at times can lead to death. Although most healthy people recover from the flu without complications, some people, such as older people, young children, and people with certain health conditions, are at high risk for serious complications from the flu.

Be Aware of Common Flu Symptoms

Influenza usually starts suddenly and may include the following symptoms:

- Fever (usually high)
- Headache
- Tiredness (can be extreme)
- Cough
- Sore throat
- Runny or stuffy nose
- Body aches
- Diarrhea and vomiting (more common among children than adults)

Having these symptoms does not always mean that you have the flu. Many different illnesses, including the common cold, ca have similar symptoms.

Know the Risks from the Flu

In some people, the flu can cause serious complications, including bacterial pneumonia, dehydration, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes. Children and adults may develop sinus problems and ear infections.

Know How the Flu Spreads

The flu usually spreads from person to person in respiratory droplets when people who are infected cough or sneeze. People occasionally may become infected by touching something with influenza virus on it and then touching their mouth, nose, or eyes.

Healthy adults may be able to infect others **1 day before** getting symptoms and up to **5 days after** getting sick. Therefore, it i possible to give someone the flu before you know you are sick as well as while you are sick.

Protection against the Flu

The single best way to protect yourself and others against influenza is to get a flu vaccination each year. Two kinds of flu vaccine are available in the United States:

- **The "flu shot"** —an inactivated vaccine (containing killed virus) that is given with a needle, usually in the arm. The flu shot is approved for use in people older than 6 months, including healthy people and people with chronic medical conditions.
- **The nasal-spray flu vaccine** —a vaccine made with live, weakened flu viruses that do not cause the flu (sometimes called LAIV for "live attenuated influenza vaccine"). LAIV is approved for use in healthy people 5 years to 49 years of age who are not pregnant.

October or November is the best time to get vaccinated, but you can still get vaccinated in December and later. Flu season can begin as early as October and last as late as springtime.

The following additional measures can help protect against the flu.

Habits for Good Health

These steps may help prevent the spread of respiratory illnesses such as the flu:

Cover your nose and mouth with a tissue when you cough or sneeze—throw the tissue away after you use it.

- **Wash your hands often with soap and water**, especially after you cough or sneeze. If you are not near water, use a alcohol-based hand cleaner.
- **Avoid close contact with people who are sick.** When you are sick, keep your distance from others to protect them from getting sick too.
- **If you get the flu, stay home from work, school, and social gatherings.** In this way you will help prevent others from catching your illness.
- **Try not to touch your eyes, nose, or mouth.** Germs often spread this way.

Antiviral Medications

Three antiviral drugs (amantadine, rimantadine, and oseltamivir) are approved for use in preventing the flu. These are prescription medications, and a doctor should be consulted before they are used. During the 2005-2006 influenza season, CDC recommends against the use of amantadine or rimantadine for the treatment or prophylaxis of influenza in the United States. For details, see the January 14, 2006 CDC Health Alert Notice (HAN).

What to Do If You Get Sick

Diagnosing the Flu

It is very difficult to distinguish the flu from other infections on the basis of symptoms alone. A doctor's exam may be needed t tell whether you have developed the flu or a complication of the flu. There are tests that can determine if you have the flu as long you are tested within the first 2 or 3 days of illness.

If you develop flu-like symptoms and are concerned about your illness, especially if are at high risk for complications of the flu you should consult your health-care provider. Those at high risk for complications include **people 65 years or older, people with chronic medical conditions, pregnant women, and young children.**

Antiviral Medications

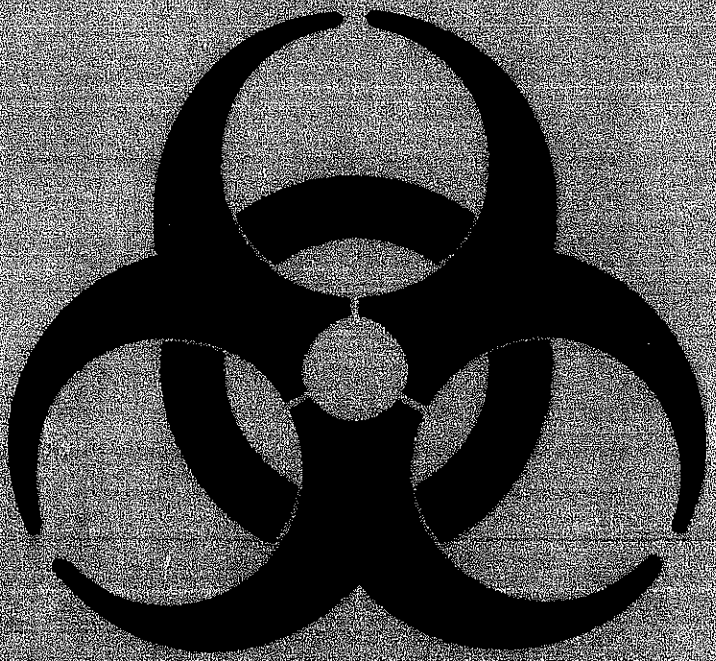
Your doctor may recommend use of an antiviral medication to help treat the flu. Four antiviral drugs (amantadine, rimantadine zanamavir, and oseltamivir) are approved for treatment of the flu. During the 2005-2006 influenza season, CDC recommends against the use of amantadine or rimantadine for the treatment or prophylaxis of influenza in the United States. (For details, see the January 14, 2006 CDC Health Alert Notice [HAN].) These are prescription medications, and a doctor should be consulted before the drugs are used. Antiviral treatment lasts for 5 days and must be started within 2 days of illness. Therefore, if you get flu-like symptoms, seek medical care early.

Other Ways to Respond to the Flu

If you get the flu, get plenty of rest, drink a lot of liquids, and avoid using alcohol and tobacco. Also, you can take medicatior such as acetaminophen (e.g., Tylenol®) to relieve the fever and muscle aches associated with the flu. **Never give aspirin t children or teenagers who have flu-like symptoms, particularly fever.**

Page last modified January 14, 2006

BIOHAZARD



INFECTIOUS AGENT: Influenza virus
ENTRY REQUIREMENTS: PPE (Respirator, Tyvek suit, 2x gloves), Training, Vaccination & EHS authorization
CONTACT: Rei-Lin Kuo (2-5566), Robert Krug (2-5563)
PHONE: Dennis Nolan at 750-0383 (emergency #)

Environmental Health and Safety
(512) 471-3511

Entry to BSL3 (Krug Lab)

Entering the BSL3 facility is by authorized access only. Access is granted by the laboratory director and/or the Institution Biosafety Officer.

1. Make sure each door is closed and locked behind you each time you enter. Do not leave doors open for extended periods of time to prevent disruption of negative pressure and for security. Deactivate intrusion alarm upon entry into Anteroom.

2. In the Anteroom, enter the shower area. Remove all street clothing and jewelry and place into locker. Put on clean scrubs. Log entry time on board.

3. Enter the Washroom. Check visual indicator for negative pressure and log on sheet. Put on gloves. Check respirator function.

4. In Order:
   1) Put on suit 2) Put on shoe covers 3) Put on respirator and activate

5. Enter Isolation room. Put on second pair of gloves.

6. All equipment will be QC'ed for airflow, temperature, alarms, etc... Anything that needs further attention will be brought to the attention of the Lab Director as soon as possible.

Exiting BSL3

1. Isolation room will be cleaned prior to vacating. This includes BSC, bagging biohazardous waste and chemical wipe down of any material that needs to be removed.

2. In Isolation room, remove contaminated secondary gloves. Decon spray suit (chest area, arms and legs). Notify staff in other rooms that you are exiting.

3. Exit to Washroom. Dispose of biohazardous materials by transferring to containers and/or autoclave.

4. In Order:
   1) Remove respirator 2) Remove shoe covers 3) Remove suit 4) Remove gloves 5) Wash hands.
   Recharge respirator and dispose of shoe covers. Dispose of suit after 20 hours use.

5. Exit to Anteroom. Enter shower area. Remove scrubs and place in autoclave bag. Shower thoroughly (10 min.) using warm water and antibacterial soap. Towel dry and place in autoclave bag. Put on street clothes. Log exit time.

Nothing to leave the BSL3 facility except in appropriate leakproof containers that have been externally decontaminated. All materials must leave through the autoclave or be chemically disinfected. No notebooks or other documents that you wish to use in the future outside of the BSL3 facility will exit except through the autoclave. BSL3 agents will leave the BSL3 only in IATA or CFR approved containers for shipment of infectious agents.

BSL 3 Emergency Algorithm

Is there an *immediate* threat to life? (Fire, Injury, Condition etc…)

Yes

Remove staff from danger
Alarm- call UTPD/EHS
Contain agent (decon)
Evacuate

No

Is the exposure outside or inside the BSC?

Inside

1) Do not remove hands from BSC cover contaminated area with Chux soaked with 3% disinfectant. If gross contamination of PPE wipe down with soaked Chux. Remove gloves. If puncture wound flush wound change gloves.

2) Wipe down all surfaces and equipment with disinfectant. Dispose of all contaminated materials into biohazard bag.

3) Change gloves. Soak chux in disinfectant. Wipe down arms up to elbows and front of suit.

4) Change gloves. Call EHS, Lab Director and Supervisor. Notify staff in other suites to evacuate to outside lab.

5) See Step #5 (Outside BSC)

6) Follow step # 6 (Outside BSC)

7) Follow steps 8-10 (Outside BSC)

Outside

1) Notify staff in other suites to evacuate immediately to outside lab.

2) Remove gross contamination on self by blotting with disinfectant soaked Chux. Change gloves.

3) Exit to washroom area. Leave respirator on.

4) Allow any puncture wounds to bleed to flush wound. Wash hands. Change gloves.

5)Cautiously remove contaminated clothing, pulling away from body. Cut away clothing that goes over head. Place all materials including respirator in biohazard bag. Remove gloves and wash hands.

6) Verify anteroom is unoccupied. Proceed to shower room. Shower in lukewarm (not hot) water using copious amounts of anti-microbial soap and water. Change into clean scrubs.

7) Call EHS, Lab Director and Supervisor

8) Post "Do Not Enter" Sign at washroom doors.

9) Initiate medical prophylaxis (Tamiflu)

10) Remain in anteroom for further instructions. Do not reenter lab.

*Staff inside BSL3 suite but outside contaminated room must evacuate directly outside BSL3 suite and remain for further instruction

Emergency Response Protocol:

1. **Check for immediate threats to life before entering or leaving exposed area. If there is a serious threat, contact emergency response personnel for further instructions.**

2. **Contain and stabilize the affected person and areas following standard first aid and Exposure Response techniques (see below).**

3. **Call 911 (UTPD) immediately and EHS (475-3511)**

4. **Proceed to decontaminate and treat as below until emergency and safety personnel arrive.**

Biological Exposure Response Protocol:
(Outside of BSC)

1. **Check for immediate threats to life before entering or leaving exposed area. If there is a threat, contact emergency response personnel for further instructions. If no immediate threat, remain in laboratory for at least 30 minutes to allow contaminated air to circulate out.**

2. **Notify staff in other suites to evacuate immediately. (Intercom)**

3. **Remove any gross contamination on self by sweeping or blotting with paper towels. Remove gloves and wash hands.**

4. **Allow any needle sticks or lacerations to bleed within reason to flush wounds from the inside out.**

5. **Put on new gloves. Leave respirator on. Remove contaminated clothing cautiously. Pull it away from the body. Clothing that would normally be removed over the head should be cut away. Place all removed contaminated materials in biohazard bag. Remove gloves. Wash hands before proceeding to next step.**

6. **Lightly spray exposed areas (not mucous membranes or broken skin) with an aerosol disinfectant (Citrace, Amphyl, Lysol)**

7. **Change into evacuation suit found in spill kit. Spray suit with aerosol disinfectant.**

8. **Clean room contamination by covering contaminated areas with paper towels and soaking with vesphene/staphene solution. Do not attempt to clean area.**

9. **Call EHS, the BSL3 Lab Director and your Laboratory Supervisor (see Emergency Contact List)**

10. **Secure the room and post doors with signs indicating this closure.**

NO ONE MAY ENTER THE FACILITY UNTIL AUTHORIZED BY THE LAB DIRECTOR AND THE UNIVERSITY BIOSAFETY OFFICER

All personnel present in the lab at the time of exposure must stay in the lab until emergency personnel arrive. No one may leave facility for any reason.

11. **Proceed to immediately to shower room. Remove suit/respirator and discard into biohazard bag. Shower in lukewarm (not hot) water using copious amounts of soap and water. Change into clean scrubs.**

12. **Proceed to Brackenridge Emergency Room by EMS/ HazMat approved method of transport with a copy of this protocol and attached MSDS.**

13. **Document the circumstances of the exposure as soon as possible. (See form) Include concentration, volume and route of exposure (i.e. inhalation, needle stick, topical, ingestion etc.).**

Biological Exposure Response Protocol:
(Inside of BSC)

1. Do not remove hands from BSC (to prevent room contamination). Immediately cover contaminated area with paper towels and soak with 3% vesphene/staphene solution. Allow to sit for 20 minutes before cleaning. If there is gross contamination of PPE, wipe down with paper towels soaked in 3% vesphene/staphene solution

2. Wipe down all surfaces and equipment in BSC with 3% vesphene/staphene solution. Dispose of all contaminated materials (paper towels, mats, consumables such as pipet tips) into biohazard bag.

3. Change gloves. Soak paper towels in 3% vesphene/staphene solution. Wipe down hands and arms up to the elbows. Wipe down suit front.

4. Change gloves. Remove Tyvek suit and place in biohazard bag. Change gloves. Change into evacuation suit found in spill kit. Spray suit with aerosol disinfectant.Notify staff in other suites to evacuate immediately. (Intercom)

5. Call EHS, Lab Director and your supervisor (Emergency Contact List)

6. Secure the room and post doors with signs indicating this closure.

   NO ONE MAY ENTER THE FACILITY UNTIL AUTHORIZED BY THE LAB DIRECTOR AND THE UNIVERSITY BIOSAFETY OFFICER

7. Proceed to immediately to shower room. Remove suit/respirator and discard into biohazard bag. Shower in lukewarm (not hot) water using copious amounts of soap and water. Change into clean scrubs.

8. Remain in lab until instructed by Biosafety Officer or Lab Director.

LAB

SAFETY

MANUAL

OFFICE OF
ENVIRONMENTAL HEALTH AND SAFETY
HAZARDOUS MATERIALS DIVISION
THE UNIVERSITY OF TEXAS AT AUSTIN

NOVEMBER 1996

iii. lubricate the glass with water or glycerol,
iv. wear heavy gloves and hold the glass not more than two inches from the end to be inserted,
v. insert the glass carefully with a twisting motion, and
vi. remove stuck tubes by slitting the stopper with a sharp knife.

Assembly of Laboratory Apparatus:

1. Keep work surfaces as uncluttered as possible.
2. Firmly clamp apparatus and set up away from the edge of the lab bench.
3. Only use equipment that is free from cracks, chips, or other defects.
4. If possible, place a pan under a reaction vessel or other container to contain liquid if the glassware breaks.
5. Do not allow burners or any other ignition sources nearby when working with flammable liquids.
6. Lubricate glass stopcocks.
7. Properly support and secure condensers and water hoses with clamps and wires. Be sure to direct the water hoses so that any drips that may come off the hoses do not splash down onto any electrical wires.
8. Position apparatus that is attached to a ring stand with the center of gravity over the base and not to one side.
9. Assemble the apparatus so that burners or baths can be removed quickly.
10. Use an appropriate vapor trap and confine the setup to a fumehood if there is a possibility of hazardous vapors being evolved.
11. Put the setup in a fumehood whenever conducting a reaction that could result in an implosion or explosion. Keep the sash pulled down. If it is not possible to use a fumehood, use a standing shield that is stabilized and secured.
12. Always wear a lab coat and proper eye and face protection.

Centrifuges

1. Securely anchor tabletop centrifuges and place in a location where the vibration will not cause bottles to fall off the bench.
2. Keep the centrifuge lid closed while operating and do not leave the centrifuge until you are certain it is running safely without vibration.
3. If the centrifuge starts vibrating, stop and check the load balances.
4. Regularly clean rotors and buckets with a non-corrosive cleaning solution.
5. Use sealed safety cups while centrifuging hazardous materials.

Ultraviolet Lamps

a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

2. Face protection (goggles, mask, face shield, or other splatter guards) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face, when the microorganisms must be manipulated outside the BSC.

3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.

4. Gloves are worn when handling infected animals and when hands may contact infectious materials, contaminated surfaces, or equipment. Wearing two pairs of gloves may be appropriate; if a spill or splatter occurs, the hand will be protected after the contaminated glove is removed. Gloves are disposed of when contaminated, removed when work with infectious materials is completed, and are not worn outside the laboratory. Disposable gloves are not washed or reused.

Laboratory Facilities (Secondary Barriers) (BSL2):

1. A method for decontamination of infectious or regulated laboratory wastes is available (e.g., autoclave, chemical disinfection, incinerator, or other approved decontamination system).

2. An eyewash facility is readily available.

6. Spills of infectious materials are decontaminated, contained, and cleaned by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material.

Safety Equipment (Primary Barriers) (BSL3):

1. Properly maintained biological safety cabinets are used (Class II or III) for all manipulation of infectious materials.
2. Outside of a BSC, appropriate combinations of personal protective equipment are used (e.g., special protective clothing, masks, gloves, face protection, or respirators), in combination with physical containment devices (e.g., centrifuge safety cups, sealed centrifuge rotors, or containment caging for animals).
3. This equipment must be used for manipulations of cultures and of those clinical or environmental materials that may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs; and necropsy of infected animals.
4. Respiratory protection is worn when aerosols cannot be safely contained (i.e., outside of a biological safety cabinet), and in rooms containing infected animals.
5. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls must be worn inside the laboratory only. Reusable laboratory clothing is to be decontaminated before being laundered.

Laboratory Facilities (Secondary Barriers) (BSL3):

1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. A clothes change room (shower optional) may be included in the passageway.
2. Each laboratory contains a sink for handwashing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.
3. The interior surfaces of walls, floors, and ceilings are water-resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontamination.
4. Windows in the laboratory are closed and sealed.
5. A method for decontaminating all laboratory wastes is available, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method).
6. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air from "clean" areas into the laboratory toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building, and is discharged to the outside with filtration and other treatment optional. The outside

exhaust must be dispersed away from occupied areas and air intakes. Laboratory personnel must verify that the direction of airflow (into the laboratory) is proper.

7. The High Efficiency Particulate Air (HEPA) filtered exhaust air from Class II or Class III biological safety cabinets is discharged directly to the outside or through the building exhaust system. If the HEPA filtered exhaust air from Class II or Class III biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system. Exhaust air from Class II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified according to the guidelines included on National Sanitation Foundation Standard 49.
8. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.
9. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent, which are routinely maintained and replaced as needed.

3. Laboratory Equipment

Biological Safety Cabinets

A biological safety cabinet is used as a primary barrier against exposure to infectious biological agents. A BSC has High Efficiency Particulate Air (HEPA) filters. The airflow in a BSC is laminar, i.e. the air moves with uniform velocity in one direction along parallel flow lines. A BSC must be used in conjunction with safe laboratory techniques, because potentially dangerous aerosols can still escape.

Depending on the design, a BSC may be vented to the outside or the air may be exhausted into the room. BSCs are <u>not</u> chemical fume hoods. A percentage of the air is recirculated in most types of BSCs. Therefore, the levels of explosive, flammable, or toxic materials will be concentrated within the cabinet. HEPA filters only trap particulates, allowing any contaminant in non-particulate form to pass through the filter.

Certification of BSCs
A BSC must be certified annually and after it has been newly installed, moved, or had a filter replaced. There are several companies in the area which provide this service. For further information, contact the OEHS Hazardous Materials Division at 471-3511.

Clean Benches
Clean benches (a.k.a. laminar flow hoods) are not considered laboratory safety equipment. However, they deserve mention because they may be confused with BSCs. A clean bench is designed to protect the product from contamination, but it does *not* protect the user. The direction of airflow in a clean bench is toward the user.

Pipetting Devices
In the distant past, some lab personnel were taught to mouth pipette. This practice has been known to result in many laboratory acquired infections. With the availability of mechanical pipetting devices, mouth pipetting is strictly prohibited. Mouth pipetting should never be used, even for innocuous materials, because you may at some time mistakenly mouth pipette something that is hazardous. To minimize aerosol production, a pipette should be drained with the tip against the inner wall of the receiving vessel. Never forcibly expel any hazardous material from a pipette.

Centrifuges, Sonicators, Homogenizers, and Blenders
All of these instruments can create aerosols and this must be considered with each use. The necessary precautions taken will depend upon what is being used in these instruments. If hazardous materials such as carcinogens, highly toxic, or infectious agents will be placed in any of these instruments, then precautions must be taken to prevent an exposure of lab personnel to aerosols or liquids.

Centrifuges
Centrifuges that have sealed buckets, safety trunnion cups, or sealed heads are effective at preventing the escape of aerosols and liquids. The potential for exposing people to a hazardous material used in a centrifuge is great if the centrifuge tube breaks without the use of the safety features mentioned above.

Routinely inspect your centrifuge to ensure leakage is not occurring. An indicator such as fluorescein can be used to detect leaks. The fluorescein can be added to water and

then centrifuged as you would other materials. An ultraviolet light can then be used to detect the fluorescein's presence on work surfaces, floors, and walls.

Sonicators, Homogenizers, and Blenders
Depending on the nature of the material being used in these instruments and also in centrifuges, it may be necessary for them to be used or opened only in a biological safety cabinet. When working with infectious agents, blenders should have leak proof bearings and a tight-fitting, gasketed lid. Inspect the lid and gaskets routinely to ensure they are in good condition. Household blenders do not prevent the spread of aerosols. Also, hearing protection may be required while using a sonicator.

4. Personal Protective Clothing

The type of personal protective clothing required in microbiological labs will depend upon the assigned Biosafety Level for that lab (see Section 2 of this chapter regarding Biosafety Levels). The protective clothing suitable for a typical undergraduate microbiology lab is a lab coat, to prevent street clothes from getting soiled, and latex or vinyl gloves. Long hair must be restrained if Bunsen burners are in use.

For a typical graduate level teaching or research microbiology lab (which are often a BSL2), lab coats or similar protective clothing should be worn while in the lab, and gloves must be worn while handling any infectious materials. Additionally, if the work involves human blood, a face shield, safety glasses or goggles, and a mask may be required if there is a potential for splash.

A research lab that is assigned a Biosafety Level 3 has additional requirements for personal protective clothing: laboratory clothing that protects street clothing must be worn, e.g., a solid-front or wrap-around gown. Typical lab coats which button down the front are not acceptable because they do not provide full protection. Gloves must be worn in the lab, and respirators worn in rooms containing infected animals.

Whenever personal protective clothing becomes contaminated, it must be removed and replaced. Leave protective clothing in the lab and do not wear it to other non-lab areas. Disposable gloves are meant to be used only once and should then be discarded. In between glove changes, thoroughly wash your hands and arms.

5. Waste Disposal

There are many types of waste generated in a microbiological lab and all need to be handled, treated, stored, and disposed of properly (refer to OEHS Procedures for Disposal of Hazardous Waste manual for more detailed information).

