

## State University of New York

DIRECTOR OF COMPLIANCE AND RISK MANAGEMENT

PO Box 6000 Binghamton, New York 13902-6000 607-777-2808, Fax: 607-777-6453

March 5, 2007

Edward Hammond The Sunshine Project 1920 Stuart St Berkeley, CA 94703

Dear Mr. Hammond:

Binghamton University is in receipt of your request for minutes from our Institutional Biosafety Committee from I May 2003 through the present. Due to an unfortunate miscommunication between the Records Access Office and the committee, the information was not gathered in a timely fashion. We sincerely apologize for this delay.

Attached please find minutes from the following meetings of the Binghamton University Institutional Biosafety Committee:

- April 21, 2004
- October 27, 2004
- June 16, 2005
- August 23, 2006

Please direct any future requests for minutes of the Institutional Biosafety Committee to our Records Access Officer at the following address.

Barbara Westbrook-Scarlett SUNY Office of University Counsel Binghamton University PO Box 6000 Binghamton, NY 13902-6000

Sincerely,

Jillian Harrington

Director, Office of Compliance and Risk Management

cc: Barbara Westbrook-Scarlett, Office of University Counsel, SUNY Stephen Gilje, AVP for Research, Binghamton University

### Minutes of April 21, 2004 Meeting Science III, Room 214

Present: Karl Wilson, Howard Fisher, David Davies, Kelly Donovan, Sharon Sickles, and

Pamela Watts

Absent: Sharon Aswad, Richard Firenze, Stephen Gilje, Kathleen Horwath and Gary James

The meeting began at approximately 8:45am.

• Minutes of February 27, 2003 were not discussed or approved.

## 1) IBC #143, Susannah Gal, Department of Biological Sciences, Substrates for the in vivo analysis of proteases.

H. Fisher pointed out that Dr. Gal had not signed off on the protocol. He also mentioned that he appreciated the "Lay person's Abstract" which was included in the project description.

IBC #143 was approved unanimously

### 2) IBC #144, O.A. Sadik, Department of Chemistry, Capillary Cell-Based Biosensor

The following concerns about this protocol were raised by the various members present:

- Why a pathogenic strain of E. coli (O157:H7)? Could a surrogate, non-pathogenic strain be used for the bulk of the initial research to minimize the potential health risks?
- Could more information be provided about the specific research being performed to better assess the risks of handling this pathogen in this project?
- Since they will have to use the autoclave in Science 3, there is concern for the general university population being exposed as contaminated waste is transported from Science 2 to Science 3.
- Will waste be handled appropriately as Regulated Medical Waste?
- Is the research lab in Science 2 equipped for Biosafety Level 2 research?
- Has the student performing the research, Jason Karasinski, been appropriately trained? Is he a graduate student or undergraduate.
- Confirm that Jason's transcript reflects having taken the appropriate Microbiology courses.
- S. Sickles agreed that she and K. Donovan would meet with Dr. Sadik to recommend the following:
- Use of a surrogate, non-pathogenic strain for bulk of the initial project
- More specific evidence of appropriate safety training of research personnel\*.
- A consultant microbiologist should be available to advise on this project, and any others that
  involve microbiological methods. (This would be standard practice for most NIH- and NSFfunded research projects.)

- How to appropriately set up the lab for handling of BSL-2 organisms.
- Appropriate methods for handling and disposal of Regulated Medical Waste.
- \*P. Watts agreed to work with Jason to train in appropriate safety practices for handling BSL-2 organisms during the <u>summer</u>.
- 3) K. Wilson asked that the Attachment E form, "Registration of Research Involving Biohazardous Materials" be corrected. The last part of line #6, should read, "If Yes, and if a toxin, is LD<sub>50</sub> less than 100 nanograms...?" (instead of "more than").
- 4) S. Sickles reviewed the "Guidelines for Handling and Disposal of Regulated Medical Waste." and noted that the digestor should be permitted soon for "treating" RMW.
- 5) The need for an additional autoclave in Science 3 was discussed again. D. Davies and P. Watts stated that a reconditioned Steris, smaller than the one in the animal care facility, but large enough to handle a 20-liter carboy would be the most desirable.
- 6) H. Fisher asked for an updated list of all IBC projects and a current list of IBC committee members.
- 7) K. Wilson motioned to adjourn and meeting was adjourned at ????.

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### Minutes of October 27, 2004 Meeting Science III, Room 214

Present: Karl Wilson, Sharon Aswad, Sharon Sickles, David Davies, Kelly Donovan, Howard

Fisher, Gary James and Pamela Watts

Absent: Stephen Gilje and Kathleen Horwath

The meeting began at approximately 8:45am.