Appendix 2

Training Materials & Documentation:

1) Initial Training Presentations (3)
- **Biological Safety**
- **Biosafety in Microbiological & Biomedical Laboratories**
- **N5N1 Avian Influenza Virus**

2) BSL3 Training Meetings (3)
- **BSL3 Meeting 7/15/2005**
- **BSL3 Meeting 12/22/2005**
- **Krug Lab BSL3 Training 11/15/2006**

3) Researcher Training Documents
- **Environmental Health & Safety Training Requirements**
- **Personal Training History**
- **Internal EHS Training**

Biological Safety

The University of Texas at Austin

Office of Environmental Health and Safety

471-3511

Course Outline

- History - Lab Infections
- Biological Hazards
- Good Lab Practices
- CDC/NIH Guidelines
- Containment Equipment
- Spills/Decontamination
- Transportation and Shipment
- Sources of Help

History of Lab Infections

- 1900 - 1976: 3,921 reported cases
- exact source known < 20%
- Top Five: brucellosis, Q fever, typhoid fever, viral hepatitis, tuberculosis
- Low Risk Agents: *rabies virus, Vibrio cholerae, Clostridium tetani, HIV*

Biological Hazards

- Organisms
  - Hepatitis B virus, *Mycobacterium tuberculosis, Shigella spp., Salmonella spp.*

Biological Hazards

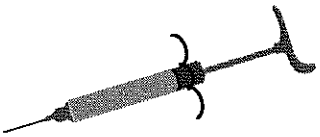
- Vertebrate Animals
- Insects
- Cell Cultures

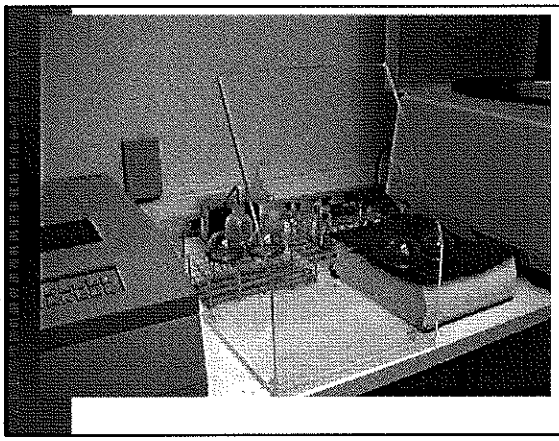
Good Lab Practices

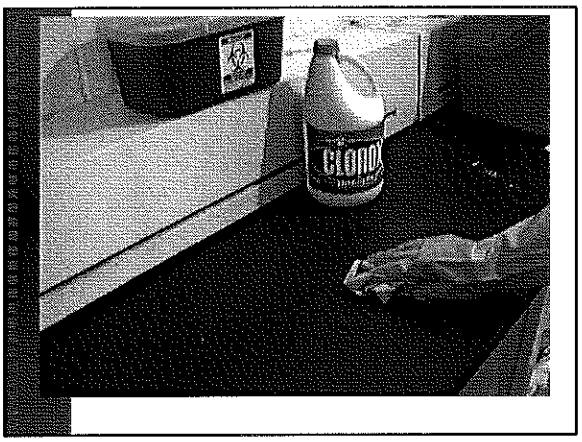
- Routes of Exposure
  - Contact
  - Oral
  - Ocular
  - Inoculation
  - Respiratory

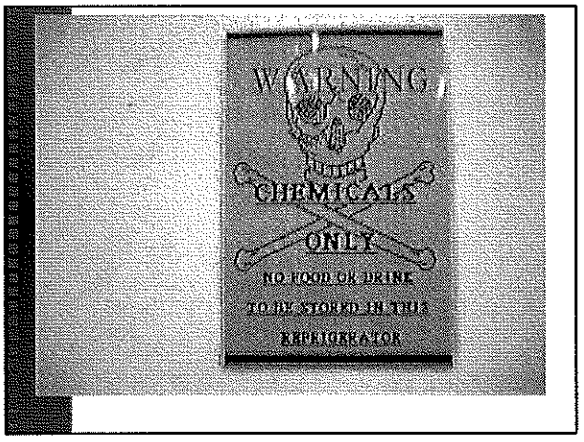
Good Lab Practices

- Seven Rules of Biosafety



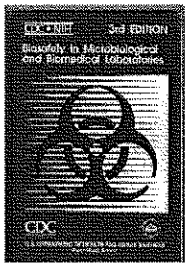






CDC/NIH Guidelines

"Biosafety in Microbiological and Biomedical Laboratories"



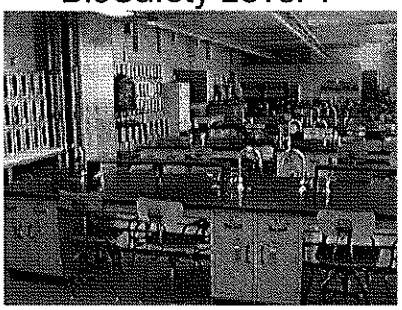
CDC/NIH Guidelines

"All work with microbiological agents at The University should follow the CDC/NIH guidelines. Research labs conducting work with microbiological agents, should at a minimum, follow the guidelines for Biosafety Level 1."

CDC/NIH Guidelines

- BioSafety Level 1
  - (default for teaching and research)
  - *Bacillus subtilus*
  - *Infectious Canine Hepatitis Virus*
- Laboratory Practices and Techniques
- Safety Equipment (primary barriers)
- Facility Design (secondary barriers)

BioSafety Level 1



CDC/NIH Guidelines

- BioSafety Level 2
  - *Shigella spp.*
  - *Clostridium tetani*
  - Human Blood and Tissues
- Laboratory Practices and Techniques
- Safety Equipment (primary barriers)
- Facility Design (secondary barriers)

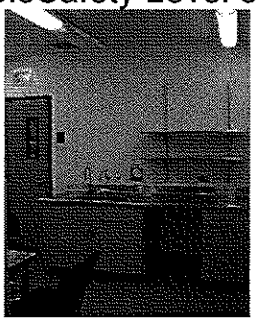
BioSafety Level 2

CDC/NIH Guidelines

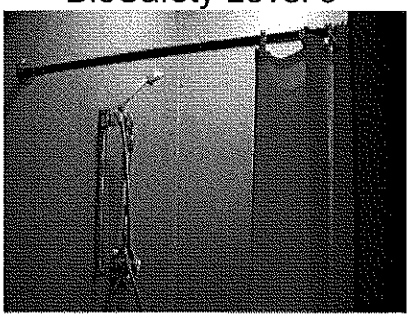
- BioSafety Level 3
  - *Mycobacterium tuberculosis*
  - *Yellow Fever Virus*
  - *Francisella tularensis*
- Laboratory Practices and Techniques
- Safety Equipment (primary barriers)
- Facility Design (secondary barriers)

BioSafety Level 3

BioSafety Level 3



BioSafety Level 3



CDC/NIH Guidelines

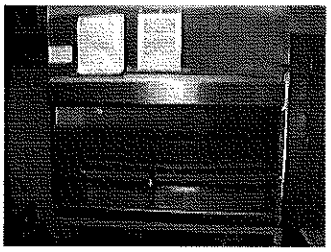
- Animal BioSafety Levels 1 - 4
- Laboratory Practices and Techniques
- Safety Equipment (primary barriers)
- Facility Design (secondary barriers)

Containment Equipment

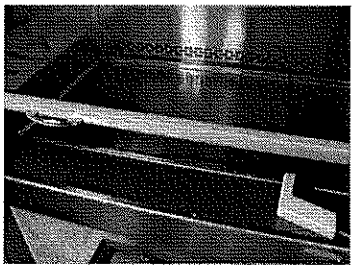
- Biological Safety Cabinets
- Sonicators, Homogenizers, Mixers
- Centrifuges

Biological Safety Cabinet

Biological Safety Cabinet



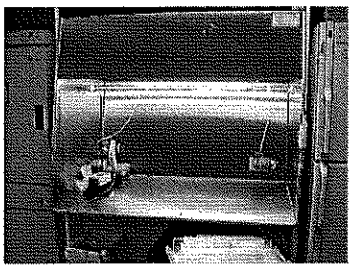
Biological Safety Cabinet



Biological Safety Cabinet

- Certification Required Annually
- And after: newly installed, moving, maintenance performed

Clean Bench - Not a BSC!!

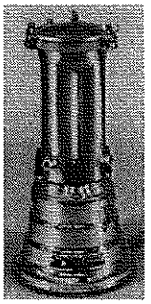


Clean Bench - Not a BSC!!

Containment Equipment

- Biological Safety Cabinets
- Sonicators, Homogenizers, Mixers

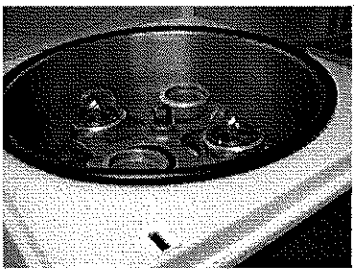
Sonicators, Homogenizers, Mixers



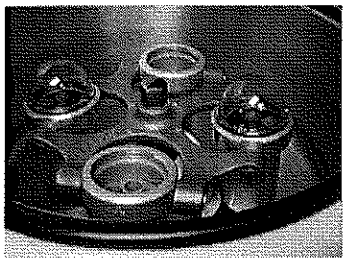
Containment Equipment

- Biological Safety Cabinets
- Sonicators, Homogenizers, Mixers
- Centrifuges

Centrifuge

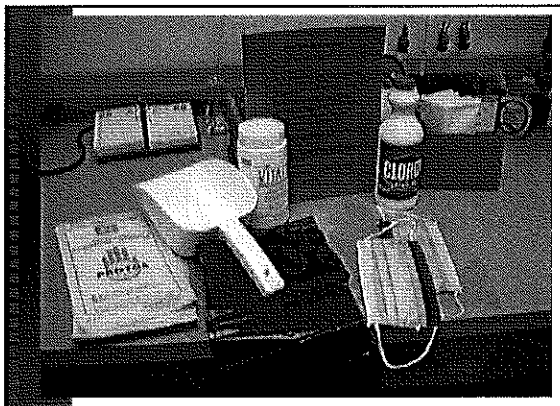


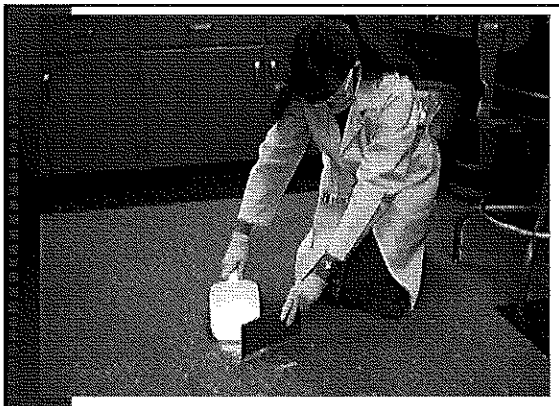
Centrifuge



Spills/Decontamination

- Disinfectants (see hand-out)
- Spill Supplies
- Aerosols - leave area & let settle 30 minutes before clean-up
- Wash or shower after clean-up
- BSL 3 - leave the area, post sign, call OEHS





Transportation & Shipment

- Various Regulations (see hand-out)
- Intent: to protect the public from accidental direct contact with materials
- Regulations also benefit shipper
- Regulations address: packaging, labeling, marking, & documentation

In Conclusion . . . .

- lab acquired infections
- how to minimize exposures through CDC/NIH Guidelines, containment equipment, & decontamination
- Transport & shipment
- Sources of help

Biosafety in Microbiological and Biomedical Laboratories

3rd Edition

JY Richmond & RW McKinney (eds.)

5th National Symposium on Biosafety:

A Rational Basis for Biocontainment

BMBL

Introduction

1941 - Meyer and Eddie

- 74 lab associated brucellosis infections in US

1949 - Sulkin and Pike

- 222 viral infections (21 fatal)
- Only 27% related to known accidents

BMBL

Introduction

1951,1965, 1976 - Sulkin and Pike

Surveys for lab-associated infections

- More than 5,000 labs
- Cumulative total of 3,921cases cited
- Most commonly reported:
  - Hepatitis
  - Brucellosis
  - Tuberculosis
  - Tularemia
  - Typhoid
  - Venzuelan Equine Encephalitis

BMBL

Introduction

1951,1965, 1976 - Sulkin and Pike (cont.)

Surveys for lab-associated infections

- Fewer than 20% associated with known accidents
- Exposure to infectious aerosols plausible (but unconfirmed) for >80% of reported cases

Principles of Biosafety

Introduction

Biosafety Levels 1-3

Guidelines to describe combinations of:

- Laboratory Practices and Techniques
  - Standard Practices
  - Special Practices
- Safety Equipment (Primary Barriers)
- Laboratory Facilities (Secondary Barriers)

Principles of Biosafety

Introduction

Biosafety Levels 1-3 Provide

- Increasing levels of personnel and environmental protection
- Guidelines for working safely in microbiological and biomedical laboratories

Lab Practices and Techniques
Introduction

- Knowledgeable supervisor
- Personnel
  - Aware of potential hazards
  - Proficient in practices/techniques
- Biosafety manual specific to lab

Safety Equipment
(Primary Barriers) - Introduction

- Biosafety cabinets (BSCs) [BSL-2/3]
- Personal protective clothing
  - Gloves
  - Gowns
- Pipetting Devices
- Safety centrifuge cups and rotors
- Eye and face protection
- Respiratory protection [BSL-3]

Biosafety Level 1
Introduction

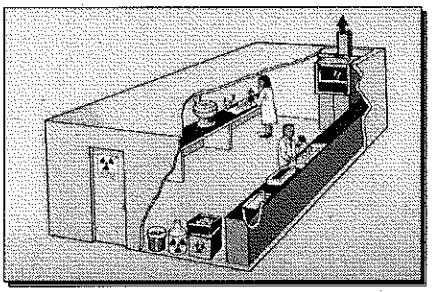
Suitable for work involving well-characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.

Biosafety Level 1
Introduction

Examples:

- *Bacillus subtilis*
- *Naegleria gruberi*
- Infectious canine hepatitis virus
- *E. coli*

Biosafety Level 1
Laboratory Facilities (Secondary Barriers)



Biosafety Level 1
Laboratory Facilities (Secondary Barriers)

- Sink for handwashing
- Work surfaces easily cleaned
- Bench tops
- Sturdy furniture
- Windows fitted with flyscreens

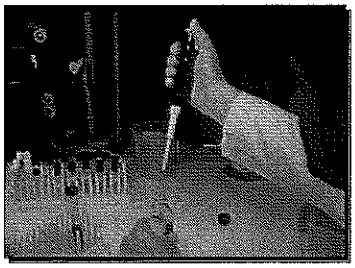
Facility Design
(Secondary Barriers) - Introduction

Easily cleaned and decontaminated

Facility Design
(Secondary Barriers) - Introduction

- Laboratory location
- Laboratory structure
- Laboratory ventilation

Biosafety Level 1
Standard Microbiological Practices



Use mechanical pipetting devices

Biosafety Level 1
Standard Microbiological Practices

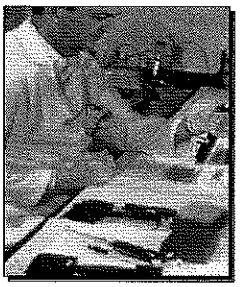
- Use mechanical pipetting devices
- Wash hands
- Restrict or limit access when working
- Prohibit eating, drinking and smoking

Biosafety Level 1
Standard Microbiological Practices (cont.)

- Minimize splashes and aerosols
- Decontaminate work surfaces daily
- Decontaminate wastes
- Maintain insect & rodent control program

Biosafety Level 1
Safety Equipment (Primary Barriers)

Protective clothing
- Lab coat
- Gloves



Biosafety Level 1
Safety Equipment (Primary Barriers)

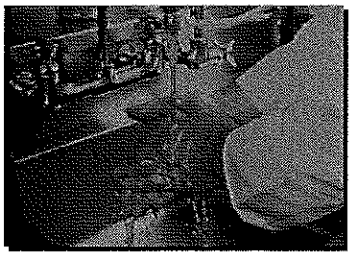
Additionally, PPE may be needed

- Face protection
- Eye protection

Biosafety Level 1
Special Practices

NONE

Biosafety Level 1
Standard Microbiological Practices



Wash hands

Biosafety Level 1

Supervision
- Scientist with general training in microbiology or related science

Lab Personnel
- Specific training in lab procedures

Biosafety Level 2

Suitable for work involving agents of moderate potential hazard to personnel and the environment.

Biosafety Level 2

Immunization or antibiotic treatment is available

Examples:
- Measles virus
- Salmonellae
- Toxoplasma spp.
- Hepatitis B virus

Biosafety Level 2

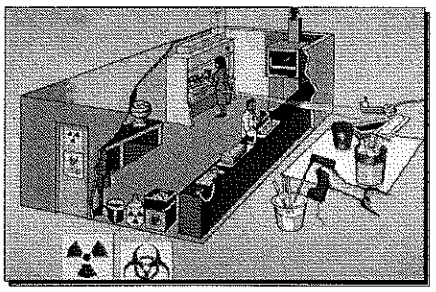
Extreme precaution with contaminated needles or sharp instruments

Examples:

- Bloodborne pathogens
- Human body fluids/particularly when visibly contaminated with blood

Biosafety Level 2

Laboratory Facilities (Secondary Barriers)



Biosafety Level 2

Standard Microbiological Practices

As in BSL-1

With emphasis on :

- Gloves
- Mechanical pipetting
- Attention to sharps

Biosafety Level 2

Special Practices

Needles & Sharps Precautions

DON'T

Break, bend, resheath or reuse syringes or needles

DO

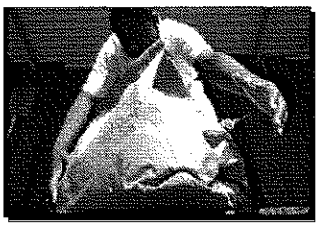
Use sharps containers

Biosafety Level 2

Special Practices (cont.)

Needles & Sharps Precautions

So someone won't be injured later



Biosafety Level 2

Special Practices (cont.)

Needles & Sharps Precautions

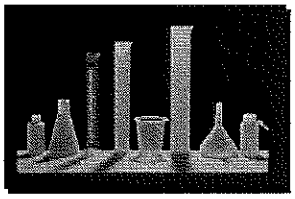
DON'T

Touch broken glass with hands

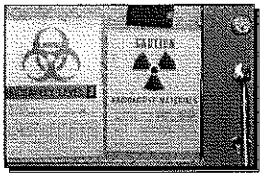
Biosafety Level 2
Special Practices (cont.)

Needles & Sharps Precautions

DO
Use plasticware



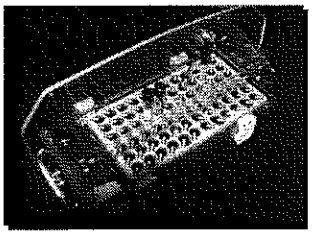
Biosafety Level 2
Special Practices (cont.)



- Policies and procedures for entry
- Biohazard warning signs
- Biosafety manual specific to lab
- Training with annual updates

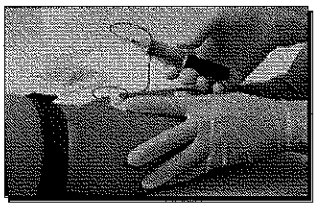
Biosafety Level 2
Special Practices (cont.)

- Use leak-proof transport containers



Biosafety Level 2
Special Practices (cont.)

- Immunizations
- Baseline serum samples



Biosafety Level 2
Special Practices (cont.)

- Decontaminate work surfaces
- Report spills and accidents
- No animals in laboratories

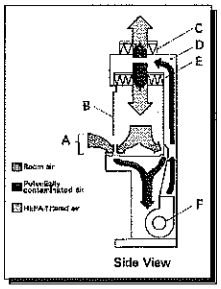
Biosafety Level 2
Safety Equipment (Primary Barriers)

BSL-1 PLUS:
Use biosafety cabinets (class II) for work with infectious agents involving:

- Aerosols and splashes
- Large volumes
- High concentrations

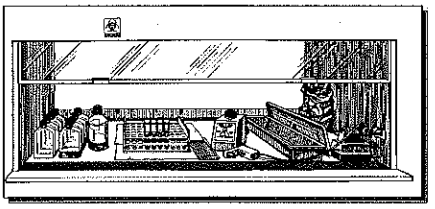
Biosafety Level 2
Safety Equipment (Primary Barriers)

Class II Biosafety Cabinets
- Airflow



Biosafety Level 2
Safety Equipment (Primary Barriers)

Class II Biosafety Cabinets
- Layout of equipment

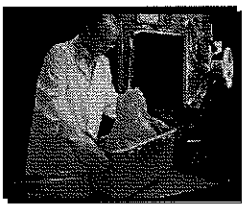


Biosafety Level 2
Safety Equipment (Primary Barriers)

Class II Biosafety Cabinets
- Technique

Biosafety Level 2
Laboratory Facilities (Secondary Barriers)

BSL-1 Facilities PLUS:



- Autoclave available
- Eyewash station available

Biosafety Level 2
Special Practices

Supervision
- Supervisor is a competent scientist with increased responsibilities
  - Limits access if immunocompromised
  - Restricts access to immunized

Lab Personnel
- Aware of potential hazards
- Proficient in practices/techniques

Biosafety Level 3

Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

Biosafety Level 3

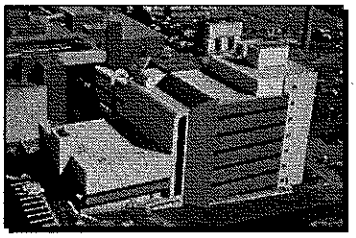
- Exposure potential to pathogens spread by aerosol
- Infection serious, possibly lethal
- Examples:
  - *M. tuberculosis*
  - St. Louis encephalitis virus
  - *Coxiella burnetii*

Biosafety Level 3
Laboratory Facilities (Secondary Barriers)

BSL-1 and 2 Facilities PLUS:

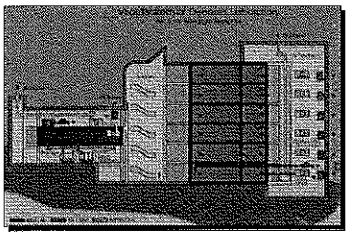
- Separate building or isolated zone
- Double door entry
- Directional inward airflow
- Single-pass air

Facility Design
(Tertiary Barriers)



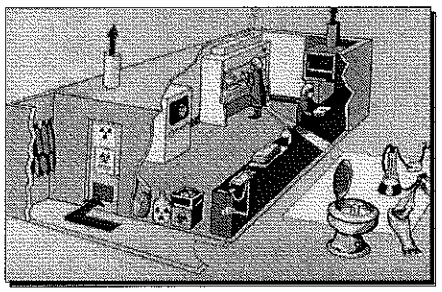
Location of CDC's MCL

Facility Design
(Tertiary Barriers)



Lab structure
Lab ventilation

Biosafety Level 3
Laboratory Facilities (Secondary Barriers)



Biosafety Level 3
Laboratory Facilities (Secondary Barriers)

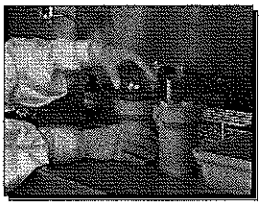
BSL-1 and 2 Facilities PLUS (cont.):

- Enclosures for aerosol generating equipment
- Room penetrations sealed
- Walls, floors and ceilings are water resistant for easy cleaning

Biosafety Level 3
Special Practices

BSL-2 Special Practices PLUS:

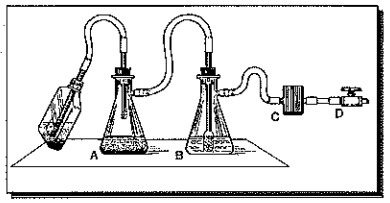
- Work in certified BSC
- Use bioaerosol-containing equipment
- Decontaminate spills promptly



Biosafety Level 3
Laboratory Facilities (Secondary Barriers)

BSL-1 and 2 Facilities PLUS:

- Vacuum lines protected



Biosafety Level 3

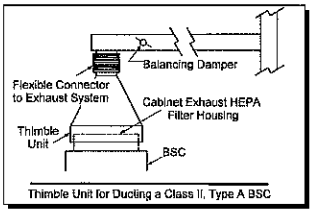
Standard Microbiological Practices

As in BSL-1 and -2

Biosafety Level 3
Safety Equipment (Primary Barriers)

BSL-1 and 2 Safety Equipment PLUS:

- BSC class II or III to manipulate infectious material

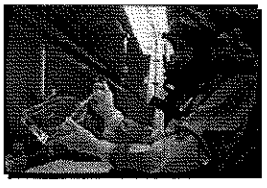


Thimble Unit for Ducting a Class II, Type A BSC

Biosafety Level 3
Safety Equipment (Primary Barriers)

BSL-1 and 2 Safety Equipment PLUS:

- Respiratory protection may be indicated



Biosafety Level 3
Special Practices

Supervision

- Supervisor is a competent scientist experienced working with agents
  - Establishes criteria for entry
  - Restricts access
  - Develops policies/procedures
  - Trains lab personnel

Biosafety Level 3
Special Practices

Lab Personnel
- Strictly follow guidelines
- Demonstrate proficiency
- Receive appropriate training
- Report incidents
- Participate in medical surveillance

Principles of Biosafety
Summary

BSL 1-3
- Standard Practices
- Special Practices
- Safety Equipment (Primary Barriers)
- Laboratory Facilities (Secondary Barriers)
- Building (Tertiary Barriers)

H5N1 avian influenza virus

H5N1 viruses isolated since 1997 in Asia

Virus generation, cell culture, experimental infection (mice, ferrets, chickens)

RISK ASSESSMENT

- Known to cause lethal infection in avian species and humans
- Aerosol transmission
- Prophylaxis available
- low human-to-human transmission

➡ RISK GROUP 3

NIH Guidelines, Sect. IIA; 9 CFR 121.3d

BIOSAFETY LEVEL

BSL-3
ABSL-3

H5N1 viruses isolated since 1997 in Asia

Molecular cloning (genetic material)

RISK ASSESSMENT

- Noninfectious
- Inability to insert into human genome

➡ RISK GROUP 1

NIH Guidelines[1], App. B.1; 9 CFR[2] 121.3f.2

➡ **BIOSAFETY LEVEL**

BSL-2

[1] NIH Guidelines, NIH Guidelines for Research Involving Recombinant DNA Molecules
[2] 9 CFR 121, Title 9 Code of Federal Regulations

H5N1 viruses isolated since 1997 in Asia

Virus generation, cell culture, experimental infection (mice, ferrets, chickens)

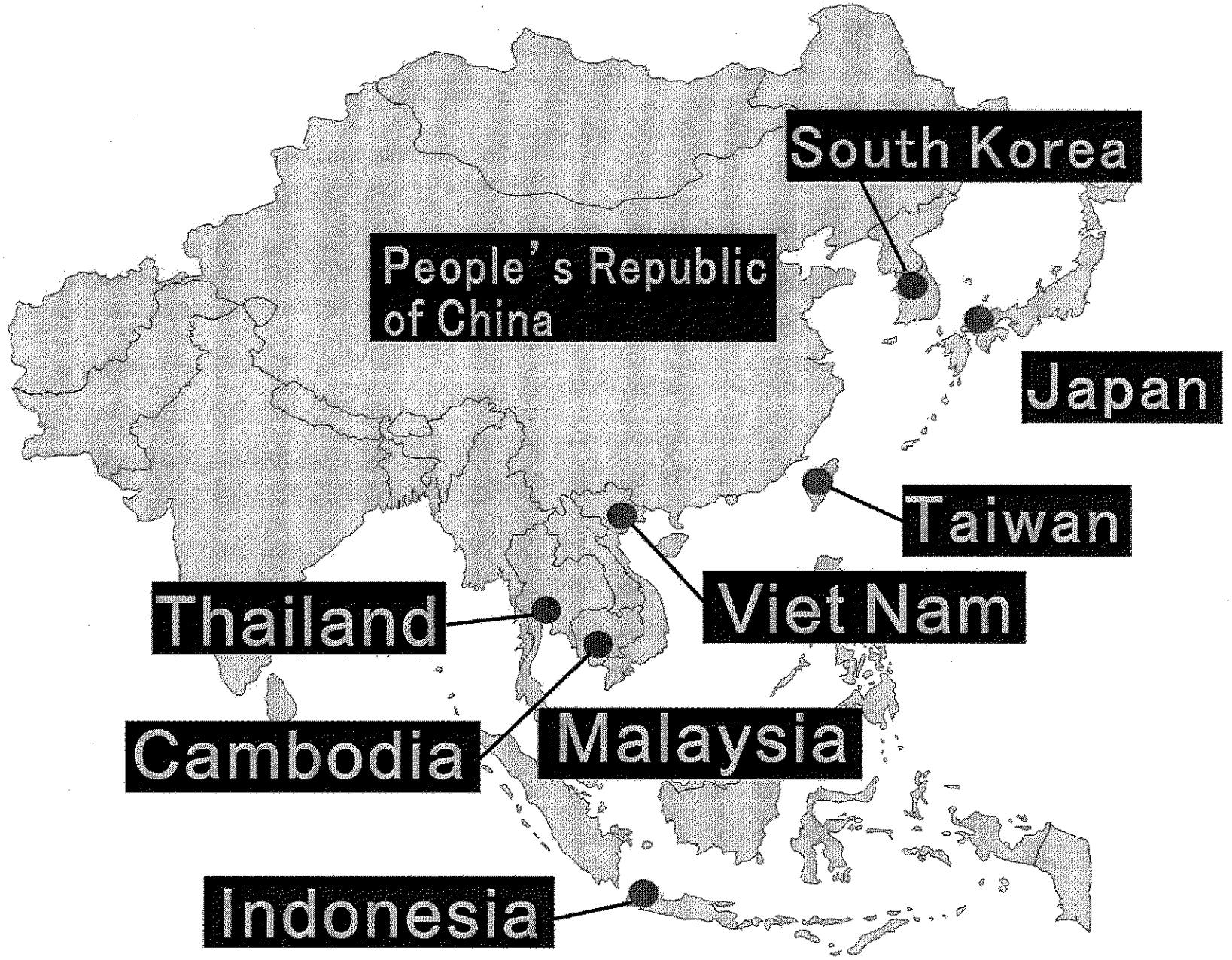
SPECIFIC PRACTICES

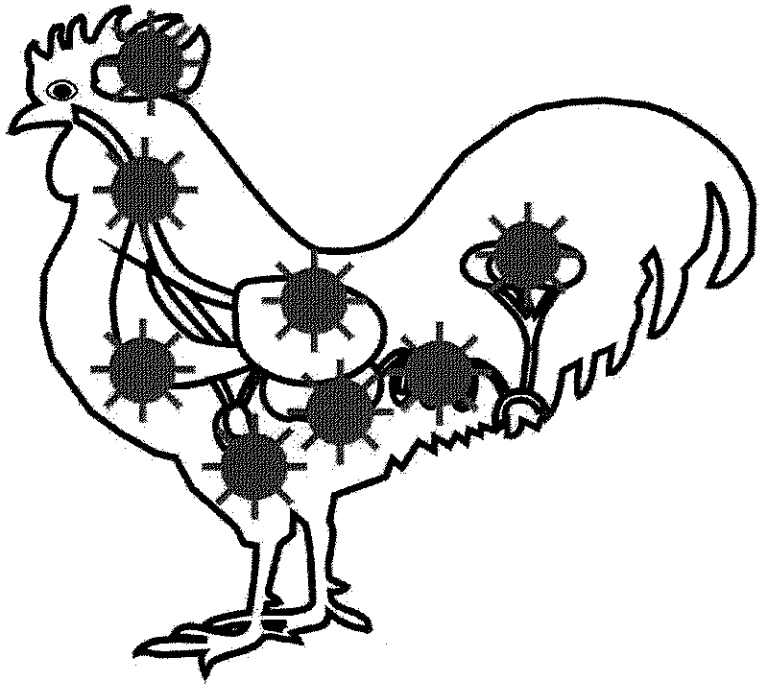
1) Annual vaccination required
2) Prophylaxis when aerosols likely
3) PAPRs with face shields
4) Shower out
5) Susceptibility testing of agents

PAPRs: Powered air-purifying respirators

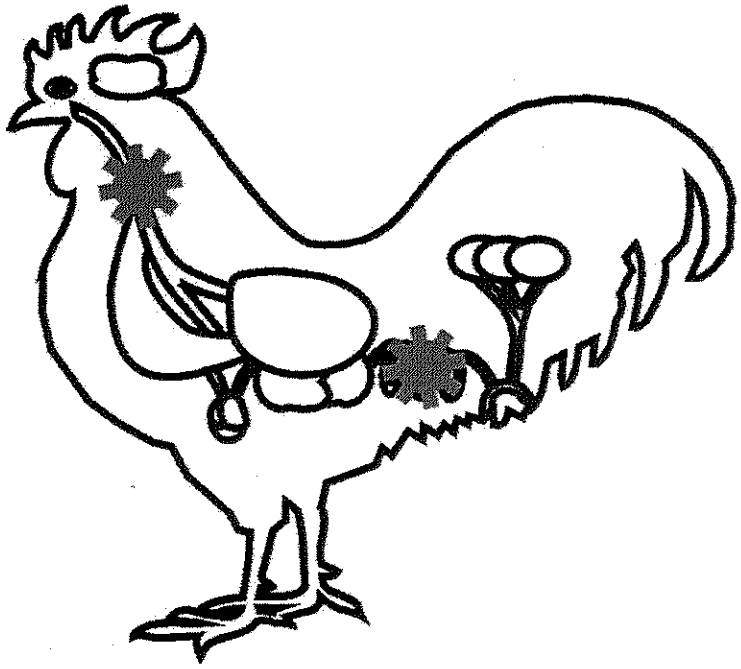
Additional features/procedures in BSL-3 at UT

1) Entry/exit through change and shower rooms
2) Double-door autoclave
3) Shower facilities
4) Daily decontamination of work surfaces
5) All personal clothing removed in outer change rooms
6) Established system for reporting and treating exposures
7) Annual inspection by federal regulatory agencies
8) Contact with non-experimental mice, ferrets, and chickens is prohibited within one week of contact with experimentally infected animals


South Korea
People's Republic of China
Japan
Taiwan
Viet Nam
Thailand
Malaysia
Cambodia
Indonesia

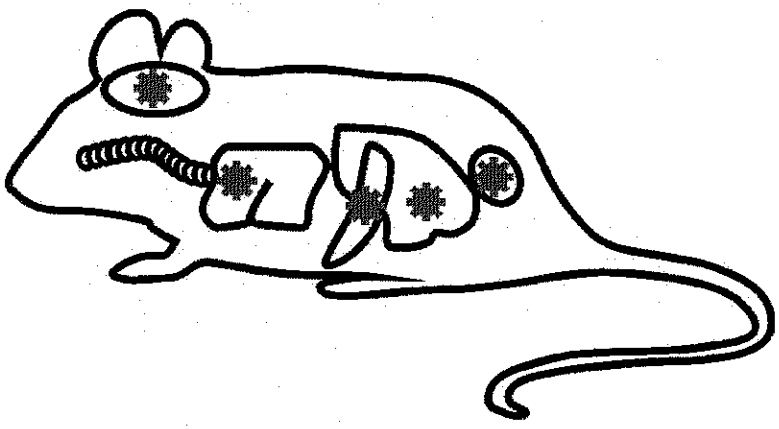


Systemic infection



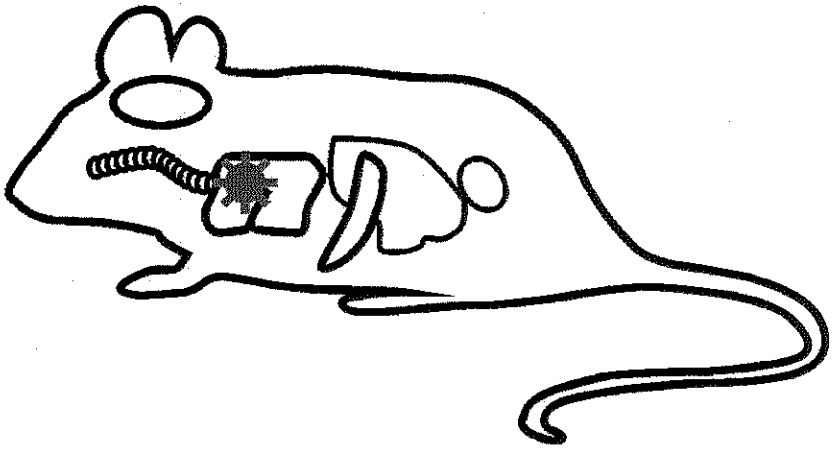
Localized infection

HK483



Systemic Infection

HK486

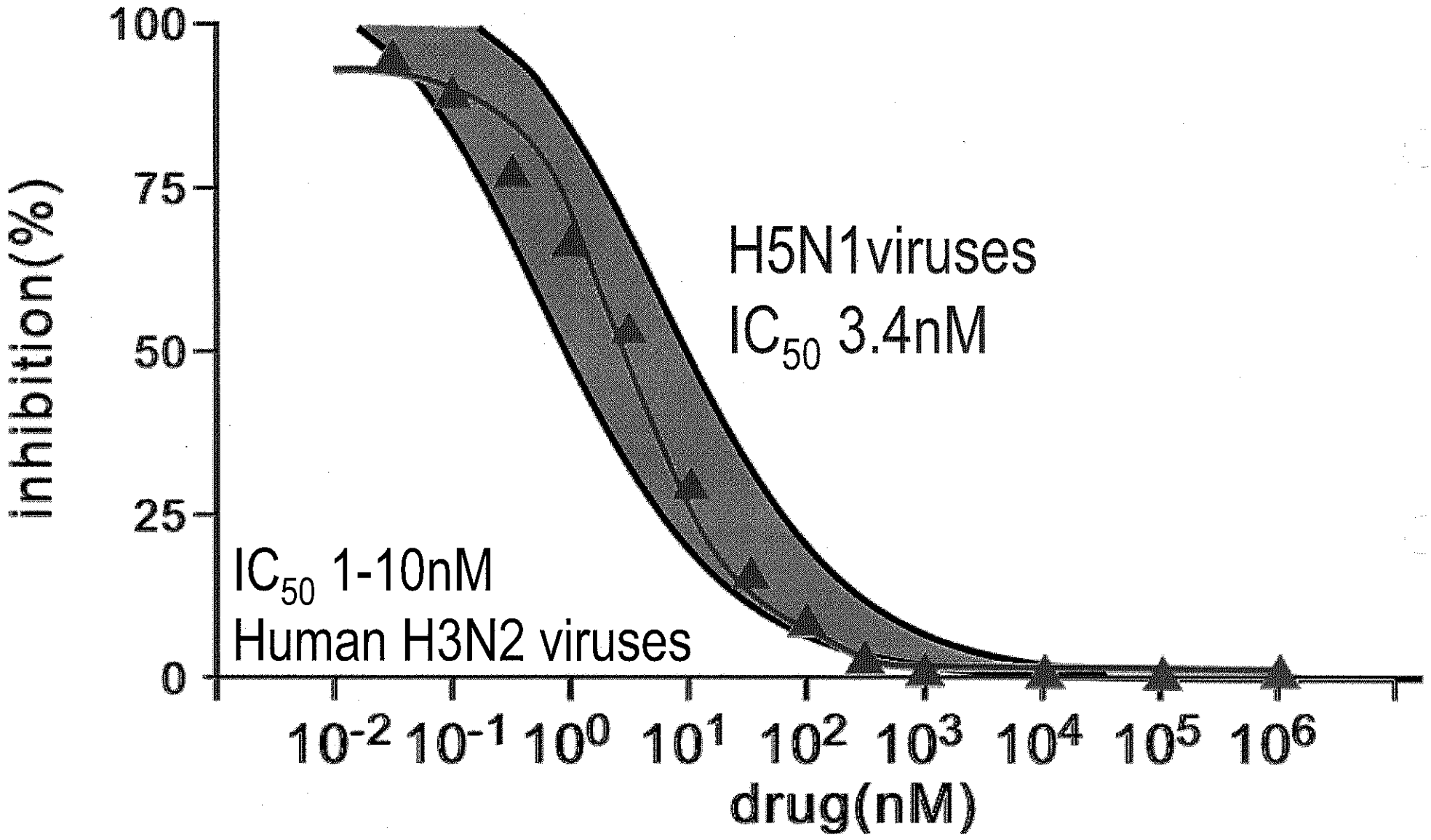


Local Infection

Determinants affecting pathogenicity of influenza virus

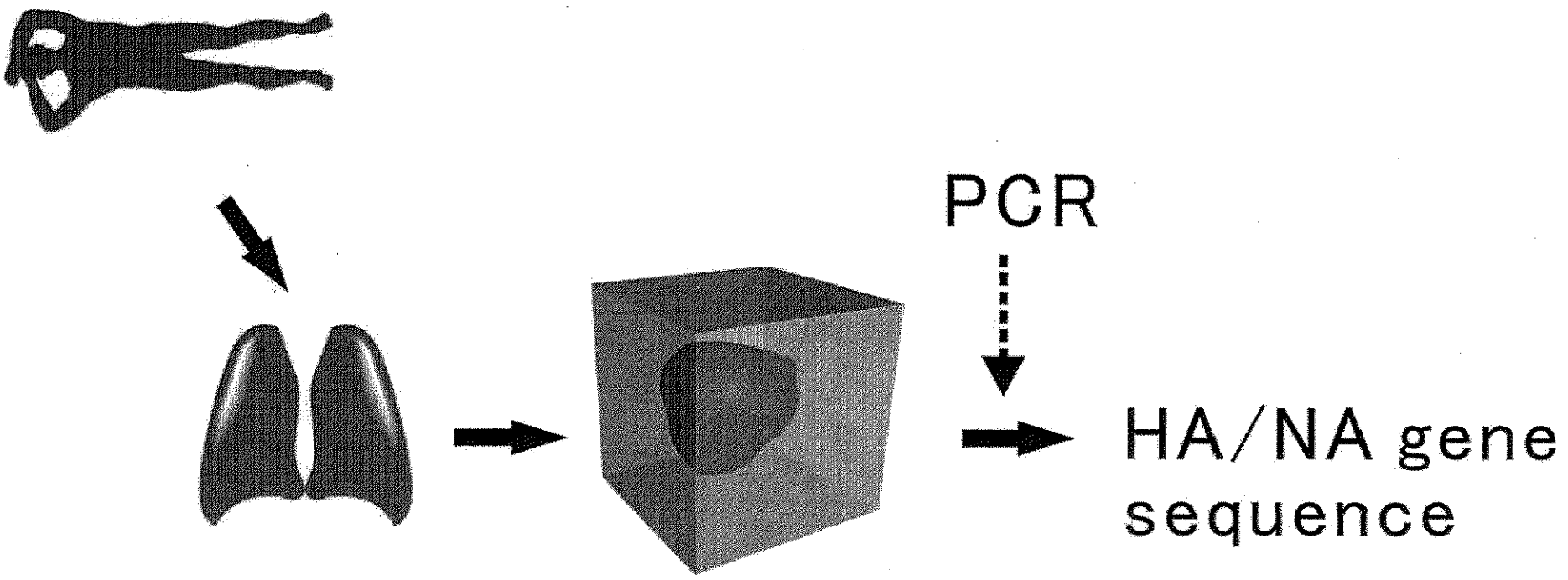
- HA cleavability
- PB2 amino acid at position 627 and others
- NS1 protein

H5N1 viruses sensitive to oseltamivir

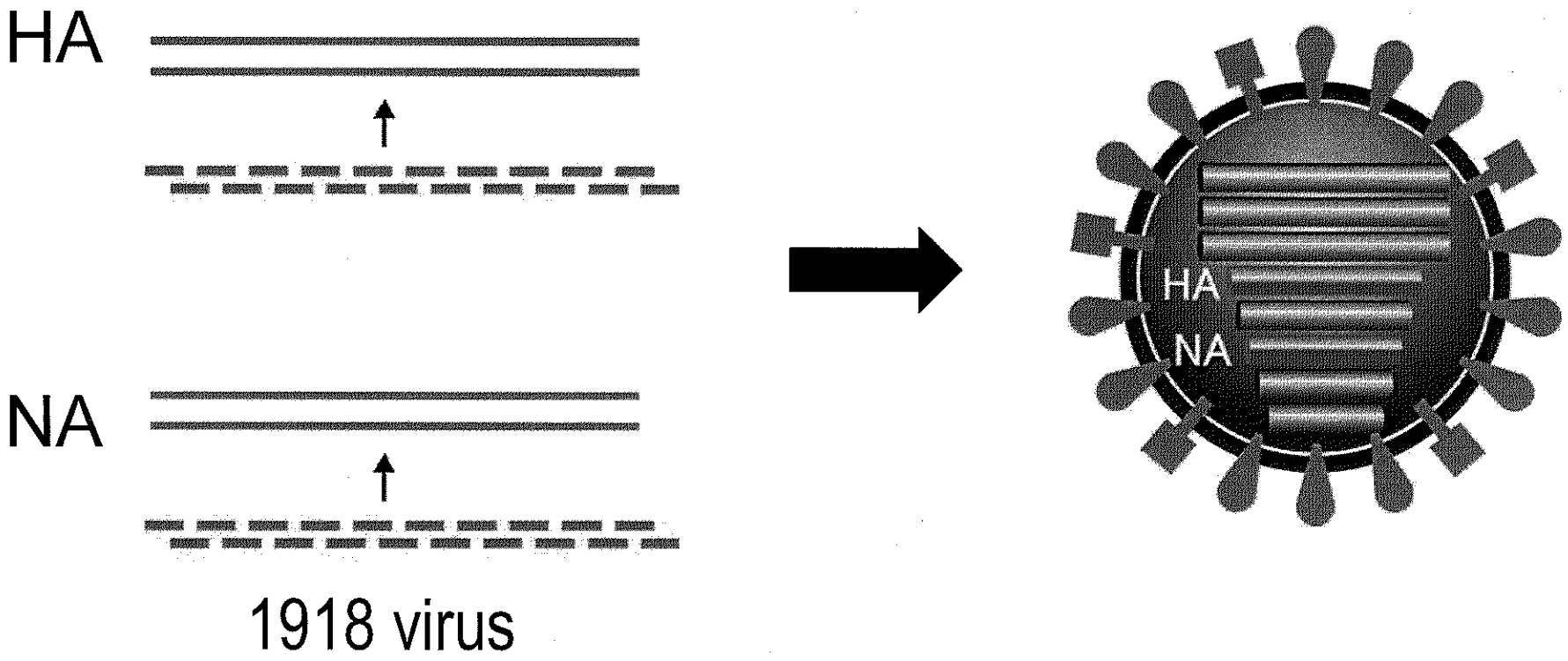


Experiments with viruses possessing the 1918 virus genes

The Spanish influenza virus does not exist.



Reid AH et al. PNAS (1999)
Reid AH et al. PNAS (2000)


HA
NA
HA
NA
1918 virus

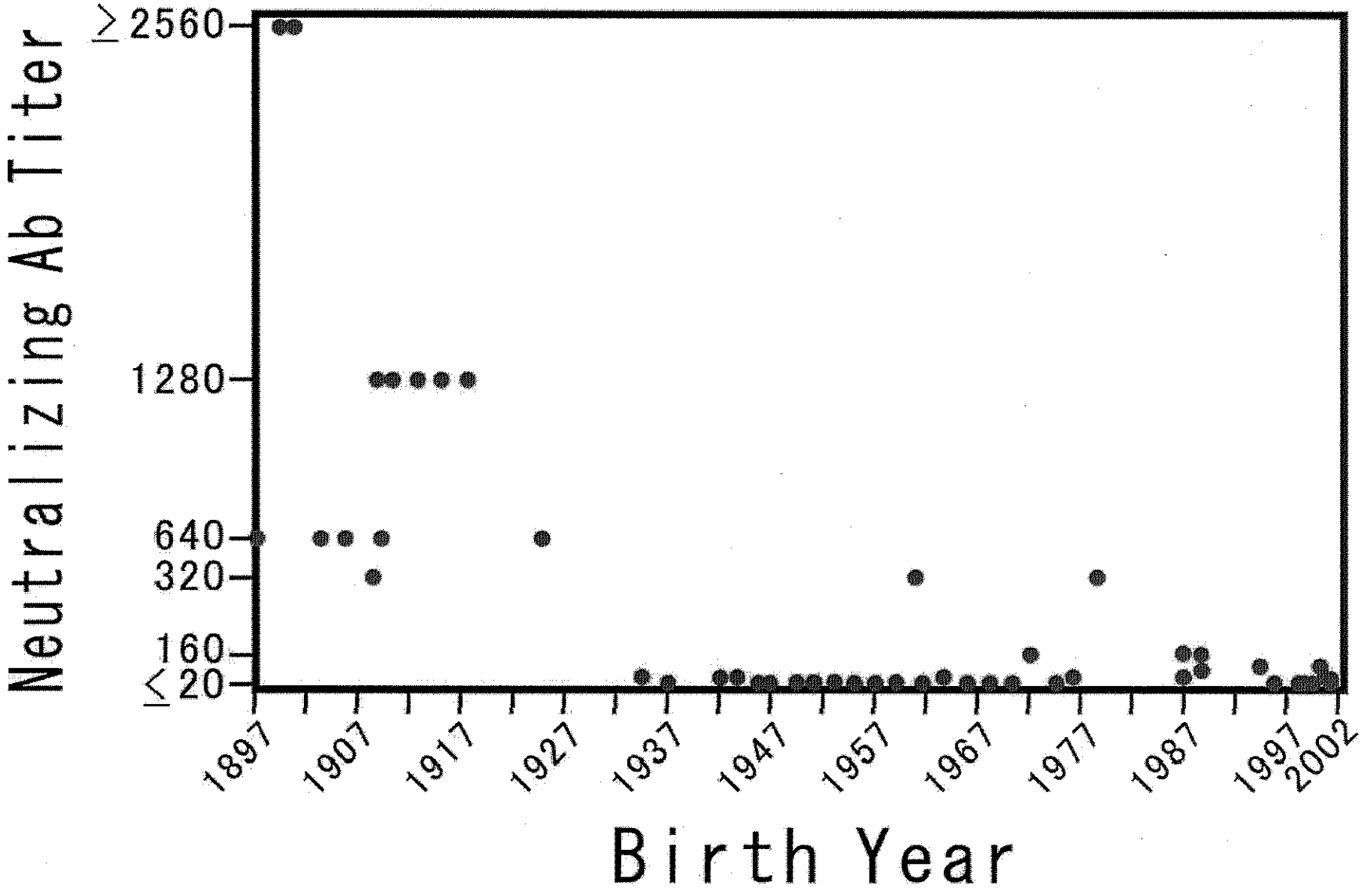
Properties of viruses with the 1918 virus HA and/or NA in mice

Virus	Origin of Genes			LD50 (Log_{10} PFU)	Virus titer in lung (Log_{10} PFU)
	HA	NA	Others		
WSN (H1N1)	WSN	WSN	WSN	3.3	5.0 ± 0.3
WSN/HspNsp	1918	1918	WSN	3.0	5.0 ± 0.1
M88 (H3N2)	M88	M88	M88	>6.2	2.9 ± 0.2
M88/Hsp	1918	K173	M88	4.4	5.1 ± 0.1
M88/HspNsp	1918	1918	M88	5.2	4.7 ± 0.2
K173 (H1N1)	K173	K173	K173	>7.4	3.5 ± 0.3
K173/Hsp	1918	K173	K173	5.2	4.8 ± 0.2
K173/HspNsp	1918	1918	K173	6.9	ND

Detection of viral neutralizing antibodies

Virus	avirus with the 1□□□virus HA and NA
Sera	1 year old (born in 200□ ⟷ 102 years old (born in 189□ 

Neutralizing antibodies to a virus with the 1918 virus HA and NA



Viruses with the 1918 virus HA and NA genes

Molecular cloning (genetic material)

RISK ASSESSMENT

- Noninfectious
- Inability to insert into human genome

➡ RISK GROUP 1

NIH Guidelines[1], App. B.1; 9 CFR[2] 121.3f.2

BIOSAFETY LEVEL

BSL-2

[1] NIH Guidelines, NIH Guidelines for Research Involving Recombinant DNA Molecules
[2] 9 CFR 121, Title 9 Code of Federal Regulations

Viruses with the 1918 virus HA and NA genes

Virus generation, cell culture, experimental infection (mice)

RISK ASSESSMENT

- Potential risk for human infection
- Increased pathogenicity
- Human population may be susceptible
- Aerosol transmission
- Potential for human-to-human transmission
- Protection with current vaccines ???
- Prophylaxis ???

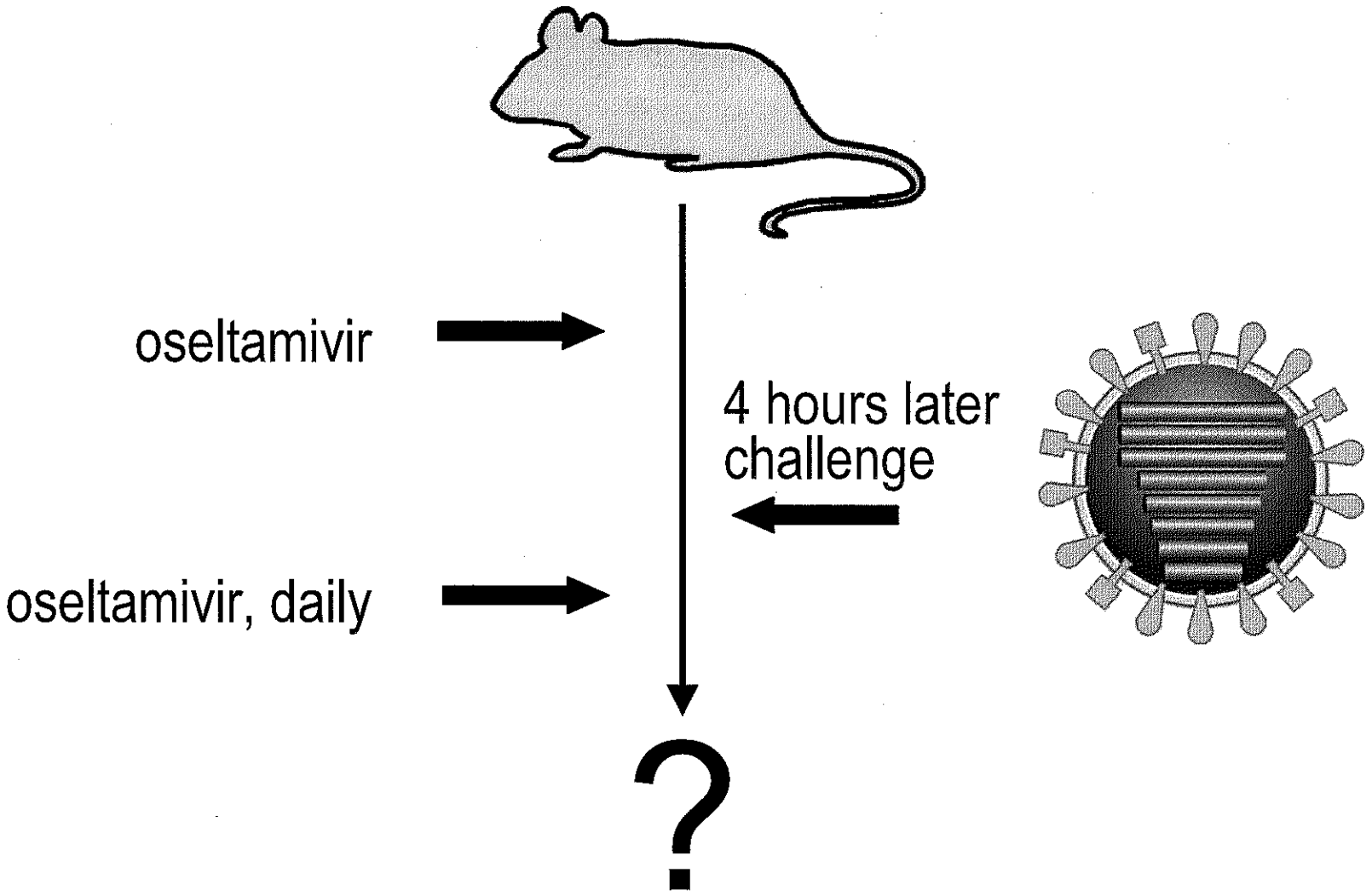
➡ RISK GROUP 3 or 4 ?

NIH Guidelines, Sect. IIA; 9 CFR 121.3d

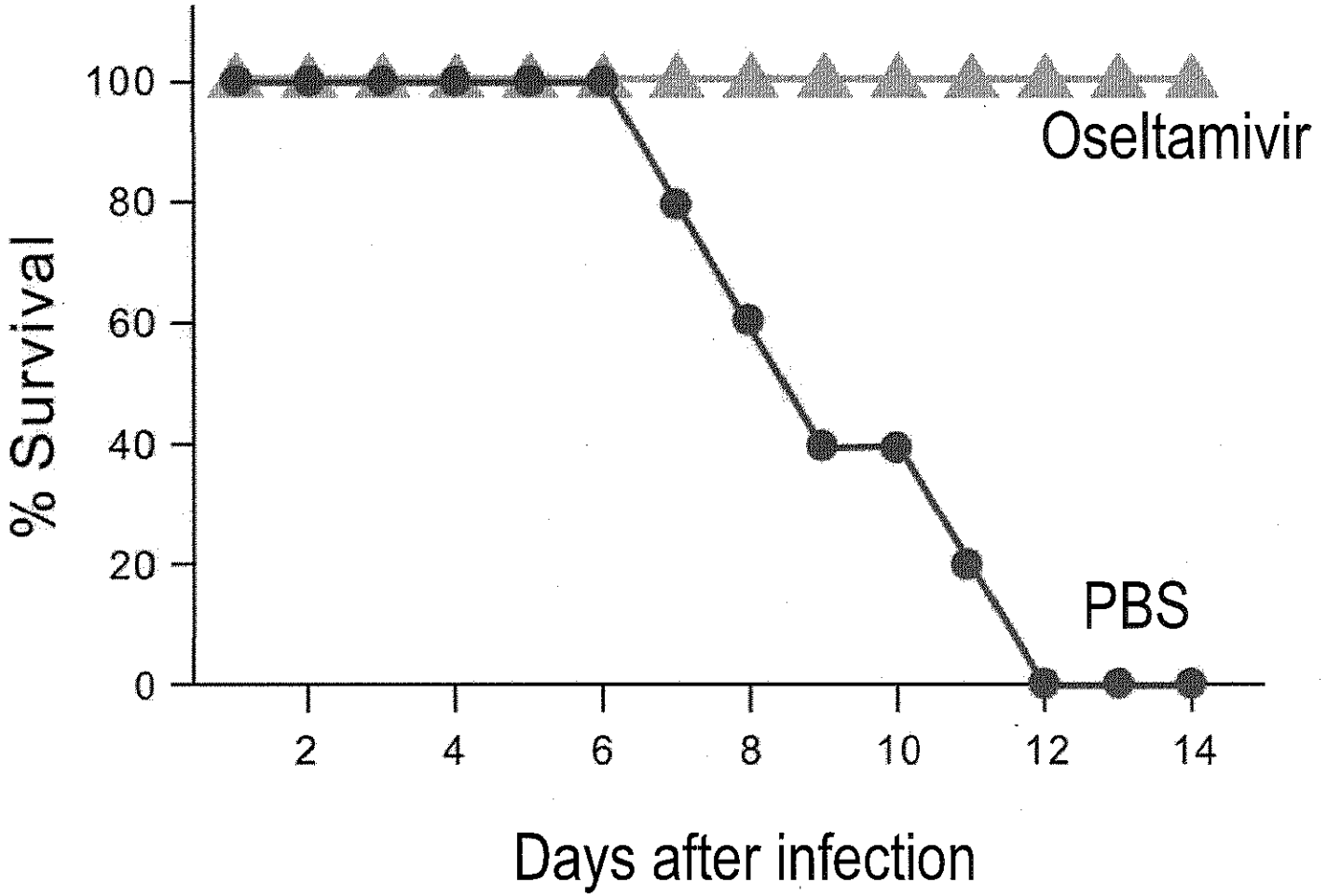
BIOSAFETY LEVEL

BSL-4

Prophylaxis of a virus with the 1918 virus HA and NA with oseltamivir



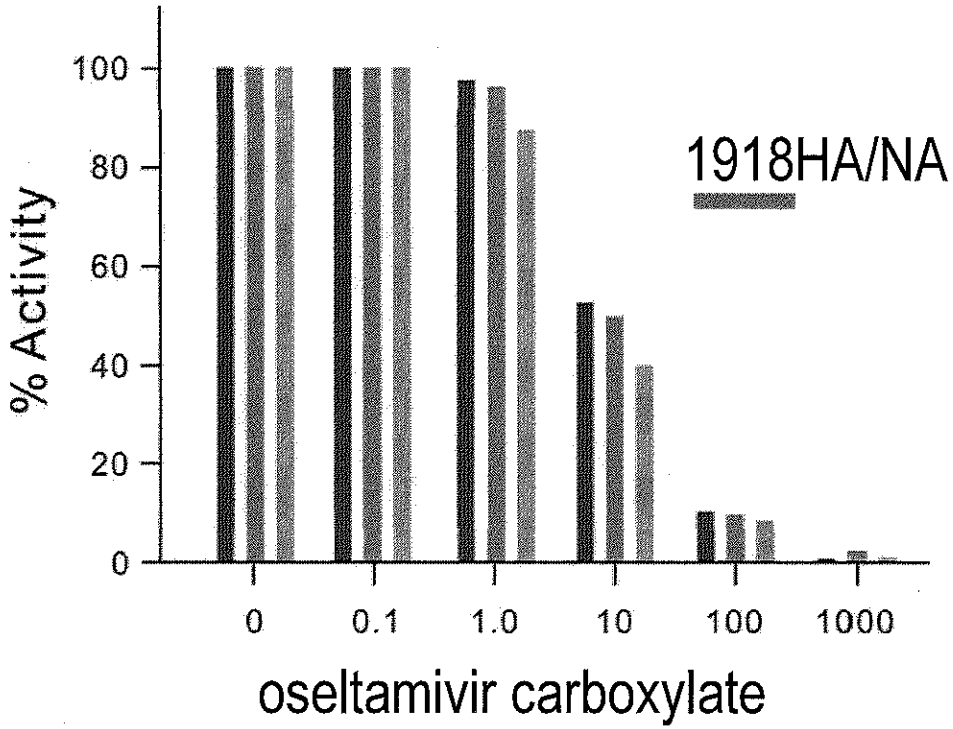
Oseltamivir protects mice from challenge with a virus possessing the 1918 virus HA and NA



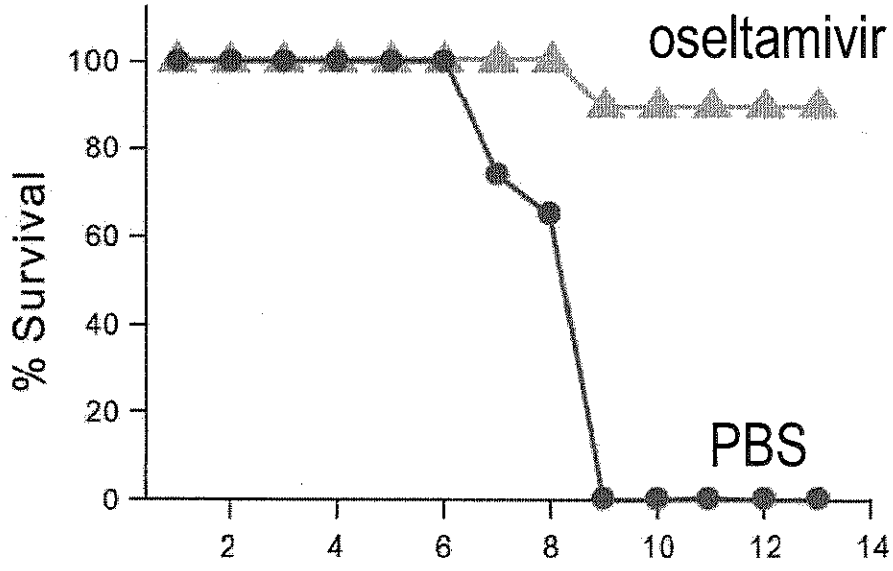
Antiviral

A virus with the 1918 virus NA is sensitive to oseltamivir carboxylate

In vitro



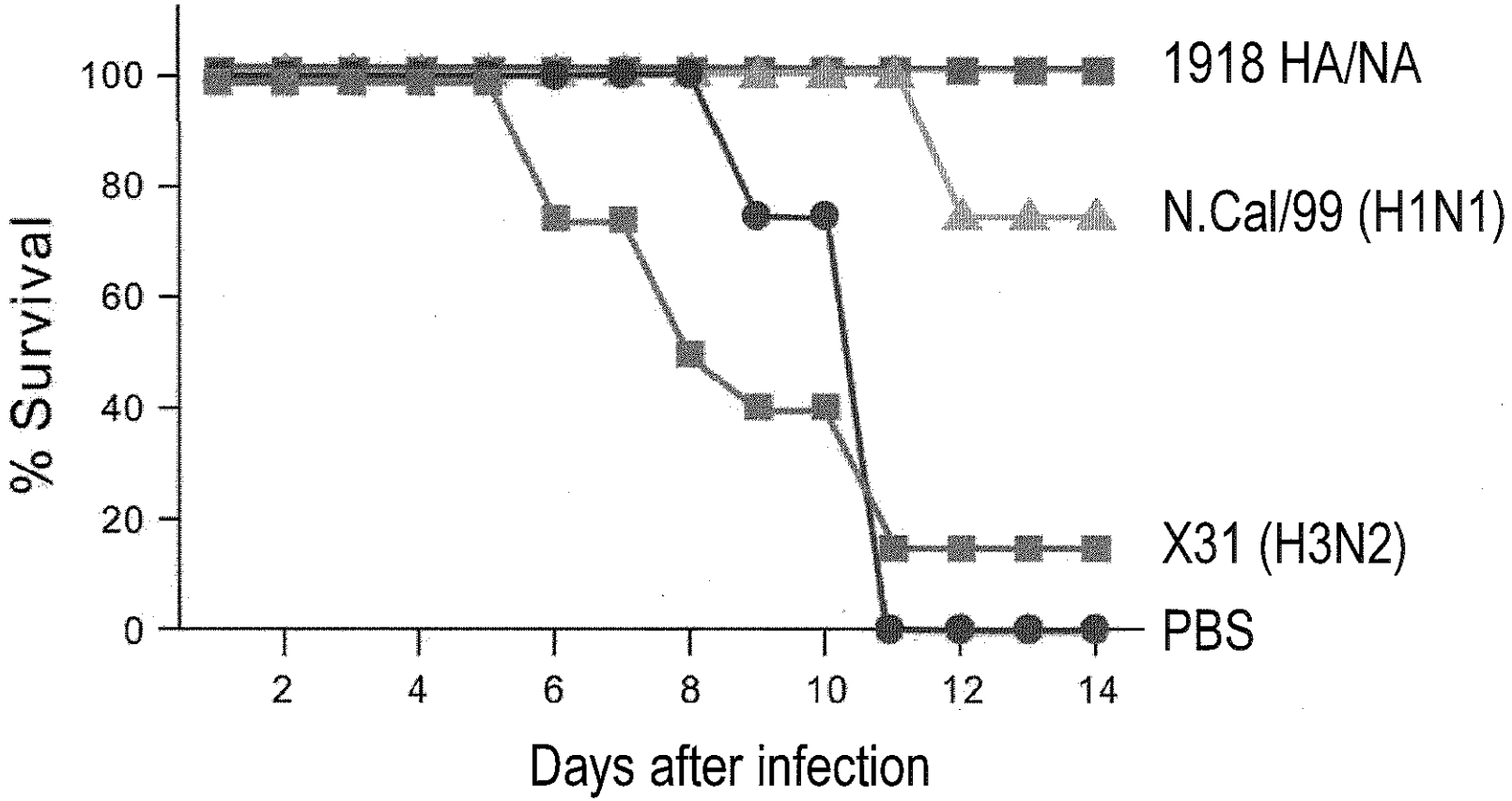
Mouse model



Tumpey et al. (2002) PNAS 99, 13849

Vaccine

Protection of mice against a virus with the 1918 HA and NA using inactivated vaccine made from a contemporary H1 strain



Tumpey et al. (2004) PNAS 101, 3166

Viruses with the 1918 virus HA and NA genes

Virus generation, cell culture, experimental infection (mice)

SPECIFIC PRACTICES

1) Annual vaccination required
2) Prophylaxis when aerosols likely
3) PAPRs with face shields
4) Shower out
5) Susceptibility testing of agents

PAPRs: Powered air-purifying respirators

Viruses with the 1918 virus HA and NA genes

Virus generation, cell culture, experimental infection (mice)

RISK ASSESSMENT

- Potential risk for human infection
- Likelihood of increased pathogenicity
- Human population may be susceptible
- Aerosol transmission
- Potential for human-to-human transmission
- Current vaccines may offer protection
- Prophylaxis available

➡ RISK GROUP 3

NIH Guidelines, Sect. IIA; 9 CFR 121.3d

BIOSAFETY LEVEL

BSL-3

Additional features/procedures in BSL-3 at UT

1) Entry/exit through change and shower rooms
2) Double-door autoclave
3) Shower facilities
4) Daily decontamination of work surface
5) All personal clothing removed in outer change rooms
6) Established system for reporting and treating exposures
7) Annual inspection by federal regulatory agencies

BSL3 Meeting 7/15/05

1) Introductions

2) CDC Inspection August 16th, 9:00am, EHS inspection August 2nd.

3) Biosafety Issues:
   - A) Agent review
   - B) Update signage
   - C) Housekeeping
   - D) Ventilation
   - E) Autoclaves
   - F) Training for new Krug/Ellington staff
   - G) New protocols
   - H) Exit procedure

4) Biosecurity Issues:
   - A) Cameras
   - B) Entrance Lock
   - C) Intrusion Alarm

5) Incident Response

6) Questions?

BSL3 Meeting 12/22/05

1) CDC Inspection

2) Security
   - -Alarm to be reactivated starting today
   - -Visitors/maintenance must sign in
   - -See stranger in lab- leave lab and call me

3) Biosafety Issues:
   - -Housekeeping (weekly)
   - -Incoming staff to make staff aware

4) Krug Issues:
   - A) New staff-training
   - B) Flu shots-provide list
   - C) UV light
   - D) Baselines

5) Ellington Issues:
   - A) Installation of locks-fridges and incubators
   - B) Update chemical hygiene plan
   - C) Annual drill-late February
   - D) Place log in room

6) Problems/Issues
   - -Need new erasers

Krug Lab BSL3 Training 11/15/06

1) Biosafety Issues:
    a) Agent review
    b) Tamiflu prescriptions
    c) Flu shot
    d) Medical surveillance
    e) PPE
        I)Suits to be used for <40 hours or one month (need to be dated)
        II) Disposable aprons to be used
    f) Develop notification system when working alone
    g) Working in a BSC video
    h) Glove removal exercise
    i) Update phone numbers

4) Biosecurity Issues:
    A) Activate alarm when leaving

5) Incident Response
    a) Review procedures

6) Lab Issues

ENVIRONMENTAL HEALTH & SAFETY TRAINING REQUIREMENTS

For information about EH&S training or to register for a course, see "Training"

REQUIRED EH&S Training for All UT Lab Employees:

OH 101: General Hazard Communication (1.5-hour lecture or online class)
Training **REQUIRED** by the Texas Hazard Communication Act for any UT employee who works with or around hazardous chemicals. Topics include container labels and material safety data sheets, safe handling of workplace chemicals, proper use of personal protective equipment, first-aid, and emergency procedures. This is a one time training class.

OH 102: Site-Specific Hazard Communication (taught in lab by supervisor)
Training **REQUIRED** by the Texas Hazard Communication Act for all UT employees who work in a lab prior to using hazardous chemicals. The lab supervisor/Principal Investigator is responsible for ensuring that site-specific training is provided to lab employees. Topics will vary based on the hazards specific to the lab. For more information, see www.utexas.edu/safety/ehs/lab/checklist.labsup2.pdf.
***** NOTE: Refresher training is REQUIRED whenever there is a significant change in the hazards of the lab. *****

OH 201: General Laboratory Safety (2-hour lecture or online class)
Topics include safety equipment and safe work practices, emergency procedures and equipment, chemical storage guidelines, how to use a spill kit, and general disposal procedures. This is a one time training class.

OH 202: Hazardous Waste Management (online class only)
Training **REQUIRED** for at least one paid lab employee out of 8 for each laboratory group. The training is only available in an online format. Topics include hazardous waste definitions and regulatory environment, chemical waste disposal and spill clean-up procedures, chemical waste storage and segregation guidelines, waste minimization, and drain disposal. This is a one time training class.

OH 205: Fire Extinguisher (1 hour hands-on learning)
Topics include basic fire extinguisher use and participants practice using a fire extinguisher to put out a controlled fire. This is a one time training class.

ADDITIONAL REQUIRED EH&S Training for All Lab Employees: (depending on lab use)

OH 218: Bloodborne Pathogens for Lab Personnel (1-hour lecture) ****** REQUIRED ANNUALLY!!! ******
Training **REQUIRED** annually for all personnel who work in labs where human blood or tissues are in use. Topics include safe work practices, the definition of bloodborne pathogens, protection from exposure including universal precautions, and spill clean-up procedures.

OH 301: Basic Radiological Health (8-hour lecture)
Training **REQUIRED** for all users of radioactive materials and radiation producing machines. Employees who took an equivalent radiation course at another location should contact the Safety Office regarding site-specific retraining and requalification requirements. Topics include how to work safely with radiation and radiation producing machinery, radiation hazards, and radiation detecting instruments. This is a one time training class.

OH 302: Basic Radiological Health Refresher (1-hour lecture)
Training is **REQUIRED** for new UT lab employees who took an equivalent radiation course at another location, and for individuals who took the 8-hour Basic Radiological Health course. Topics include current regulations related to radiation, recent changes to the regulations, the responsibilities of radiation users, and campus-specific issues related to radiation.

Verify Your Training History:

To see your training history, go to TXCLASS (https://utdirect.utexas.edu/txclass/index.WBX). Begin by logging in using your UT EID and password. After successfully logging in, click on the "Training History" link on the left side of the screen. A list of all the classes you have attended through TXCLASS, along with the dates the classes were completed will appear on the screen. Remember to Logoff of UT Direct when you are finished.

UT Direct - The University of Texas at Austin

TXClass UT Austin

NAVIGATION MENU

TxClass Home

Course Listing

Class Listing

Class Profile

Enroll/Withdraw

Training History

UT Components

Help

Administrative Functions

Personal Training History

Training History Lookup

You can view the training history of a person other than yourself by entering their EID. Then click the View Training History button.

rk562 View Training History

Personal Information			
Name	Kuo, Rei-Lin	E-mail	rlkuo@mail.utexas.edu
Job Title	Postdoctoral Fellow	Phone	
Dept. Title	Icmb-Pi-Krug	Address	
State Agency	University of Texas	Mail Code	A4800

Current and Completed Classes				
Course ID	Course Title	Date	CEU Credit	Completed?

CW 163	Contracts & Agreements (3 min.)	7/18/2006		complete
CW 102	Use of U.T. Austin Property (4 min.)	7/18/2006		complete
CW 108	Copyrighted Property (5 min.)	7/18/2006		complete
OH 102	Site-specific Hazard Communication	2/27/2006		complete
CW 123	Equal Employment Opportunity -EEO- (18 min.)	5/22/2005		complete
CW 125	Family and Medical Leave Act -FMLA (4 min.)	5/22/2005		complete
CW 124	Overtime Compensation, Exempt & Nonexempt Timekeeping (3 min.)	5/22/2005		complete
CW 121	Sexual Harassment (9 min.)	5/22/2005		complete
CW 107	Political Activities and Contributions (3 min.)	5/22/2005		complete
CW 106	Gifts and Gratuities (4 min.)	5/22/2005		complete
CW 103	Information and Records (6 min.)	5/22/2005		complete
CW 101	Introduction to U.T. Compliance Program (10 min.)	5/22/2005		complete
OH 201	Laboratory Safety	7/14/2003		complete
OH 101	Hazard Communication	7/14/2003		complete
CW 123	Equal Employment Opportunity -EEO-	6/19/2003		complete

	(18 min.)			
CW 121	Sexual Harassment (9 min.)	6/19/2003		complete
OH 301	Basic Radiological Health	6/16/2003		complete

Note: CW101, CW 121, CW 123, CW 500, and CW 502 are required every two years. For current information, please review the Office of Institutional Compliance website.

Transfer training information to an Excel spreadsheet. If you are using Internet Explorer, the spreadsheet should open automatically. If you choose instead to save it to disk or are using a different browser, make sure that the filename you give it when saving ends in the file extension ".xls" instead of ".WBY". If you try to open it and Excel asks you what data type describes your data, choose "tab-delimited".

Download Training History

	PIN	UTEID	Orientation	Initial Training	Evaluation	Training	Training	Training
Rei-Lin Kuo	9476	rk562	1/5/2005	3/15/2005	4/21/2005	7/15/2005	12/8/2005	11/15/2006

Appendix 3

USDA Permit and Documentation:

1) **USDA Permit**

2) **USDA Correspondence**

3) **CDC Correspondence**

Page 106 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not public information, Other Agency Document

Nolan, Dennis H

From: Lebansky, Rachel A
Sent: Tuesday, February 13, 2007 8:36 AM
To: Nolan, Dennis H
Subject: FW: USDA Permit

From: Dennis H Nolan
Sent: Monday, August 30, 2004 10:28 AM
To: 'Robert Krug'
Cc: Erle Janssen; Rachel A Lebansky; Abraham Ybarra
Subject: USDA Permit

Dr. Krug,

I spoke with Dr. Muhmed who is responsible for permitting at USDA. The following will need to occur before you can import your GM:

1) Obtain a letter from Dr. Doddy (USDA SA program) formally excluding your project from the Select Agent program. I've sent him an email today requesting that. Dr. Muhmed will need that as part of our application.

2) Submit an application to import USDA controlled materials (form VS 16-3)
VS 16-3 can be found at: http://www.aphis.usda.gov/vs/pdf_files/info-n.pdf and http://www.aphis.usda.gov/forms/vs16-3.pdf
You will need to fill out this form and send them to me. I will review them and forward to Dr. Muhmed.

3) Dr. Muhmed will then need to verify that our BSL3 lab has been inspected by USDA or CDC. Because the MBB's BSL3 has been inspected as part of the SA program, USDA will be able to access our records.

4) Following approval, Dr. Muhmed will issue an importation permit VS 16-6, allowing you to import your GM.

Let me know if I can be of further assistance on this.

Dennis

Dennis Nolan
Assistant Director Environmental Health & Safety
The University of Texas at Austin
P.O. Box 7729, Austin, Texas 78713
phone 512-232-4999
fax 512-471-6918

Nolan, Dennis H

From: Lebansky, Rachel A
Sent: Tuesday, February 13, 2007 8:36 AM
To: Nolan, Dennis H
Subject: FW: USDA Permit Status

From: Dennis H Nolan
Sent: Thursday, August 19, 2004 1:20 PM
To: 'Robert Krug'
Cc: Erle Janssen; Rachel A Lebansky
Subject: USDA Permit Status

Dr. Krug,

I have been in contact with USDA regarding your permit. I am waiting for a response from Dr. Muhmed, who will give me the permit information and any special biosafety requirements USDA has for this work. I have not heard anything from him.

I met with Alana today to see about plumbing the CO2 gas into your lab. We think there is a CO2 gas line into the room already but will need to verify. If so, getting the gas line set-up will be relatively inexpensive.

CDC will allow us to isolate select agents to one or two isolation labs, however, that will mean that the SA rooms will need their own autoclave. Since the entire suite was originally dedicated for select agents, this will require the purchase of a benchtop autoclave for the SA lab. I purchased a model from Fisher for my old BT lab that worked well. You can find it at:

https://www1.fishersci.com/Coupon?cid=1341&gid=2371252

I would recommend the model with the printer for QC purposes.

Dennis Nolan
Assistant Director Environmental Health & Safety
The University of Texas at Austin
P.O. Box 7729, Austin, Texas 78713
phone 512-232-4999
fax 512-471-6918

Nolan, Dennis H

From: Lebansky, Rachel A
Sent: Tuesday, February 13, 2007 8:36 AM
To: Nolan, Dennis H
Subject: FW: CDC Select Agent Program Website Update

From: Dennis H Nolan
Sent: Thursday, August 19, 2004 1:02 PM
To: Erle Janssen
Cc: Rachel A Lebansky; Abraham Ybarra
Subject: RE: CDC Select Agent Program Website Update

I've sent another email today to Dr. Muhmed at USDA requesting he contact me regarding permit and biosafety issues. I also sent Dr. Krug a list of bioaerosol tight centrifuge cups/rotors for him to pick from for his centrifuge. I haven't given him the news that he will need to buy a tabletop autoclave, but will do so today.

Dennis

From: Erle Janssen
Sent: Thursday, August 19, 2004 6:56 AM
To: Rachel A Lebansky; Dennis H Nolan
Cc: Abraham Ybarra; Kyle Cavanaugh (kylec@mail.utexas.edu)
Subject: RE: CDC Select Agent Program Website Update

I really happy to see the lead agency concept. That means for select agents CDC will handle our overlap agents.
Dennis, any progress on Krug and his USDA permit ? What about the centrifuge ?

From: Rachel A Lebansky
Sent: Wednesday, August 18, 2004 3:43 PM
To: Dennis H Nolan; Erle Janssen
Subject: FW: CDC Select Agent Program Website Update

-----Original Message-----
From: Laboratories Registration/SAT [mailto:lrsat@cdc.gov]
Sent: Wednesday, August 18, 2004 3:41 PM
Subject: CDC Select Agent Program Website Update

Please be advised that the CDC Select Agent Program website has been updated to provide:

1. New information regarding the security risk assessment (SRA) procedures for visitors (see: http://www.cdc.gov/od/sap/faq.htm#sec3q21).

2. New guidance regarding your application with CDC is available (see: http://www.cdc.gov/od/sap/faq.htm#sec3q45). In order to minimize the burden to the public that register for select agents and toxins, CDC and APHIS are working together to provide a single point of contact. This single point of contact is referred to as the lead agency, and as such, is responsible for coordinating all activities and communications with respect to your registration, including coordination with both the non-lead agency and with FBI/CJIS. The lead agency will retain responsibility for your application through the life of your registration certificate (2-3 years), even if your entity chooses to discontinue registration of overlap agents.

If you have questions concerning this new guidance, please contact your CDC representative. If you do not know who your representative is, please call 404-498-2255.

Charles Brokopp, DrPH, Director
Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road N.E., MS E-79
Atlanta, GA 30333
Telephone: 404-498-2255; FAX: 404-498-2265

http://www.cdc.gov/od/sap/

Nolan, Dennis H

From: Lebansky, Rachel A
Sent: Tuesday, February 13, 2007 8:35 AM
To: Nolan, Dennis H
Subject: FW: Select agent question

-----Original Message-----
From: Dennis H Nolan
Sent: Thursday, August 19, 2004 11:49 AM
To: Waleid.I.Muhmed@aphis.usda.gov
Cc: Erle Janssen; Rachel A Lebansky; Abraham Ybarra
Subject: RE: Select agent question

Dr. Muhmed,

I was wondering if you have had a chance to review our previous correspondence regarding the permitting and biosafety requirements for working with constructs containing genetic elements of avian influenza. Our researcher would like to begin the process of obtaining the plasmids and I would like to know if there are any facility modifications that need to be made. Please let me know if there is any I can do to advance this project.

Thanks in advance,

Dennis Nolan
Assistant Director Environmental Health & Safety The University of Texas at Austin P.O. Box 7729, Austin, Texas 78713 phone 512-232-4999
fax 512-471-6918

Pages 112 through 115 redacted for the following reasons:
- -
Other Agency Document

Nolan, Dennis H

From: Lebansky, Rachel A
Sent: Tuesday, February 13, 2007 8:34 AM
To: Nolan, Dennis H
Subject: FW: New Select Agent Contact Person

From: Erle Janssen
Sent: Monday, August 09, 2004 6:52 PM
To: Dennis H Nolan
Cc: Rachel A Lebansky (rlebansky@austin.utexas.edu)
Subject: RE: New Select Agent Contact Person

Let's all three meet and discuss.

From: Dennis H Nolan
Sent: Monday, August 09, 2004 3:44 PM
To: Erle Janssen
Subject: RE: New Select Agent Contact Person

In case Krug asks, we are going to treat his work as a select agent until we get notification otherwise?

I need to write a letter to CDC to add and remove some people from our SA application. Should I also request modifying our registration to reflect isolating SA to one room?

Dennis

From: Erle Janssen
Sent: Monday, August 09, 2004 2:08 PM
To: Rachel A Lebansky; Dennis H Nolan; Abraham Ybarra
Cc: Cheryl L Krisher
Subject: New Select Agent Contact Person

David Holmes is our new select agent person.
I talked with him about all three items we have pending.
1. Coyle's ADV-5 work. He has it in hand and will call us as soon as it is approved (or not) as a non-select agent.
2. I briefed him on Krug's H5N1 work and told him I send him some of the emails.
3. I discussed separation of select agent work vs. non-SA work in the same suite. We'll have to amend our
permit but it's not to hard. Dennis, please get with Krug on the desktop autoclave. We can change our permit to
control only one room in the suite if the agent is in that room and others not approved for SA work can not access.
That means the hinges need to be pinned.

We can discuss in more detail soon.
Cheryl, we need a meeting Rachel, Dennis and I. Abe if he can attend.

Phone 404-498-2243
cell 404-274-3985
email cuv4@cdc.gov

Erle Janssen CIH
Director Environmental Health & Safety
The University of Texas at Austin
P.O. Box 7729, Austin, Texas 78713
phone 512-471-3511
fax 512-471-6918

4

Appendix 4

Correspondence with Local, State and Federal Agencies:

1) **CDC Correspondence**

Pages 120 through 122 redacted for the following reasons:
- -
Other Agency Document

Appendix 5

IBC minutes:

1) **rDNA Protocol 2004-10-0175**
2) **IBC Minutes November 15, 2005**
3) **Biosafety Protocol 2005-03-0128**
4) **IBC Chairperson Email Approval**
5) **IBC Minutes April 17, 2006**

Approval Status:

SYNOPSIS FOR RESEARCH INVOLVING RECOMBINANT DNA

IBC Protocol Number: **2004-10-0175**

P.I. Name: **Robert M Krug** P.I. Email address: **RKRUG@MAIL.UTEXAS.EDU**

Source of DNA: **genes for the internal proteins of avian influenza viruses**

Brief Description of Inserted DNA:
Genes for the internal (non-surface, i.e., not the hemagglutinin and not the neuraminidase) proteins of avian influenza viruses: PB1, PB2, PA, M and NS genes of influenza A/HK/483/97 (HK97), and the NS gene of A/Vietnam/ 1203 (VN04)

Hosts for recombinant DNA:
E. coli (laboratory strains), HeLa cells

Cloning vectors:
pcDNA3 (polymerase II promoter)

Will foreign gene be expressed?
If yes, what protein or RNA will be produced?
The messenger RNAs for these viral proteins, and the viral proteins themselves, but not virion RNAs and not virus.

Are the proposed experiments exempt from NIH Guidelines? No

Yes, under section: _____

No, as described in section: III-D-2

Primary Research Location Building MBB Room 2.122

Complete all the following which are applicable before submission.

1.) Insert or vector DNA is Risk group 2, 3, 4 or restricted. Use of these agents requires EH&S approval: http://www.utexas.edu/research/osp/forms/inf_ag.pdf **Yes**

Identify agent and risk group: **DNA of the NS genes of HK97 & VNo4**

2.) Recombinant DNA involves gene(s) for a toxin with an LD_{50} of less then 100 nanograms per kilogram body weight. This requires EH&S approval: http://www.utexas.edu/research/osp/forms/inf_ag.pdf **No**

Identify toxin: _____.

3.) Use of infectious DNA or RNA, or defective virus in the presence of helper virus, in tissue culture systems. This requires EH&S approval: http://www.utexas.edu/research/osp/forms/inf_ag.pdf

Identify infectious agent: _____

4.) Cultures of more than 10 Liters will be produced at one time **No**

5.) Drug resistance genes will be transferred to organism not known to acquire that trait naturally **No**

Will acquisition of the trait compromise the use of this drug?

6.) DNA will be transferred into whole animals or primary animal cells. If animals are used IACUC approval must be obtained: http://www.utexas.edu/research/rsc/animalresearch/ **No**

Briefly describe these experiments

7.) DNA will be transferred into higher plants. **No**

Briefly describe these experiments

8.) DNA will be transferred into human subjects or primary human cells or stem cells. These experiments require IRB approval: http://www.utexas.edu/research/rsc/humanresearch/ **No**

Briefly describe these experiments

9.) Project involves intentional release into the environment of DNA from any source in any form.
No
Briefly describe these experiments

10.) Experiments require laboratory containment conditions other than BSL1. **Yes**

Containment conditions for these experiments: **BSL2**

Laboratory certified by EH&S for this level? **Yes**

11.) Additional comments:
Although some of these experiments are exempt under Section III-F, we will nonetheless carry out these experiments under BSL2 conditions. which is the atated requirement of Section III-D-2.

PI Signed at:
10:10 AM 10/23/2006

12) IBC Comments
11/9/06- Reviewed by entire committee- Approved.

IBC Approved at: **11:33 AM 11/17/2006**

The University of Texas at Austin
Institutional Biosafety Committee
Minutes
Tuesday, November 15, 2005

The Institutional Biosafety Committee met on Tuesday, November 15, 2005. The meeting was called to order at 2:00 pm in the ACES Building. Dr. Shelley Payne chaired the meeting.

Members Present

Shelley Payne, Ph.D., Chair
Lisa Leiden, Ph.D.
Glen Otto, DVM
Ann Harasimowitz, B.S.
Sharon Brown, Ph.D.
Erle Janssen
Tom McGarity, J.D.
Jon Robertus, Ph.D
Dennis Nolan, M.P.H.
Rachel Lebansky
John Ekerdt, Ph.D.

Members Absent

Chris Callsen
Adolfo Valadez, Ph.D.

Non-Members Present

Janell Laca
Wolfgang Bollich

I. **REVIEW OF MINUTES- September 6, 2005**
Changes to the minutes need to be made prior to approval.

II. **CHAIR POSITION**
Shelley Payne, Ph.D. is resigning as Chair.

III. **UPDATE**
Federal Register regulations regarding when flu virus is considered a select agent

IV. **NEW BUSINESS**

a. Review of Non-Exempt Recombinant DNA Studies:

1.) 2005-10-0119, Bose, BSL2: This is a new application using avian retroviral vectors. This study was approved.
2.) 2005-09-0102, Brown, BSL3: This is a new application using a M. tuberculosis insert. This study was approved.
3.) 2005-08-0078, Chen: Agrobacterium tumefaciens in plants. This study was approved.
4.) 2004-07-0069, Croyle, BSL2: This is a new application using adenovirus type 5 expressing ebola virus genes.

Clarification on where the animal work will be done is needed. The animal section was not approved, pending animal space determination. Use of rDNA in the lab approved.

5.) 2004-09-0070, Dudley, BSL2: This is a renewal of a previously accepted application. This study involved MMTX, MuLV and lentivirus. This study was approved. Noted was the fact that the lab will be moving soon.

6.) 2005-09-0132, Florin, BSL2: This is a new application for adenovirus. This study is provisionally approved until the use of BSL2 is approved by EHS.

7.) 2005-09-0131, Florin, BSL2: This is a new application for influenza virus. This study is provisionally approved until the use of BSL2 is approved by EHS.

8.) 2003-01-0025, Harris: This is a renewal of a previously approved study involving rDNA in mice. It was approved.

9.) 2005-07-0023, Jeromin, BSL2: This is a new application for the use of Sindbis virus. This study was given provisional approval pending approval of the fourth floor laboratory in NMS.

10.) 2005-10-0036, Krug, BSL2/3: Application for the use of recombinant influenza virus. Not categorized as a select agent based on the reference material. This study was approved.

11.) 2004-10-0175, Krug: Avian Influenza virus. This study was approved.

12.) 2004-08-0009, Krug, BSL3: This is the renewal of a previously approved study. The study was approved. A biosafety form covering the 1918 strain is needed.

13.) 2003-11-0049, Stevens: This is the renewal of a previously approved study for rDNA for a transgenic colony. This study was approved.

Shelley Payne, Ph.D.
Chair

Erle Janssen
Vice-Chair & Director, EH&S

UT Direct - The University of Texas at Austin

Biosafety Form for study 2005-03-0128

NAVIGATION MENU

Institutional Biosafety Committee

Human Subjects Database

Research Manager System

Biosafety Listing Page

Recombinant DNA Listing Page

MTA Database

Print Upload Documentation

The following information was provided concerning the research.

PI: Robert M Krug
Infectious Agents: Yes
Agent influenza A virus with H5N1 internal genes
Biosafety Level Group (Risk Group): 3
Is this Organism a CDC/HHS/USDA select agent? No
Brief description of the proposed research
Recombinant influenza A viruses containing the surface (HA and NA) genes of human influenza A/Udorn/72 and one or more of the internal genes (PB1, PB2, PA, NP, M and NS) of H5N1 avian viruses will be generated. These viruses will be used to infected tissue culture cells to determine biochemical events occurring in infected cells.

Toxin with an LD50 of less than 100 nanograms per kilogram body weight. No

---

Agents or Toxins will be used in whole animals or primary animal cells No

---

Research involves human subjects, primary human cells, human stem cells, human blood or human tissues: No

---

Project Location: Bldg: ublic inforn Room(s): Not public information
Indicate laboratory containment conditions for these experiments, e.g. Biosafety Level: 3
Laboratory certified by EH&S for this level: Yes
Will any personnel not trained for use of these materials have access to them: No

How are these agents or materials kept secure in the laboratory?
In a freezer that is in MBB3.230B that can only be accessed by trained personnel.

Do you currently possess the material?No
If not, where will it be obtained?
The recombinant viruses will be generated using DNA plasmids which we currently possess.

Additional Comments
See risk assessment in the e-mail sent to Dr. Shelley Payne.

Biosafety Request Results

I have read and agree to abide by the guidelines published at (http://bmbl.od.nih.gov/) and agree to update this form whenever there is a substantive change in any of the information.
PI Signed at: 03:10 PM 06/08/2006

EH&S Approved at: 03:27 PM 07/03/2006

Approval Status Approved
Approved from 07/03/2006 through 07/03/2007

Additional Actions Required
Please modify to reflect that you currently possess the material. Note that risk assessment on file at EHS.

Risk Group 2, 3 or 4 Information

Description of the mechanism of transmission of the pathogen and signs and symptoms of the disease.

Transmission usually by aerosol. Symptoms: fever, respiratory distress, muscular aches.

Estimated infectious dose for humans
Influenza A 2-790 p.f. units (nasophayngeal route)

Is immunization recommended by CDC? Yes
If yes, have all personnel been immunized? Yes
If not immunized, explain:

The following protective clothing or equipment will be used when handling these materials:

- ☑ Gloves and lab Coat
- ☑ Cover Gown/Booties
- ☑ Goggles
- ☑ Face Shield
- ☑ Mask
- ☑ Safety centrifuge/blender
- ☑ Biological safety cabinet
  - Building MBB Room 3.230B
  - Certified? Yes
- ☑ Respirator

Type: Airmate 10
Have personnel contacted EH&S for respirator selection, fit testing and training? Yes

A manual containing lab-specific protocols and safety procedures must be available for all personnel. Has the manual been reviewed by EH&S? Yes
Where is the manual located?
Building MBB Room 3.230

What are the procedures for treatment and disposal of the biohazardous waste?
All contaminated and potentially infectious materials are autoclaved prior to disposal

What steps are taken in the event of an accidental exposure or spill?
See protocol in e-mail sent to Dr. Shelley Payne..

Krisher, Cheryl L

From: Leiden, Lisa I
Sent: Thursday, February 15, 2007 10:02 AM
To: Krisher, Cheryl L
Subject: FW: Your Study has been Approved

------ Forwarded Message
From: Shelley Payne <payne@mail.utexas.edu>
Date: Wed, 14 Feb 2007 12:05:18 -0600
To: Lisa Leiden <lisa.leiden@mail.utexas.edu>
Conversation: Your Study has been Approved
Subject: Fwd: Your Study has been Approved

Begin forwarded message:

From: ejanssen@mail.utexas.edu
Date: July 6, 2005 12:12:09 PM CDT
To: RKRUG@ICMB.UTEXAS.EDU, payne@mail.utexas.edu, ejanssen@mail.utexas.edu, lebansky@mail.utexas.edu, dnolan@austin.utexas.edu
Subject: Your Study has been Approved

Study Number 2005030128 has been approved by the IBC. Please see the details at https://utdirect.utexas.edu/vr/biosafety.WBX?s_study_nbr=2005030128&s_what_to_do=view

------ End of Forwarded Message

The University of Texas at Austin
Institutional Biosafety Committee Minutes
Monday, April 17, 2006

The Institutional Biosafety Committee met on Monday, April 17, 2006. The meeting was called to order at 2:00 p.m. in the NMS Building, Room 2.106. Dr. Jaquelin Dudley chaired the meeting.

Members Present
Dr. Jaquelin Dudley, IBC Chair, Molecular Genetics and Microbiology
Dr. John Ekerdt, Chemical Engineering
Ms. Ann Harasimowitz, Office of the Dean of Natural Sciences
Mr. Erle Janssen, Office of Environmental Health and Safety
Ms. Rachel Lebansky, Office of Environmental Health and Safety
Dr. Lisa Leiden, Office of Research Support and Compliance
Mr. Dennis Nolan, Office of Environmental Health and Safety
Dr. Glen Otto, Animal Resource Center
Dr. Shelley Payne, Molecular Genetics and Microbiology
Ms. Janet Pichette, Office of the Health Authority
Dr. Jon Robertus, Department of Chemistry and Biochemistry

Members Absent
Dr. Eric Anslyn, Chemistry and Biochemistry
Dr. Sharon Brown, Associate V.P. for Research
Mr. Tom McGarity, School of Law
Dr. Adolfo Valadez, Office of the Health Authority

Non-Members Present
Ms. Janell Laca, IBC Program Coordinator, Office of Research Support and Compliance

I. OLD BUSINESS

A. Database Improvements Suggested

1. Include area for Project Description in the database to have some additional background information.
2. There are problem with items getting cut-off between the application and the final version.
3. There are problems when an investigator mentions N/A on application and it not being transferred to the report page.
4. Give more room for location(s) and comments.
5. Make sure the database is properly noting provisionally approved.
6. Include a question for the use of live viruses (*Baculovirus*, for example)
7. When viral vectors are used, the type of envelope protein should be clarified.

B. Sunshine Group- Three years of minutes requested

1. The committee would like to provide all minutes to the Sunshine Group as soon as possible, but the University lawyers should be consulted concerning the rules of Open Records Requests.
2. Investigators' names should be possibly redacted on the older minutes.
3. The committee would like to consider posting all of their minutes on the website in the future.

I. NEW BUSINESS

A. Questions about Engineered Viruses

1. What biosafety level should be considered when viruses are engineered and the host tropism is changed? This seems particularly relevant in the animal research facility- should animals be housed at BSL1 or BSL2 when infected with the virus?
2. It was suggested that the Office of Biotechnology Activities of the NIH be contacted to answer this question.

B. BSL-3 related business

1. A lab using H3N2 virus thought their centrifuge tubes broke (it seemed the wrong ones were used in the centrifuge), releasing possible viral aerosol into the lab. The virus had H5N1 structural proteins included.
2. It was determined that the liquid on the tube was probably condensation and the tube had not broken. However, the situation was handled as a release of virus situation. The medical response required two steps. 1. Teresa Spalding of University Health Services (UHS) provided authorization for Tamiflu to be given. 2. The PI agreed to receive and take it. He will be on Tamiflu until Tuesday.
3. The proper tubes for the centrifuge have been obtained.

C. Review of Non-Exempt Recombinant DNA Studies:

1. 2006-03-0060- DNA transfer into whole plants.
   - Clone cDNA's into an expression vector then used for knock-down experiments.
   - *Agrobacterium* requires BL-1P
   - Research needs to be done to determine regulations by NIH to cover transgenic plant research

   Tabled by 11 members to determine guidelines.

2. 2006-02-0119 – Developing transgenic animals.
   - Mice should be listed under rDNA host.

   Approved by 11 members with this change.

3. 2006-02-0055 – Adenovirus and helper virus (BSL2).
   - Biosafety approval is current until 2/2007.
   - BSL2 conditions are used for the animal research in the ARC.
   - The approved IACUC protocol number should be noted on the application.

   Approved by 11 members with this change.

4. 2006-01-0118 – Retroviral Vectors (BSL2).
   - Introducing an RNA to knock-down the level of caspases and other apoptotic regulators.
   - Biosafety approval is current until 3/2007.
   - Is the payload oncogenic?

   Approved by 11 members once question is answered.

5. 2005-09-0132- Recombinant Adenovirus (BSL2).
   - Physics Professor working in a Pharmacy Laboratory to develop virus
   - Biosafety approval is current until 9/2006.
   - Clarify what is being infected (mice, cell lines, macrophages).
   - Clarify the location of the infection and whether or not the adenoviral infected materials will be transported anywhere. Clarify the lab where experiments are being performed.
   - Clarify staff involved in experimentation.

   Tabled by 11 members pending additional clarification.

6. 2005-09-0126
   - Clarify what molecules are being tagged and if they are using an HA tag.
   - The individual who has submitted is not the PI.
   - Resubmit by the PI and be more clear about the experiment.

   Tabled by 11 members pending additional clarification.

7. 2005-02-0149 – Large Scale Production
   - This must be reviewed by the entire committee only because it is large scale production.
   - Experiments will be performed in the MBB building.

   Approved by 11 members.

8. 2005-02-0134 – Baculovirus
   - It should be noted that they are using live virus.
   - They are cloning DNA polymerases from mitochondria and HIV reverse transcriptase into Baculovirus.
   - It contains more than 2/3 of the virus genome.

   Approved by 11 members.

9. 2005-02-0087 – cloning regulators of apoptosis
    - It is being reviewed by full committee since a very small piece of HIV is used as a means of getting certain proteins into the cultured cells.
    - It is not more than 2/3 of the viral genome.
    - A non-infectious portion of HIV is being used.

    Approved by 11 members.

10. 2005-02-0008 – It is actually exempt
    - It will be reviewed by Dr. Dudley for approval.

11. 2005-01-0088 – Baculovirus use

    Approved by 11 members.

12. 2004-07-0069 – Ebola virus genes
    - Biosafety approval is valid until 2/2007
    - Confirm the approval of the IACUC protocol associated with this proposal.
    - Area in ARC should be inspected prior to the work beginning.
    - The gene for one protein of the Ebola virus is being used. She will work under BSL2 conditions for precaution.

    Approved by 9 members under these conditions.

13. 2004-05-0060 – Using recombinant viral vectors (Adenovirus, AAV, Sindbis and Lentivirus)
    - Biosafety approval is valid until 8/2006
    - Confirm the approval of the IACUC protocol associated with this proposal. Clarify constructs that will be used.
    - Area in ARC should be inspected prior to the work beginning.

    Approved by 9 members under these conditions.

14. 2004-04-0148 – It is actually exempt
    - It will be reviewed by Dr. Dudley for approval.

15. 2004-04-0091 – It is actually exempt
    - It will be reviewed by Dr. Dudley for approval.

16. 2004-03-0063 – The DNA is from Chlamydia.
    - The organism is not in the lab.

    Approved by 9 members.

17. 2004-01-0085 – Bacilovirus and Papilloma viral vectors.
    - Must be voted on by the entire committee since viruses are used.

    Approved by 9 members.

18. 2004-01-0065 – Risk group II bacterium used.
    - Group II introns are placed into a variety of other organisms (*E. coli, Staphylococcus*, etc.)
    - Biosafety approval is valid until 3/2007

    Approved by 9 members.

19. 2003-09-0061 – *Agrobacterium* lab engineered strains
    - Regulations need to be checked to determine the level of hazard.
    - Proper containment would be the issue.

    Approved by 9 members following confirmation of the regulations.

20. 2003-06-0036 – Recombinant vectors into mice.
    - Confirm IACUC protocol approval.
    - BSL1 is required since no more than 2/3 of a viral genome is being used.

    Approved by 9 members following confirmation of IACUC approval.

21. 2003-01-0025 – Development of transgenic mice.
    - IACUC protocol approval confirmed.

    Approved by 9 members.

22. 2002-09-0041 – Baculovirus use
    - Ask PI if there are multiple protocols for the same experiments.
    - It was submitted as exempt, but it is not.

    Approved by 9 members.

23. 2002-09-0040 – Moloney Murine Leukemia virus
    - Ask for clarification of the envelope protein.

    Tabled by 9 members, pending a response to the question.

24. 2004-12-0037 - Murine Leukemia Virus, HIV and VSV
    - None of the viral genes clones are hazardous to humans.
    - Only one gene is cloned from HIV.

    Approved by 8 members, one abstaining.

Jaquelin Dudley, Ph.D.
IBC Chair

Erle Janssen
Vice-Chair & Director, EH&S

The University of Texas at Austin
Addendum to Minutes of the
Institutional Biosafety Committee Minutes

Date: Monday, April 17, 2006
Time: 2:00 p.m.
Location: NMS Building, Room 2.106

The following addendum is made to the minutes for the April 17, 2006 meeting of the Institutional Biosafety Committee to correct the virus in Line 1, Part B in I. NEW BUSINESS.

I. NEW BUSINESS

B. BSL-3 related business

1. *The virus had H5N1 structural proteins included* should read as follows: The virus was composed of H3N2 A/Udorn/72 with the NS gene substituted with H5N1 A/Hong Kong/483/97.

2. *The proper tubes for the centrifuge have been obtained* should read as follows: The proper cups for the centrifuge have been obtained.

Jaquelin Dudley, Ph.D.
IBC Chair

Erle Janssen, MS, CIH
Vice-Chair

Appendix 6

Additional Documents:

1) **Laboratory Inspection Form 3/06**
2) **Centrifuge Sign**
3) **Incident Reporting Form**

The University of Texas at Austin

BioSafety Level 3 Inspection

Bldg: [redacted] Rm: [redacted] Department: ICMB PI: Krug / Ellington / Payne + Dudley

Inspector: Rachel LeBansky Date: 3/22/06

Contact: Mary Lozano, Amos Yan Contact Phone: 471-9886

Inspection Items — Results — Comments

Basic Checklist

A. Housekeeping	Yes	No	Other	N/A
1. Is the room free of clutter?	☑	☐	☐	☐
2. Are all aisles from the work areas to the available exits maintained clear of obstruction?	☑	☐	☐	☐
3. Are all safety equipment items unobstructed and ready for use?	☑	☐	☐	☐
4. Is the room clean?	☑	☐	☐	☐

B. Fire Safety	Yes	No	Other	N/A
1. Is the fire extinguisher hung in its proper place, ready for use, and unobstructed?	☑	☐	☐	☐
2. Are there excess flammables located outside National Fire Protection Association (NFPA) approved cabinetry?	☐	☑	☐	☐
3. Are all Class IA flammables that are in breakable containers in pint or smaller containers?	☑	☐	☐	☐
4. Are all class IB flammables that are in breakable containers in liter or smaller containers?	☑	☐	☐	☐

C. Chemical Safety	Yes	No	Other	N/A
1. Are the chemicals stored with compatible materials?	☑	☐	☐	☐
2. Have the chemical fume hoods been certified in the last 6 months?	☐	☐	☐	☑
3. Are the eyewash and deluge shower unobstructed and ready for use?	☑	☐	☐	☐
4. Are the eyewash and deluge shower tested regularly to document proper operation?	☑	☐	☐	☐
5. Is the organic waste container maintained in a closed position?	☑	☐	☐	☐
6. Are all reagents and solutions properly labeled?	☑	☐	☐	☐
7. Is a spill kit within a reasonable distance from the work areas?	☑	☐	☐	☐
8. Is the appropriate protective clothing available for the chemical hazards present?	☑	☐	☐	☐
9. Is there a written hazard communication program?	☑	☐	☐	☐
10. Have the personnel in the laboratory been trained in the provisions and principles of the hazard communication program?	☑	☐	☐	☐
11. Are MSDS's located where they are available to the laboratory workers?	☑	☐	☐	☐

→ Work Request taped to Mary –

12. Is there a written chemical hygiene pl	☑	☐	☐	☐

D. Radiation Safety	**Yes**	**No**	**Other**	**N/A**
1. Are the radioactive materials stored in double containers?	☐	☐	☐	☑
2. Is the containment for the radiation waste container adequate to preclude the spread of radiation?	☐	☐	☐	☑
3. Are all containers appropriately labeled with radiation labels ?	☐	☐	☐	☑
4. Are all entrances to the room appropriately labeled?	☐	☐	☐	☑

E. Electrical Safety	**Yes**	**No**	**Other**	**N/A**
1. Are excess extension cords being utilized?	☐	☑	☐	☐
2. Are any frayed cords in the room?	☐	☑	☐	☐
3. Are there any cords on the floor across normal traffic patterns in the room?	☐	☑	☐	☐

F. General Laboratory Safety	**Yes**	**No**	**Other**	**N/A**
1. Are sharps discarded and destroyed in a safe manner?	☑	☐	☐	☐
2. Are work surfaces decontaminated daily and after a spill?	☑	☐	☐	☐
3. Is the appropriate attire worn by everyone in the room?	☑	☐	☐	☐
4. Is there evidence that personnel eat, drink, smoke, or store food, drinks, or tobacco in the room?	☐	☑	☐	☐
5. Was mouth pipetting observed?	☐	☑	☐	☐
6. Are all gas cylinders secured and are all cylinders not in use capped?	☑	☐	☐	☐
7. Are cylinders of oxidizers stored at least 20 feet from cylinders of flammable gases in the same room?	☑	☐	☐	☐
8. Are the contents of the cylinders clearly labeled?	☑	☐	☐	☐
9. Are the cylinders transported on appropriate dollies or hand trucks?	☑	☐	☐	☐
10. Is there a written respiratory protection program where respirators are used?	☑	☐	☐	☐

G. Etiologic agents	**Yes**	**No**	**Other**	**N/A**
1. Are all containers of etiologic agents appropriately labeled?	☑	☐	☐	☐
2. Are freezers, refrigerators, and similar storage units labeled with the biohazard warning sign?	☑	☐	☐	☐
3. Are the storage and shipping containers adequate and properly labeled?	☑	☐	☐	☐
4. Have all personnel been adequately trained in general microbiological techniques?	☑	☐	☐	☐

5. Are laboratory doors kept closed when experiments are in progress?	☑	☐	☐	☐
6. Are all operations conducted over plastic-backed absorbent paper or spill trays?	☐	☐	☐	☑

H. Standard Microbiological Practices	Yes	No	Other	N/A
1. Access to the laboratory is limited or restricted.	☑	☐	☐	☐
2. Lab personnel wash their hands frequently.	☑	☐	☐	☐
3. No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing food in the work area	☑	☐	☐	☐
4. Mechanical pipetting devices are used.	☑	☐	☐	☐
5. Sharps are handled safely according to policy.	☑	☐	☐	☐
6. All procedures are performed carefully to minimize the creation of splashes or aerosols.	☑	☐	☐	☐
7. Work surfaces are decontaminated at least once a day and after any spill of viable material.	☑	☐	☐	☐
8. All cultures, stocks, and other regulated wastes are properly decontaminated before disposal.	☑	☐	☐	☐
9. An insect and rodent control program is in effect.	☑	☐	☐	☐

I. Special Practices	Yes	No	Other	N/A
1. Laboratory doors are kept closed when experiments are in progress.	☑	☐	☐	☐
2. The laboratory director controls access to the laboratory and restricts access to only those persons whose presence is required for program or support purposes.	☑	☐	☐	☐
3. Only persons who have been advised of the potential hazards and meet specific entry requirements may enter the laboratory.	☑	☐	☐	☐
4. When infectious materials or infected animals are present in the laboratory, a warning sign (incorporating the universal biohazard symbol, identifying the agent, listing the names and telephone numbers of responsible personnel, and any special requirements for entering the lab) is posted.	☑	☐	☐	☐
5. Laboratory personnel receive the appropriate immunizations and/or tests for the agents handled or potentially present in the laboratory.	☑	☐	☐	☐
6. Baseline and/or additional serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel.	☑	☐	☐	☐
7. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual prepared specifically for the lab.	☑	☐	☐	☐
7.1. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.	☑	☐	☐	☐
8. Lab and support personnel receive the appropriate training and refresher training on the potential hazards and precautions of the work involved.	☑	☐	☐	☐

9. The laboratory director is responsible f[illegible]suring that, before working with organisms at BSL3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility.	☑	☐	☐	☐	
10. A high degree of precaution is taken with all contaminated sharp items.	☑	☐	☐	☐	
10a. Needles and glassware are used only when there is no safer alternative available.	☑	☐	☐	☐	
10b. Only needle-locking syringes or disposable syringe-needle units are used for injection or aspiration of infectious materials, and they are not unnecessarily manipulated, and are disposed in a proper sharps container.	☑	☐	☐	☐	
10c. Syringes which re-sheathe the needle, needleless systems, and other safe devices are used when appropriate.	☑	☐	☐	☐	
10d. Mechanical means (such as a brush and dustpan, tongs, or forceps) are used to remove broken glassware. Broken glassware and sharps are decontaminated and disposed according to local, state, and federal regulations.	☑	☐	☐	☐	
11. All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module and clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.	☑	☐	☐	☐	
12. Laboratory equipment and work surfaces are decontaminated routinely with an effective disinfectant after work with infectious materials is finished and especially after overt spills, splashes, or other contamination with infectious materials.	☑	☐	☐	☐	
12a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.	☑	☐	☐	☐	
12b. Contaminated equipment must be decontaminated before removal from the facility for repair, maintenance, or packaging for transport in accordance with applicable local, state, or federal regulations.	☑	☐	☐	☐	
13. Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.	☑	☐	☐	☐	
14. All potentially contaminated waste materials from laboratories are decontaminated before disposal or reuse.	☑	☐	☐	☐	

15. Spills and accidents that result in overt potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.	☑	☐	☐	☐	
16. Animals and plants not related to the work being conducted are not permitted in the laboratory.	☑	☐	☐	☐	
17. Is the autoclave being properly maintained and certified?	☑	☐	☐	☐	
18. If available, has the UV pass box output been certified within the last 3 months?	☐	☐	☐	☑	

J. Safety Equipment (Primary Barriers)	**Yes**	**No**	**Other**	**N/A**	
1. Protective laboratory clothing is worn by workers while in the laboratory and is removed before leaving. Reusable clothing is decontaminated before being laundered. Clothing is changed when overtly contaminated.	☑	☐	☐	☐	
2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.	☑	☐	☐	☐	
3. Lab personnel frequently change their gloves and wash their hands. Disposable gloves are not reused.	☑	☐	☐	☐	
4. All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc., are conducted in a Class II or Class III biological safety cabinet.	☑	☐	☐	☐	
5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment and physical containment devices are used.	☑	☐	☐	☐	
6. Respiratory and face protection are used when in rooms containing infected animals.	☑	☐	☐	☐	

K. Laboratory Facilities (Secondary Barriers)	**Yes**	**No**	**Other**	**N/A**	
1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building and access to the laboratory is restricted.	☑	☐	☐	☐	
1.1. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors.	☑	☐	☐	☐	
1.2. Doors are lockable.	☑	☐	☐	☐	
1.3. A clothes change room may be included in the passageway.	☑	☐	☐	☐	
2. Each laboratory room contains a hands-free or automatically operated sink for handwashing and it is located near the room exit door.	☑	☐	☐	☐	
3. The interior surfaces of walls, floors, and ceilings of areas where BSL3 agents are handled are constructed for easy cleaning and decontamination.	☑	☐	☐	☐	
3.1. Seams, if present, must be sealed.	☑	☐	☐	☐	

3.2. Walls, ceilings, and floors should be s- -th, impermeable to liquids and resistant to the -micals and disinfectants normally used in the laboratory.	☑	☐	☐	☐	
3.3 Floors should be monolithic and slip-resistant.	☑	☐	☐	☐	
3.4. Consideration should be given to the use of coved floor coverings.	☑	☐	☐	☐	
3.5. Penetrations in floors, walls, and ceiling surfaces are sealed.	☑	☐	☐	☐	
3.6. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.	☑	☐	☐	☐	
4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.	☑	☐	☐	☐	
5. Laboratory furniture can be easily decontaminated and is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.	☑	☐	☐	☐	
6. All windows in the laboratory are closed and sealed.	☑	☐	☐	☐	
7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors. Consideration should be given to means of decontaminating equipment.	☑	☐	☐	☐	
8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.	☑	☐	☐	☐	
9. A ducted exhaust air ventilation system is provided.	☑	☐	☐	☐	
9.1. This system creates directional airflow which draws air into the laboratory from "clean" areas and toward "contaminated" areas.	☑	☐	☐	☐	
9.2. The exhaust air is not recirculated to any other area of the building.	☑	☐	☐	☐	
9.3. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements and specific agent manipulations and use conditions.	☑	☐	☐	☐	
9.4. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered.	☑	☐	☐	☐	
9.5. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper.	☑	☐	☐	☐	
9.6. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry.	☑	☐	☐	☐	
9.7. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory.	☑	☐	☐	☐	

9.8. Audible alarms should be considered to notify personnel of HVAC system failure.	☑	☐	☐	☐	
10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually.	☑	☐	☐	☐	
10.1 When exhaust air from Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system.	☑	☐	☐	☐	
10.2 When Class III biological safety cabinets are used they should be directly connected to the exhaust system.	☑	☐	☐	☐	
10.3 If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.	☑	☐	☐	☐	
11. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.	☑	☐	☐	☐	
11.1. These HEPA systems are tested at least annually.	☑	☐	☐	☐	
11.2. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.	☑	☐	☐	☐	
12. Vacuum lines or portable vacuum pumps are protected with liquid disinfectant traps and HEPA filters (which are replaced as necessary), or their equivalent.	☑	☐	☐	☐	
13. An eyewash station is readily available inside the laboratory.	☑	☐	☐	☐	
14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.	☑	☐	☐	☐	
15. The Biosafety Level 3 facility design and operational procedures must be documented.	☑	☐	☐	☐	
15.1. The facility must be tested for verification that the design and operational parameters have been met prior to operation.	☑	☐	☐	☐	
15.2. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.	☑	☐	☐	☐	
16. Additional environmental protection should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.	☑	☐	☐	☐	

In the Event of an Centrifuge Accident

DO NOT OPEN

For at least 30 minutes!

Notify Lab Director

The University of Texas - Austin
NIH Significant Event Form

Date of Occurrence: _____

Name(s) of Personnel Exposed: _____ Telephone #: _____

Location: Building _____ Room #: _____

PI Name: _____

Agent(s): _____

Type of Exposure: _____

Quantity/Concentration of Agent(s): _____

Name of Parties Notified: _____

Description of Incident: _____

Use the back of the form if you need more lines.

Did personnel seek medical attention?	☐ YES	☐ NO
	Name of Physician _____	
	Address: _____	
	Telephone #:	
Public Health Notified	☐ YES	☐ NO
Was the room contaminated?	☐ YES	☐ NO

If so, describe the decontamination process.

What measure(s) have been taken to prevent future incidents:

Use the back of the form if you need more lines.

Reviewed By: _____ **Date:** _____

Harris, Kathryn (NIH/OD)

From: Shipp, Allan (NIH/OD) [E]
Sent: Thursday, February 08, 2007 4:41 PM
To: 'Nolan, Dennis H'
Cc: Whitney, Bruce (NIH/OD) [C]; Harris, Kathryn (NIH/OD); Groesch, Mary (NIH/OD) [E]; Lacourciere, Karen (NIH/NIAID) [E]
Subject: RE: Teleconference

I've annotated the list below slightly (in blue), but you've captured nearly everything. The only things I would add are:

1) Photographs of the damaged safety cup or centrifuge materials (if any exist), and

2) Copies of correspondence with local or state health departments or other local, state or federal agencies concerning this incident (you mentioned that a report was made to the local health department, for example).

Also, you should feel free to add any other supporting materials that you believe would help us understand this incident and the institution's response.

We would like to have these materials by close of business, Friday, February 16. Perhaps there is someone else who would have the authority to review them before they are sent? If Mr. Janssen would like to add something upon his return, that would be fine, as well.

Thank you,

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----
From: Nolan, Dennis H [mailto:dnolan@austin.utexas.edu]
Sent: Thursday, February 08, 2007 11:16 AM
To: Shipp, Allan (NIH/OD) [E]
Subject: RE: Teleconference

Allan,

I am working on assembling the documents you requested. (See list below) Is there any additional information/documents that you need?

1) Written description of the agent (including genetic insert)

2) Centrifuge make and model #

3) BSL3 biosafety SOP's (including centrifuge safety)

4) Biosafety training materials and documentation of training (including training records for Rei-Lin)

5) Occupational health requirements (including mention of how those requirements are communicated to workers in the BL3 facility)

6) Video recording of the incident (since we understand the room is under recorded video surveillance)

7) USDA permit and documentation

8) Incident reporting SOP and form (as was in use at the time of the event)

9) IBC minutes: 1) For the meeting at which the IBC initally approve Krug 's research
2) For the meeting at which the incident report would have been reviewed by the committee

Also, Erle is out of the country until February 21st. We would prefer that he reviews the documents before they are submitted. Let me know if that is acceptable.

Dennis

From: Shipp, Allan (NIH/OD) [E] [mailto:ShippA@OD.NIH.GOV]
Sent: Tuesday, February 06, 2007 12:13 PM
To: Nolan, Dennis H
Subject: RE: Teleconference

Dear Dr. Nolan,

We would like to speak with him privately. Does 2:00 pm ET/1:00 pm CT on Thursday, February 8 still work for him?

Thank you for coordinating this call on your end.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----
From: Nolan, Dennis H [mailto:dnolan@austin.utexas.edu]
Sent: Tuesday, February 06, 2007 12:59 PM
To: Shipp, Allan (NIH/OD) [E]
Subject: RE: Teleconference

Allan,

I will have him call the number listed below. Did you want to speak with him privately or can a representative from UT be present?

Dennis

From: Shipp, Allan (NIH/OD) [E] [mailto:ShippA@OD.NIH.GOV]
Sent: Friday, February 02, 2007 4:35 PM
To: Nolan, Dennis H
Cc: Patterson, Amy (NIH/OD) [E]; Groesch, Mary (NIH/OD) [E]; Lacourciere, Karen (NIH/NIAID) [E]; Janssen, Erle
Subject: RE: Teleconference

Thank you for arranging that. We'll use the same conference line as last time:

Conference call number
Private Number
Participant code: Private Number

Also, I realized that I wasn't clear about which time zone I was referencing. I had meant 2:00 pm ET/1:00 pm CT. Is that possible? Would you like for us to contact the postdoc directly?

Thanks again.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----
From: Nolan, Dennis H [mailto:dnolan@austin.utexas.edu]
Sent: Friday, February 02, 2007 5:17 PM
To: Shipp, Allan (NIH/OD) [E]
Cc: Janssen, Erle
Subject: FW: Teleconference

Allen,

The researcher is available at the time you requested. Will you be providing contact information?

Dennis

From: Shipp, Allan (NIH/OD) [E] [mailto:ShippA@OD.NIH.GOV]
Sent: Tuesday, January 30, 2007 12:15 PM
To: Janssen, Erle
Cc: Nolan, Dennis H; Patterson, Amy (NIH/OD) [E]; Groesch, Mary (NIH/OD) [E]; Lacourciere, Karen (NIH/NIAID) [E]
Subject: RE: Teleconference

Dear Mr. Janssen,

Thank you for speaking with us and our colleagues from NIAID yesterday regarding the centrifuge incident in your BL3 facility. We would still like to speak with the postdoc regarding this incident. The conversation should take less than an hour.

Would it be possible to have that conversation on February 8 at 2:00 pm? If not, can you recommend two or three dates and times when this would be possible?

Thank you.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----
From: Shipp, Allan (NIH/OD) [E]
Sent: Tuesday, January 23, 2007 6:28 PM
To: 'Janssen, Erle'
Subject: Teleconference

Mr. Janssen,

We've taken a look at the final report of the centrifuge incident and have a few questions we'd like to ask you, your lab director, and the post doc involved, to get a better understanding of the events that took place.

We would like to speak to the postdoc in a separate conversation from that with you and your laboratory director.

January 25 (Thursday) at 2:00 pm ET, 1:00 pm CT would be possible for us. Could you and your colleagues be available at that time? January 26 (Friday) after 1:00 pm ET, 12:00 noon CT is also available.

Many thanks for your prompt reply. You may also call me at the number below.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

Whitney, Bruce (NIH/OD) [C]

From: Shipp, Allan (NIH/OD) [E]
Sent: Friday, February 02, 2007 5:37 PM
To: Whitney, Bruce (NIH/OD) [C]; Harris, Kathryn (NIH/OD)
Subject: FW: Teleconference

FYI until confirmed. Bruce, can you extract out of the interview questions we used last time the ones that would be pertinent for the postdoc? And add other questions that you think would be worth probing? Then we can take a look at them collectively.

Thanks!

-----Original Message-----
From: Shipp, Allan (NIH/OD) [E]
Sent: Friday, February 02, 2007 5:35 PM
To: 'Nolan, Dennis H'
Cc: Patterson, Amy (NIH/OD) [E]; Groesch, Mary (NIH/OD) [E]; Lacourciere, Karen (NIH/NIAID) [E]; 'Janssen, Erle'
Subject: RE: Teleconference

Thank you for arranging that. We'll use the same conference line as last time:

Conference call number
Private Number
Participant code: Private Number

Also, I realized that I wasn't clear about which time zone I was referencing. I had meant 2:00 pm ET/1:00 pm CT. Is that possible? Would you like for us to contact the postdoc directly?

Thanks again.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

> -----Original Message-----
> **From:** Nolan, Dennis H [mailto:dnolan@austin.utexas.edu]
> **Sent:** Friday, February 02, 2007 5:17 PM
> **To:** Shipp, Allan (NIH/OD) [E]
> **Cc:** Janssen, Erle
> **Subject:** FW: Teleconference
>
> Allen,
>
> The researcher is available at the time you requested. Will you be providing contact information?
>
> Dennis
>
> ---
>
> **From:** Shipp, Allan (NIH/OD) [E] [mailto:ShippA@OD.NIH.GOV]
> **Sent:** Tuesday, January 30, 2007 12:15 PM

To: Janssen, Erle
Cc: Nolan, Dennis H; Patterson, Amy (NIH/OD) [E]; Groesch, Mary (NIH/OD) [E]; Lacourciere, Karen (NIH/NIAID) [E]
Subject: RE: Teleconference

Dear Mr. Janssen,

Thank you for speaking with us and our colleagues from NIAID yesterday regarding the centrifuge incident in your BL3 facility. We would still like to speak with the postdoc regarding this incident. The conversation should take less than an hour.

Would it be possible to have that conversation on February 8 at 2:00 pm? If not, can you recommend two or three dates and times when this would be possible?

Thank you.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----
From: Shipp, Allan (NIH/OD) [E]
Sent: Tuesday, January 23, 2007 6:28 PM
To: 'Janssen, Erle'
Subject: Teleconference

Mr. Janssen,

We've taken a look at the final report of the centrifuge incident and have a few questions we'd like to ask you, your lab director, and the post doc involved, to get a better understanding of the events that took place.

We would like to speak to the postdoc in a separate conversation from that with you and your laboratory director.

January 25 (Thursday) at 2:00 pm ET, 1:00 pm CT would be possible for us. Could you and your colleagues be available at that time? January 26 (Friday) after 1:00 pm ET, 12:00 noon CT is also available.

Many thanks for your prompt reply. You may also call me at the number below.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

Shipp, Allan (NIH/OD) [E]

From: Shipp, Allan (NIH/OD) [E]
Sent: Wednesday, January 24, 2007 4:33 PM
To: 'Nelson, John D'
Cc: dnolan@austin.utexas.edu; 'Janssen, Erle'
Subject: RE: Teleconference

Let's arrange the call for Monday, January 29 at 3:00 pm CT (4:00 pm ET). You can use our conference line:

Private Number leader code : ——

Participant Code: Private Number

We'll look forward to talking to Drs. Janssen and Nolan then. Also please let us know when it might be possible to speak to the postdoc.

Many thanks.

Allan

-----Original Message-----
From: Nelson, John D [mailto:jnelson@austin.utexas.edu]
Sent: Wednesday, January 24, 2007 2:34 PM
To: Shipp, Allan (NIH/OD) [E]
Cc: dnolan@austin.utexas.edu
Subject: FW: Teleconference

Mr. Shipp,

Unfortunately Erle Janssen is not available during the times you suggest. I have availability for both he and Dennis Nolan on 1/29/07: 8:00-12:00 noon and 2:30-4:00 pm. Are either of these periods a possibility for your?

John Nelson
Senior Administrative Associate
Environmental Health and Safety
512-475-8158

From: Janssen, Erle
Sent: Wednesday, January 24, 2007 12:41 PM
To: Nelson, John D
Subject: FW: Teleconference

From: Shipp, Allan (NIH/OD) [E] [mailto:ShippA@OD.NIH.GOV]
Sent: Tuesday, January 23, 2007 5:28 PM
To: Janssen, Erle
Subject: Teleconference

Shipp, Allan (NIH/OD) [E]

From: Janssen, Erle [ejanssen@austin.utexas.edu]
Sent: Thursday, January 18, 2007 3:01 PM
To: Shipp, Allan (NIH/OD) [E]
Subject: FW: Final Report for NIH

Alan, attached are the final report and our talking points. Please let me know you got these. Thanks Erle

Erle Janssen CIH, RBP,RO, Biosafety Officer
Director Environmental Health & Safety
The University of Texas at Austin
P.O. Box 7729, Austin, Texas 78713
phone 512-471-3511
fax 512-471-6918

Rchn Krug – PI

BSL3 Laboratory Incident Report

Released Briefing

On April 12, 2006 at approx. 2:15 pm, a researcher working in the BSL3 Lab in MBB was involved in an incident that resulted in the contamination of a laboratory centrifuge. The agent that was being used was a modified laboratory Influenza A (H3N2)—**NOT** the Avian Influenza virus (H5N1) previously described. University researchers **DO NOT** work with H5N1. Our researchers work with non-contagious elements of that virus.

previously they said no contam

by whom?

what about pathogenic elements

The researcher was wearing full BSL3 PPE (respirator, suit and gloves) and was working in a negative pressure room. The researcher followed standard decontamination procedures and notified the Laboratory Director. The Lab Director notified the University Biosafety Officer and consulted with the UHS Medical Director. The researcher was started on drug prophylaxis as a precaution.

Again, the agent that was being used was a commonly used laboratory Influenza A (H3N2) virus. The lab will be further decontaminated by EHS staff this morning and will be operational later this week. There is no public health risk associated with this lab contamination.

Timeline of Events

Wednesday April 12th (Actions by Lab Director)

2:15: Incident occurred (described as tube containing flu virus broken in centrifuge)
2:25: Laboratory director (Dennis) notified by researcher (Rei-Lin) . Instructions were given to decontaminate work surfaces and follow posted decontamination protocol.
2:35: Briefed Associate Director (Abe), consulted Director (Erle-Biosafety Officer)
2:50: Lab Director went to lab to inspected decontamination procedures.
3:15: Lab Director briefed PI (Krug), attempted to contact Occupation Health Physician (Hefner)
3:45: Second briefing with Associate Director
4:15: Consulted UHS medical director (Theresa) for clearance to use Tamiflu.
4:40: Consulted with EHS Director of plan to treat researcher and further decontaminate lab.
5:00: Third briefing with Associate Director
5:15: Notified researcher to start Tamiflu prophylaxis
6:00: Researcher emailed his report of event, reply sent to complete "First Notice of Injury" form.

Actions by Associate Director:
2:40 – 4:20: Worked with Lab Director and Biosafety Officer on action Plan.
4:30: Called AVP CS&S, spoke with Exec. Asst . and informed her about a call back.

?

5:30: Called AVP CS&S and left voice mail
5:50: Connected with AVP CS&S and conducted briefing.

Thursday April 13th (Actions by Lab Director)

7:00: Contacted by Associate Director to write incident briefing
9:00: Incident briefing completed and sent to Director of Communications (Rhonda).
9:45: PI called that accident was likely due to wrong size centrifuge cup.
11:15:Lab director met with researcher. Interviewed researcher about report.
11:30:Secondary decontamination of room.

why? Not too late?

Actions by Associate Director:

6:40: Contacted by Biosafety Officer
7:00: Contacted Asst. Director (Nolan) about briefing document.
7:50: Connected with AVP CS&S and conducted briefing
8:00: Connected with Assoc. Director CNS (Ann H.) and conducted briefing
8:15: Connected with Dir of Communications (Weldon) and conducted briefing
8:45: First Draft Briefing Document Reviewed

Researcher Report (emailed 5:12 pm 4/12/06)

This is what happened.
When I was doing centrifugation, one of the lid of the bucket was broken. Then the centrifuge lost balance. I stopped the centrifuge, opened the centrifuge, and found the volume in one of the tubes was decreased a little.

What I have done.

1. *Remove my samples.*
2. *Sprayed Lysol and Venephene into the whole chamber of the centrifuge, waited for 10 min.*
3. *Cleaned the bucket in the BSC with more Venephene.*
4. *Wiped the chamber and the rotor with Lysol*
5. *Wiped the bench, equipments, the surface of refrigerator, incubators, and cabinet with Lysol.*
6. *Sprayed Lysol on the surface of the sink.*
7. *Mopped the floor with "Swiffer Wetjet" (before that I sprayed Lysol on the floor)*
8. *Packed the trash.*
8. *Sprayed Lysol on myself.*
9. *Walked out of the room, put trash into the autoclave.*
10. *took off the suit put into a trash bag.*
11. *Autoclaved the trash.*
12. *Cleaned the respirator and hose.*
13. *Put the sign on the door of room B*
14. *Took shower, threw away the scrub*

Biosafety Comments

It was determined that the centrifuge safety cup was wrong size, causing the lid to break. The researcher had two centrifuges that are same model but different voltages. It was assumed that the lids were interchangeable because they were the same model. This incident was due to human error.

The centrifuge should have rested at least 20 minutes before attempting to open. Once open, the samples should not have been removed from the bucket, but decontaminated intact.

On a second interview with the researcher on 4/13, it was determined that the tube had not been broken but was recovered completely intact (tube and cap). The researcher thought that the volume of the tube had possibly changed, but was not 100% sure of the original volume. There was liquid on the outside of the tube, but that was likely from condensation. It is highly probable that there was no leak and therefore no contamination occurred.

As a precaution, the laboratory has been fully decontaminated using 10% bleach and EHS continued to proceed as if the contamination had occurred.

Public Health

The modified H3N2 virus does contain some genes from H5N1. However, in discussing with the PI, it is highly likely that the researcher would have antibodies for the H3N2 virus, thereby being "vaccinated" against the virus. Full PPE and a negative pressure lab was used to ensure that the researcher would not be exposed. CDC recommends BSL2 practices for H3N2, but it was decided that BSL3 would be prudent for the use with this transgenic agent. The researcher discarded all clothing and showered out as part of the decon protocol. Tamiflu prophylaxsis was initiated only as a precaution. It is extremely unlikely that this would have been a threat to public health. Austin-Travis County Health Department Epidemiology was notified by phone of the event.

Update

Based on the subsequent interviews with the researcher and EHS investigation, it was determined that this incident would not be considered a significant accident as there was no release and therefore no exposure. NIH was not notified based on that decision.

The Institutional Biosafety Officer is in the process of developing a reporting SOP for future incidents involving exposure.

The centrifuge was decontaminated and replaced with the proper sized rotor and safety cups.

The incident will be used for future training in laboratory safety.

Messages for Lab Incident:

1. Researchers at The University of Texas at Austin DO NOT work with H5N1. Our researchers work with non-contagious elements of that virus.

- The agent being used was a seasonal virus-- Influenza A (H3N2). This is a commonly used laboratory virus.
- Most of the population, including the researcher, has antibodies for H3N2.
- The researcher was given Tamiflu purely as a precaution as the investigation continued.

2. Based on evidence from investigation and interviews with the researcher, the university concluded that there was no leak or contamination during this incident. There was no public health risk.

- The tube was intact (tube and cap).
- Only the cap of the centrifuge safety cup or safety bucket was damaged.
- The researcher thought the volume of the tube had possibly changed, but was not 100% sure of the original volume.

3. During this incident, the research was being conducted in a biosafety lab (BSL3) with an infrastructure that exceeds CDC requirements for this agent (H3N2).

- CDC recommends BSL2 practices for H3N2, but it was decided that BSL3 would be prudent for use with this transgenic agent.
- The researcher followed biosafety protocol when he thought there might have been an accident.
- Environmental Health and Safety followed its appropriate protocol (including notifying the public health authority and communications personnel) as the staff began investigating a possible accident.
- There was no accident.

4. The Sunshine Project article is based on three gross misstatements of fact:

- The first misstatement: ". . . the genetically engineered influenza pandemic that might have started in Austin, Texas.
    - Fact: Our researchers were working with Influenza A (H3N2)—a seasonal virus commonly used in this type of lab work. All the surface proteins are H3N2.
- The second misstatement: "The tube was the wrong type for the centrifuge . . . Because the tube was the wrong type, its cap didn't fit correctly. It cracked." "highly probable"
    - Fact: The tube was correct and intact after the incident. The safety bucket was wrong for the centrifuge. The cap on the safety bucket came off in the centrifuge. Again, the tube and cap in the safety bucket were intact.
- The third misstatement: There was "certainly enough H5N1 genetic material to create an unpredictable and potentially extremely dangerous (pandemic) reassortant."
    - Fact: The surface proteins **of this virus** are from H3N2. **Pathogenicity of H5N1 viruses requires that the hemagglutinin (HA) surface protein is a H5 HA. Consequently, the substitution of a H3 HA eliminates pathogenicity. The particular H3N2 virus in this instance had a single internal gene from a 1997 H5N1 virus, specifically the NS gene. Subsequent experiments showed that this 1997 NS gene actually attenuates virus replication. Substitution of this 1997 NS gene for the NS gene of the H3N2 virus resulted in a virus that replicated in tissue culture 100-fold less rapidly than the H3N2 virus itself.** ← true??

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The researcher was wearing full BSL3 PPE (respirator, suit and gloves) and was working in a negative pressure room. The researcher followed standard decontamination procedures and notified the Laboratory Director. The Lab Director notified the University Biosafety Officer and consulted with the UHS Medical Director. The researcher was started on drug prophylaxis as a precaution.

Again, the agent that was being used was a commonly used laboratory Influenza A (H3N2) virus. The lab will be further decontaminated by EHS staff this morning and will be operational later this week. There is no public health risk associated with this lab contamination.

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3:45: Second briefing with Associate Director
4:15: Consulted UHS medical director (Theresa) for clearance to use Tamiflu.
4:40: Consulted with EHS Director of plan to treat researcher and further decontaminate lab.
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6:00: Researcher emailed his report of event, reply sent to complete "First Notice of Injury" form.

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2:40 – 4:20: Worked with Lab Director and Biosafety Officer on action Plan.
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3. Cleaned the bucket in the BSC with more Venephene.
4. Wiped the chamber and the rotor with Lysol
5. Wiped the bench, equipments, the surface of refrigerator, incubators, and cabinet with Lysol.
6. Sprayed Lysol on the surface of the sink.
7. Mopped the floor with "Swiffer Wetjet" (before that I sprayed Lysol on the floor)
8. Packed the trash.
8. Sprayed Lysol on myself.
9. Walked out of the room, put trash into the autoclave.
10. took off the suit put into a trash bag.
11. Autoclaved the trash.
12. Cleaned the respirator and hose.
13. Put the sign on the door of room B
14. Took shower, threw away the scrub

Biosafety Comments

It was determined that the centrifuge safety cup was wrong size, causing the lid to break. The researcher had two centrifuges that are same model but different voltages. It was assumed that the lids were interchangeable because they were the same model. This incident was due to human error.

The centrifuge should have rested at least 20 minutes before attempting to open. Once open, the samples should not have been removed from the bucket, but decontaminated intact.

On a second interview with the researcher on 4/13, it was determined that the tube had not been broken but was recovered completely intact (tube and cap). The researcher thought that the volume of the tube had possibly changed, but was not 100% sure of the original volume. There was liquid on the outside of the tube, but that was likely from condensation. It is highly probable that there was no leak and therefore no contamination occurred.

As a precaution, the laboratory has been fully decontaminated using 10% bleach and EHS continued to proceed as if the contamination had occurred.

Public Health

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Update

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- The researcher thought the volume of the tube had possibly changed, but was not 100% sure of the original volume.

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- CDC recommends BSL2 practices for H3N2, but it was decided that BSL3 would be prudent for use with this transgenic agent.
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- There was no accident.

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    - Fact: Our researchers were working with Influenza A (H3N2)—a seasonal virus commonly used in this type of lab work. All the surface proteins are H3N2.
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Harris, Kathryn (NIH/OD)

From: Shipp, Allan (NIH/OD) [E]
Sent: Friday, January 12, 2007 8:45 AM
To: Patterson, Amy (NIH/OD) [E]; Groesch, Mary (NIH/OD) [E]; Harris, Kathryn (NIH/OD); Whitney, Bruce (NIH/OD) [C]; Rosenthal, Eugene (NIH/OD) [E]; O'Reilly, Marina (NIH/OD) [E]; Jambou, Robert (NIH/OD) [E]; Shih, Tom (NIH/OD) [E]
Subject: Fw: Final Report for NIH

BSL3 Lab Incident Report Apr 2...

To: Biosafety Staff

I can't read the attchment on my blackberry, but take a look and maybe we can discuss this on Tuesday.

Allan

----- Original Message -----
From: Janssen, Erle <ejanssen@austin.utexas.edu>
To: Shipp, Allan (NIH/OD) [E]; aroda@leo.gov <aroda@leo.gov>
Sent: Thu Jan 11 18:45:10 2007
Subject: FW: Final Report for NIH

Allen, the attached was updated after the request from the Sunshine project. Tony, (FBI-WMD), the attached is a more complete version of what was given under the open records request. The Sunshine Project email is below.

From: "Martin Enserink" <menserin@aaas.org>

Date: January 11, 2007 12:52:37 PM CST

To: <lclippard@mail.utexas.edu>

Subject: Fw: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

Hello Lee,

Below is that email from the Sunshine Project I was talking about. Perhaps you can put me in touch with a scientist involved in the study?

Thanks in advance, best regards,

Martin Enserink

Martin Enserink

European correspondent, Science (www.science.com)

Paris, France

tel. +33 1 4340 0685

menserin@aaas.org

----- Original Message ----- From: "Edward Hammond" <hammond@sunshine-project.org>

To: <biodefense@lists.sunshine-project.org>

Sent: Thursday, January 11, 2007 6:37 AM

Subject: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

The Sunshine Project

Biosafety Bites #21 (v.2) - 11 January 2007

http://www.sunshine-project.org

The Bird Flu Lab Accident that Officially Didn't Happen, or How the University of Texas at Austin Could Have Caused the Next Influenza Pandemic, but Everybody Lived to Cover It Up

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Don't ask the National Institutes of Health (NIH) about the genetically engineered influenza pandemic that might have started in Austin, Texas in April 2006. That's because until NIH reads this Biosafety Bites, they almost certainly haven't heard anything about it. And that shows yet again that the US biotechnology and laboratory safety oversight system is a dangerous failure.

NIH's Office of Biotechnology Activities (OBA) doesn't enforce biosafety rules, so the University of Texas (UT) didn't report the unsettling Bird Flu accident. UT must have reasoned: Why draw attention to a lab accident when there's no cost for burying such incidents? It surely wouldn't be the first time such an event has been swept under the rug.

BSL-3 in the Heart of Texas

According UT records obtained by the Sunshine Project, the accident happened on a Wednesday afternoon, 12 April 2006. A postdoc was working in the Molecular Biology Building ("MBB") on the University of Texas campus in Austin, just a couple minutes' walk away from tightly packed dormitories, the kind of place where a virulent new influenza strain might eagerly take hold. A little over a kilometer south is the Texas Capitol and a warren of state office buildings teeming with public employees.

Centrifuge Accident Aerosolizes Genetically Engineered Influenza

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The postdoc was working alone in a beefed-up BSL-3 laboratory wearing a full lab suit. A respirator system provided oxygen through an air hose. The high-tech safety measures were in place because the viruses in the lab were not your average flu. They were something much more dangerous. They were genetically engineered influenza strains that mixed and matched genes of the common human H3N2 influenza and those of deadly H5N1 "Bird Flu". The kind of unpredictable reassorted flu strain that public health officials fear could cause the next human pandemic.

In the BSL-3 lab, a quantity of the engineered influenza was ready for work. It had been grown mixed with cells. The experiments required purified virus. So, a little after 2:00PM, the researcher transferred a quantity of the virus mixture into a tube. The tube was capped and placed in a centrifuge on a lab bench. The centrifuge would separate out the virus through spinning - centrifugal force.

But the tube was of the wrong type for the centrifuge. There were two almost identical centrifuges in the lab, and their non-interchangeable parts had become mixed up.

The postdoc pushed a button and the centrifuge began to spin. Because the tube was the wrong type, its cap didn't fit correctly. It cracked. The centrifuge lost balance. Turning the machine off, the postdoc observed that the level of virus fluid in the tube had gone down and that its exterior had become wet, both indicators of a leak. This was a serious problem because as the machine spun around, the leaked virus had become aerosolized, at least within the centrifuge.

The Inevitable Human Error

The problem was then compounded by human error, an ever-present factor in lab work. Rather than waiting for the aerosolized flu to settle, the centrifuge was immediately opened. In an invisible puff of air, virus particles wafted out of the machine. Now, the virus was floating around the whole lab, stirred by air movements, then slowing settling on exposed surfaces or being sucked out the exhaust which, hopefully, had effective HEPA filtration (the UT documents are silent on this item).

It was something like a Bird Flu victim walking into the room and coughing all around, spreading virus where he went. Except this mixed up lab creation of H5N1 virus was possibly more efficient at infecting humans than natural "Bird Flu" because of its H3N2 human influenza parts.

The researcher sprayed Lysol and wiped up surfaces in the work area, exited the lab, took a shower, and put on new clothes. Within hours, the postdoc was taking Tamiflu, in the hope that it would stop the virus if the researcher had been infected. For several uncomfortable days, the University of Texas staff waited to see if the researcher developed symptoms. None are reported to have appeared.

The University of Texas at Austin had dodged a bullet. It took longer for a UT biosafety team to straighten out the lab and reopen it. Under any of a variety of plausible scenarios, the accident might resulted in disaster. For example, if the cap leaked but didn't crack, without the postdoc noticing, thereby multiplying the danger to include everyone working in the lab over a longer time.

UT's Bird Flu Hybrid and Deceptive Records

Reading UT's records, it is clear that the University was thinking in terms of public relations from practically the moment that the accident occurred. UT records unscientifically discuss (downplay) the risks and neglect to precisely describe the flu strain. For example, they state that the virus should be considered like far less dangerous H3N2 despite it being a hybrid with "some genes from H5N1". This is deceptive, because the bug that causes flu is composed of only 8 short pieces of RNA that collectively encode just 11 proteins.

Assuming "some genes from H5N1" means at least three RNA pieces or more, or the RNA to encode three proteins, UT's hybrid Bird Flu virus would be about 25% H5N1 (somewhere between 3/11ths and 3/8ths), and potentially much more if the "some genes" were larger ones. That's certainly enough H5N1 genetic material to create an unpredictable and potentially extremely dangerous (pandemic) reassortant. Tiny differences in genes can make huge differences in the bug. Nobody knows for sure how dangerous UT's flu was because, by good fortune, this story doesn't end in human infection.

UT's report also deceptively states "CDC recommends BSL2 practices for H3N2, but it was decided that BSL3 would be prudent for use with this agent," as if UT was acting with an abundance of caution. But UT was was working with a potentially pandemic combination of H5N1 and H3N2. And well before April 2006, there had been scientific discussion and government recommendations made about the need for BSL-3 or higher containment for flu viruses like UT's. Thus, contrary to the implication of its PR-wise assertions, UT was not taking any major steps above and beyond the basic measures that should have been used for such a virus.

Echoes of 2005's Flu Accident

It must have weighed heavily on the minds of University of Texas public relations officials (who were called than 2 hours after the accident) that one year before, on 12 April 2005, global headlines were dominated by the story of Meridian Biosciences Inc., which sent 3,700 samples of potentially dangerous noncontemporary H2N2 flu to labs in the US and across the world. If the UT accident became public at that time, its occurrence on the anniversary of the Meridian story might have cast an extra bright and unflattering light on the University of Texas, potentially unsettling the Molecular Biology Building's many neighbors, many of whom would be unhappy to learn that they came too close for comfort to being ground zero of a deadly flu pandemic.

Need for Federal Reporting

Although it would serve public health and accountability ends, perhaps it is presently optimistic to expect a university to quickly issue bad news about itself, especially when that bad news evokes images of it authoring a public health disaster. But it must be expected that such accidents definitely will be reported to the federal officials that oversee lab safety so that, at least, other labs can learn from the mistake and, for example, not put two identical centrifuges whose parts are NOT interchangeable in the same lab. And so that federal safety officials and funders could examine the accident and impose penalties if institutional safety deficiencies are identified.

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The accident was miraculously converted into a figment of the postdoc's imagination. Pondering the possibility of being at the center of an embarrassing incident that might impair funding and anger UT leaders, was there pressure to change the story? The postdoc knows for certain; but in the absence of any enforced reporting requirements, there were precious few incentives to move forward with accident reporting. Or perhaps UT management insisted that nothing happened unless the Tamiflu-taking postdoc affirmed absolute certainty of details remembered while in the midst of scrambling to contain a potentially life-threatening accident?

Certainly, UT management seized upon the (reported) "not 100% sure" statement. On that basis UT decided that an accident had not occurred. The following gem of illogic (read carefully) provides the University's reasoning that the accident didn't happen: "There is the possibility that there was no leak and therefore no contamination occurred."

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condensation". The broken c_ isn't mentioned. Nor is the pre curely opened centrifuge. Nor is the decrease in the volume of the virus in the tube.

Condensation? According to the accident report, the "condensation" was observed not long after the tube was filled and almost immediately after it had been spinning at several hundred, perhaps several thousand, revolutions per minute. If it was condensation and not virus culture, then UT seems to have set a world laboratory record for the fastest-forming and most remarkably adhesive water condensation ever seen.

But as far as UT was concerned, the case was closed. No authorities were told. Officially, no accident took place, although despite the fact that nothing officially happened, UT curiously proceeded to decontaminate the entire lab "as if the contamination had occurred." The accident report remained labeled "draft" and was not finalized.

And there the story would have ended, before this Biosafety Bites.

You received this message as a subscriber on the list:

biodefense@lists.sunshine-project.org

For all list information and functions, see:

http://lists.sunshine-project.org/lists/info/biodefense

Harris, Kathryn (NIH/OD)

From: Shipp, Allan (NIH/OD) [E]

Sent: Thursday, January 11, 2007 4:14 PM

To: Whitney, Bruce (NIH/OD) [C]; Carr, Sarah (NIH/OD) [E]; Groesch, Mary (NIH/OD) [E]; Harris, Kathryn (NIH/OD); Hill, Ronna (NIH/OD) [C]; Jambou, Robert (NIH/OD) [E]; Johnson, Michelle (NIH/OD) [C]; Lanman, Robert (NIH/OD) [C]; O'Reilly, Marina (NIH/OD) [E]; Patterson, Amy (NIH/OD) [E]; Rojo, Minerva (NIH/OD) [E]; Rosenthal, Eugene (NIH/OD) [E]; Shih, Tom (NIH/OD) [E]; Stewart, Ansalan (NIH/OD) [E]

Subject: FW: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

FYI

-----Original Message-----
From: Janssen, Erle [mailto:ejanssen@austin.utexas.edu]
Sent: Thursday, January 11, 2007 3:41 PM
To: Shipp, Allan (NIH/OD) [E]
Subject: FW: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

---

From: Janssen, Erle
Sent: Thursday, January 11, 2007 1:49 PM
To: 'ashipp@od.nih.gov'
Subject: FW: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

Please call me. This is full of errors.

Erle Janssen CIH RBP
Director Environmental Health & Safety
The University of Texas at Austin
P.O. Box 7729, Austin, Texas 78713
phone 512-471-3511
fax 512-471-6918

From: Lee Clippard [mailto:lclippard@mail.utexas.edu]
Sent: Thursday, January 11, 2007 1:20 PM
To: ejanssen@mail.utexas.edu
Subject: Fwd: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

Erle,

Email from Sushine Project below.

Thanks,
Lee

****
Lee Clippard

Director of Communications
College of Natural Sciences
The University of Texas at Austin
William C. Hogg Building 2.308
1 University Station G2500
Austin, TX 78712
512.232.0675 (o)
512.944.4886 (c)
512.471.1660 (f)
http://cns.utexas.edu

What starts here changes the world
****

Begin forwarded message:

From: "Martin Enserink" <menserin@aaas.org>
Date: January 11, 2007 12:52:37 PM CST
To: <lclippard@mail.utexas.edu>
Subject: Fw: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

Hello Lee,

Below is that email from the Sunshine Project I was talking about. Perhaps you can put me in touch with a scientist involved in the study?

Thanks in advance, best regards,
Martin Enserink

Martin Enserink
European correspondent, Science (www.science.com)
Paris, France
tel. +33 1 4340 0685
menserin@aaas.org

----- Original Message ----- From: "Edward Hammond" <hammond@sunshine-project.org>
To: <biodefense@lists.sunshine-project.org>
Sent: Thursday, January 11, 2007 6:37 AM
Subject: [biodefense] BB#21: The Bird Flu Accident that Didn't Happen in Austin, Texas

The Sunshine Project
Biosafety Bites #21 (v.2) - 11 January 2007
http://www.sunshine-project.org

The Bird Flu Lab Accident that Officially Didn't Happen, or
How the University of Texas at Austin Could Have Caused the
Next Influenza Pandemic, but Everybody Lived to Cover It Up

Don't ask the National Institutes of Health (NIH) about the genetically engineered influenza pandemic that might have started in Austin, Texas in April 2006. That's because until NIH reads this Biosafety Bites, they almost certainly haven't heard anything about it. And that shows yet again that the US biotechnology and laboratory

safety oversight system is a dangerous failure.

NIH's Office of Biotechnology Activities (OBA) doesn't enforce biosafety rules, so the University of Texas (UT) didn't report the unsettling Bird Flu accident. UT must have reasoned: Why draw attention to a lab accident when there's no cost for burying such incidents? It surely wouldn't be the first time such an event has been swept under the rug.

BSL-3 in the Heart of Texas

According UT records obtained by the Sunshine Project, the accident happened on a Wednesday afternoon, 12 April 2006. A postdoc was working in the Molecular Biology Building ("MBB") on the University of Texas campus in Austin, just a couple minutes' walk away from tightly packed dormitories, the kind of place where a virulent new influenza strain might eagerly take hold. A little over a kilometer south is the Texas Capitol and a warren of state office buildings teeming with public employees.

Centrifuge Accident Aerosolizes Genetically Engineered Influenza

The postdoc was working alone in a beefed-up BSL-3 laboratory wearing a full lab suit. A respirator system provided oxygen through an air hose. The high-tech safety measures were in place because the viruses in the lab were not your average flu. They were something much more dangerous. They were genetically engineered influenza strains that mixed and matched genes of the common human H3N2 influenza and those of deadly H5N1 "Bird Flu". The kind of unpredictable reassorted flu strain that public health officials fear could cause the next human pandemic.

In the BSL-3 lab, a quantity of the engineered influenza was ready for work. It had been grown mixed with cells. The experiments required purified virus. So, a little after 2:00PM, the researcher transferred a quantity of the virus mixture into a tube. The tube was capped and placed in a centrifuge on a lab bench. The centrifuge would separate out the virus through spinning - centrifugal force.

But the tube was of the wrong type for the centrifuge. There were two almost identical centrifuges in the lab, and their non-interchangeable parts had become mixed up.

The postdoc pushed a button and the centrifuge began to spin. Because the tube was the wrong type, its cap didn't fit correctly. It cracked. The centrifuge lost balance. Turning the machine off, the postdoc observed that the level of virus fluid in the tube had gone down and that its exterior had become wet, both indicators of a leak. This was a serious problem because as the machine spun around, the leaked virus had become aerosolized, at least within the centrifuge.

The Inevitable Human Error

The problem was then compounded by human error, an ever-present factor in lab work. Rather than waiting for the aerosolized flu to settle, the centrifuge was immediately opened. In an invisible puff of air, virus particles wafted out of the machine. Now, the virus was floating around the whole lab, stirred by air movements, then slowing settling on exposed surfaces or being sucked out the exhaust which, hopefully, had effective HEPA filtration (the UT documents are silent on this item).

It was something like a Bird Flu victim walking into the room and coughing all

around, spreading virus where he went. Except this mixed up lab creation of H5N1 virus was possibly more efficient at infecting humans than natural "Bird Flu" because of its H3N2 human influenza parts.

The researcher sprayed Lysol and wiped up surfaces in the work area, exited the lab, took a shower, and put on new clothes. Within hours, the postdoc was taking Tamiflu, in the hope that it would stop the virus if the researcher had been infected. For several uncomfortable days, the University of Texas staff waited to see if the researcher developed symptoms. None are reported to have appeared.

The University of Texas at Austin had dodged a bullet. It took longer for a UT biosafety team to straighten out the lab and reopen it. Under any of a variety of plausible scenarios, the accident might resulted in disaster. For example, if the cap leaked but didn't crack, without the postdoc noticing, thereby multiplying the danger to include everyone working in the lab over a longer time.

UT's Bird Flu Hybrid and Deceptive Records

Reading UT's records, it is clear that the University was thinking in terms of public relations from practically the moment that the accident occurred. UT records unscientifically discuss (downplay) the risks and neglect to precisely describe the flu strain. For example, they state that the virus should be considered like far less dangerous H3N2 despite it being a hybrid with "some genes from H5N1". This is deceptive, because the bug that causes flu is composed of only 8 short pieces of RNA that collectively encode just 11 proteins.

Assuming "some genes from H5N1" means at least three RNA pieces or more, or the RNA to encode three proteins, UT's hybrid Bird Flu virus would be about 25% H5N1 (somewhere between 3/11ths and 3/8ths), and potentially much more if the "some genes" were larger ones. That's certainly enough H5N1 genetic material to create an unpredictable and potentially extremely dangerous (pandemic) reassortant. Tiny differences in genes can make huge differences in the bug. Nobody knows for sure how dangerous UT's flu was because, by good fortune, this story doesn't end in human infection.

UT's report also deceptively states "CDC recommends BSL2 practices for H3N2, but it was decided that BSL3 would be prudent for use with this agent," as if UT was acting with an abundance of caution. But UT was was working with a potentially pandemic combination of H5N1 and H3N2. And well before April 2006, there had been scientific discussion and government recommendations made about the need for BSL-3 or higher containment for flu viruses like UT's. Thus, contrary to the implication of its PR-wise assertions, UT was not taking any major steps above and beyond the basic measures that should have been used for such a virus.

Echoes of 2005's Flu Accident

It must have weighed heavily on the minds of University of Texas public relations officials (who were called than 2 hours after the accident) that one year before, on 12 April 2005, global headlines were dominated by the story of Meridian Biosciences Inc., which sent 3,700 samples of potentially dangerous noncontemporary H2N2 flu to labs in the US and across the world. If the UT accident became public at that time, its occurrence on the anniversary of the Meridian story might have cast an extra bright and unflattering light on the University of Texas, potentially unsettling the Molecular Biology Building's many neighbors, many of whom would be unhappy to learn that

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The accident was miraculously converted into a figment of the postdoc's imagination. Pondering the possibility of being at the center of an embarrassing incident that might impair funding and anger UT leaders, was there pressure to change the story? The postdoc knows for certain; but in the absence of any enforced reporting requirements, there were precious few incentives to move forward with accident reporting. Or perhaps UT management insisted that nothing happened unless the Tamiflu-taking postdoc affirmed absolute certainty of details remembered while in the midst of scrambling to contain a potentially life-threatening accident?

Certainly, UT management seized upon the (reported) "not 100% sure" statement. On that basis UT decided that an accident had not occurred. The following gem of illogic (read carefully) provides the University's reasoning that the accident didn't happen: "There is the possibility that there was no leak and therefore no contamination occurred."

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prematurely opened centrifuge. Nor is the decrease in the volume of the virus in the tube.

Condensation? According to the accident report, the "condensation" was observed not long after the tube was filled and almost immediately after it had been spinning at several hundred, perhaps several thousand, revolutions per minute. If it was condensation and not virus culture, then UT seems to have set a world laboratory record for the fastest-forming and most remarkably adhesive water condensation ever seen.

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And there the story would have ended, before this Biosafety Bites.

OFFICE OF THE VICE PRESIDENT AND CHIEF FINANCIAL OFFICER

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 8179 • Austin, Texas 78713-8179
(512) 471-1422 • Fax (512) 471-7742

December 8, 2006

Mr. Edward Hammond
The Sunshine Project
1920 Stuart St.
Berkeley, California 94703

RE: OPEN RECORDS REQUEST – Research Protocols

Dear Mr. Hammond:

This is in final response to your Open Records Request received via e-mail on September 12, 2006. You requested that The University of Texas provide you with copies of certain research protocols referenced in the November 15, 2005, UT Institutional Biosafety Committee (IBC) meeting minutes.

The Attorney General has issued AG Ruling OR2006-14063. Enclosed is a copy of the ruling, whereby the AG upheld the University's position that the requested research protocols were excepted from disclosure in their entirety in accordance with §51.914(1), *Education Code*. For Item #2 of your request, you asked that the scope include all records concerning an incident in a BSL-3 laboratory involving trangenic influenza virus referenced in the April 17, 2006, IBC meeting minutes. You asked that the University's document response include, but not be limited to, reports made to state or federal agencies in relation to the April 17 incident. The AG further concluded that this draft report and related documents are accepted from disclosure. However, only in part. Accordingly, enclosed are copies of the remaining responsive documents, which have been redacted in accordance with the AG ruling.

The University provides less than 50 copies at no cost. You may contact Ms. Annela Lopez at (512) 471-1422 if you require any further assistance.

Sincerely,

Margo Iwanski

Margo Iwanski
Executive Assistant
to the Vice President

MI:aml
Enclosures

ENVIRONMENTAL HEALTH AND SAFETY OFFICE

ENVIRONMENTAL HEALTH AND SAFETY OFFICE

Mr. Erle Janssen, Director
Mr. Abraham Ybarra, Associate Director
Mr. Dennis H. Nolan, Assistant Director

OEHS Reports to:
Dr. Bob Harkins, Associate Vice President for Campus Safety and Security

Item #2

BSL3 Laboratory Incident Report

Original Briefing

On April 12, 2006 at approx. 2:15pm, a researcher working in the BSL3 Lab in MBB was involved in an incident that resulted in the contamination of a laboratory centrifuge. The agent that was being used was **not** the Avian Influenza virus (H5N1). The researcher was wearing full BSL3 PPE (respirator, suit and gloves) and was working in a negative pressure room. The researcher followed standard decontamination procedures and notified the Laboratory Director. The Lab Director notified the University Biosafety Officer and consulted with the UHS Medical Director. The researcher was started on drug prophylaxis as a precaution.

Again, the agent that was being used was **not** the Avian Influenza virus (H5N1). The virus was commonly used laboratory Influenza A (H3N2) virus that contained some genetic elements of H5N1. The lab will be further decontaminated by EHS staff this morning and will be operational later this week.

Released Briefing

On April 12, 2006 at approx. 2:15 pm, a researcher working in the BSL3 Lab in MBB was involved in an incident that resulted in the contamination of a laboratory centrifuge. The agent that was being used was a modified laboratory Influenza A (H3N2)—**NOT** the Avian Influenza virus (H5N1) as was indicated in previous email. University researchers **DO NOT** work with H5N1. Our researchers work with non-contagious elements of that virus.

The researcher was wearing full BSL3 PPE (respirator, suit and gloves) and was working in a negative pressure room. The researcher followed standard decontamination procedures and notified the Laboratory Director. The Lab Director notified the University Biosafety Officer and consulted with the UHS Medical Director. The researcher was started on drug prophylaxis as a precaution.

Again, the agent that was being used was a commonly used laboratory Influenza A (H3N2) virus. The lab will be further decontaminated by EHS staff this morning and will be operational later this week. There is no public health risk associated with this lab contamination.

Timeline of Events

Wednesday April 12th (Actions by Lab Director)

2:15: Incident occurs (described as tube containing flu virus broken in centrifuge)
2:25: Laboratory director (Dennis) notified by researcher (Rei-Lin) . Instructions given to decontaminate work surfaces and follow posted decontamination protocol.

2:35: Briefed Associate Director (Abe), consulted Director (Erle-Biosafety Officer)
2:50: Lab Director went to lab to inspect decontamination procedures.
3:15: Lab Director briefed PI (Krug), attempted to contact Occupation Health Physician (Hefner)
3:45: Second briefing with Associate Director
4:15: Consulted UHS medical director (Theresa) for clearance to use Tamiflu.
4:40: Consulted with EHS Director of plan to treat researcher and further decontaminate lab.
5:00: Third briefing with Associate Director
5:15: Notified researcher to start Tamiflu prophylaxsis
6:00: Researcher emailed his report of event, reply sent to complete "First Notice of Injury" form.

Actions by Associate Director:
2:40 – 4:20: Worked with Lab Director and Biosafety Officer on action Plan.
4:30: Called AVP CSAS , spoke with Exec. Asst. and informed her about a call back.
5:30: Called AVP CSAS and left voice mail
5:50: Connected with AVP CSAS and conducted briefing.

Thursday April 13th (Actions by Lab Director)

7:00: Contacted by Associate Director to write incident briefing
9:00: Incident briefing completed and sent to Director of Communications (Rhonda).
9:45: PI called that accident was likely due to wrong size centrifuge cup.
11:15:Lab director met with researcher. Interviewed researcher about report.
11:30:Secondary decontamination of room.

Actions by Associate Director:

6:40: Contacted by Biosafety Officer
7:00: Contacted Asst. Director (Nolan) about briefing document.
7:50: Connected with AVP CSAS and conducted briefing
8:00: Connected with Assoc. Director CNS (Ann H.) and conducted briefing
8:15: Connected with Dir of Communications (Weldon) and conducted briefing
8:45: First Draft Briefing Document Reviewed

Researcher Report (Emailed 5:12pm 4/12/06)

This is what happened.
When I was doing centrifugation, one of the lid of the bucket was broken. Then the centrifuge lost balance. I stopped the centrifuge, opened the centrifuge, and found the volume in one of the tubes was decreased a little.

What I have done.

1. Remove my samples.
2. Sprayed Lysol and Venephene into the whole chamber of the centrifuge, waited for 10 min.
3. Cleaned the bucket in the BSC with more Venephene.
4. Wiped the chamber and the rotor with Lysol
5. Wiped the bench, equipments, the surface of refrigerator, incubators, and cabinet with Lysol.
6. Sprayed Lysol on the surface of the sink.
7. Mopped the floor with "Swiffer Wetjet" (before that I sprayed Lysol on the floor)
8. Packed the trash.
8. Sprayed Lysol on myself.
9. Walked out of the room, put trash into the autoclave.
10. took off the suit put into a trash bag.
11. Autoclaved the trash.
12. Cleaned the respirator and hose.
13. Put the sign on the door of room B
14. Took shower, threw away the scrub

Biosafety Comments

It has been determined that the centrifuge safety cup was wrong size, causing the lid to break. The researcher has two centrifuges that are same model but different voltages. It was assumed that the lids were interchangeable because they were the same model. This accident was due to human error.

The centrifuge should have rested at least 20 minutes before attempting to open. The samples should not have been removed from the bucket, but decontaminated intact.

On interviewing the researcher again on 4/13, it was determined that the tube had not been broken but was recovered intact (tube and cap). The researcher thought that the volume of the tube had changed, but was not 100% sure of the original volume. There was liquid on the outside of the tube, but that may have been from condensation. There is the possibility that there was no leak and therefore no contamination occurred.

The laboratory has been decontaminated and EHS will continue to proceed as if the contamination had occurred.

Public Health

The modified H3N2 virus does contain some genes from H5N1. However, in discussing with the PI, it is highly likely that the researcher would have antibodies for the H3N2 virus, thereby being "vaccinated" against the virus. Full PPE and a negative pressure lab is used to ensure that the researcher would not be exposed. CDC recommends BSL2 practices for H3N2, but it was decided that BSL3 would be prudent for the use with this agent. The researcher discarded all clothing and showered out as part of the decon

[552.11]

protocol. Tamiflu prophylazsis was initiated only as a precaution. It is extremely unlikely that this would be a threat to public health.

Critique

[ ]

Erle Janssen

From: Abraham Ybarra
Sent: Thursday, April 13, 2006 12:48 PM
To: 'bharkins@mail.utexas.edu'; Erle Janssen
Cc: Dennis H Nolan
Subject: RE: Incident Report 2nd Draft
Attachments: BSL3 Lab Incident Report Apr 2006(2).doc

Here is an updated Incident Report and can be considered a FINAL DRAFT. We will add more comments to the bottom section. Please notice comments of today regarding conversation with Researcher that happened late this morning. Comments are under the heading, "**Biosafety Comments".**

From: Dennis H Nolan
Sent: Thursday, April 13, 2006 12:21 PM
To: Abraham Ybarra
Cc: Erle Janssen
Subject: Incident Report 2nd Draft

Other than the lessons learned, I think this report is complete. Let me know if there are any additional changes.

Dennis

Erle Janssen

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