Minutes of April 21, 2004 were not discussed or approved.

# 1) IBC #146, Gerald Sonnenfeld, Department of Biological Sciences, Oral Administration of Active Hexose Correlated Compound and Oligonol to Modulate Surgical Wound Infection.

The following points were discussed briefly:

- Klebsiella pneumoniae is normal human intestinal flora/an opportunistic pathogen.
- It will be handled at a BSL-2 level, but it is not assigned to Risk Group 2.
- When not in cages, mice will be handled in laminar flow hood/changing stations.
- K. Donovan expressed a concern to warn University Police to stay out of the animal rooms while in use for this project.
- K. Wilson noted a change be made to Hernan Aviles' title from "Ass't Prof." to "Research Ass't Prof."

**IBC** #146 was approved unanimously

## 2) Northeast Biological Safety Association (NBSA) Application for Affiliation with the American Biological Safety Association (ABSA)

S. Sickles passed out information on the ABSA and a copy of the Charter for the newly formed Northeast Biological Safety Association of which K. Donovan, S. Sickles and R. Snyder are members.

#### 3) General Business

- D. Davies voiced concern over the restricted usage of the autoclave in the Animal Care area. (The majority of this conversation was not recorded as the matter is not an IBC issue.)
- P. Watts voiced concern over the possible inappropriate handling of Regulated Medical Waste (RMW) that is being brought into and left in the Molecular Core area on weekends and evenings. The red-bagged waste appears unlabelled; no tags identifying its source are on the bags. At times, the bags are found on the floor of the core area, unautoclaved.
- S. Sickles will speak with Joanne Pfeil and Bob Snyder to see if it can be determined where the waste is originating from.
- Individuals generating RMW are responsible for its proper labeling, handling and transport on campus until it reaches S3 B20, the RMW repackaging and storage area for the campus. Individuals should refer to the University's Guidelines for the Handling and Disposal of Regulated Medical Waste. From S3, B20, RMW is transported offsite by DEC authorized

haulers to a permitted treatment/disposal facility. The campus is not authorized by DEC to receive RMW from other offsite generators for consolidation with waste generated by the University.

• S. Sickles reiterated the need for an additional autoclave in Science 3 and proposed that the IBC submit a memo/request for funding to appropriate parties. P. Watts proposed that new quotes be obtained and a meeting to draft said memo be scheduled.

The meeting was adjourned at approximately 9:30am.

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### Minutes of June 16, 2005 Meeting Science III, Room 214

Present: David Davies, Kelly Donovan, Howard Fisher, Stephen Gilje, Gary James, Pamela Watts and

Karl Wilson

Absent: Sharon Aswad and Kathleen Horwath

The meeting began at approximately 9:07am.

## 1) Approval of minutes from October 27, 2004 meeting

• G. James moved to approve minutes, motion was seconded by S. Gilje and minutes were unanimously approved.

#### 2) Current Committee Review

- The current committee member list was reviewed and expiring terms discussed.
- The terms of both non-university-affiliated members are expiring in August of 2005. H. Fisher
  agreed to continue to serve on the committee. S. Gilje will contact Sharon Aswad regarding her reappointment.
- D. Davies suggested Karin Sauer as a replacement for Kathleen Horwath whose appointment is also expiring in August. K. Wilson will ask Karin if she is willing to serve on this committee.

#### 3) Review of red bag handling procedures

- K. Wilson briefly reviewed the issue of mishandled Regulated Medical Waste (RMW), citing the recent incident of leaking cow brains from a red biohazard bag left on the floor in the molecular core area in Science 3.
- K. Donovan and P. Watts identified some specific problems that have been noted in the handling of RMW:
  - ✓ un-labeled red-bag waste (waste-generating lab not identified)
  - ✓ RMW not transported in closed, rigid containers
  - ✓ leaking red bags
  - ✓ autoclaving of RMW
  - ✓ confusing and, in some cases, incorrect "Guidelines for Handling and Disposal of Regulated Medical Waste"
- K. Wilson suggested that a subcommittee (consisting of K. Donovan and P. Watts) should work to re-define the "Guidelines for Handling and Disposal of Regulated Medical Waste" for review and approval by the IBC.
- P. Watts suggested the possibility of re-locating the Beta Star autoclave currently located in the Animal Care Area in Science 3. The university could then apply for certification to treat RMW which could then be disposed of as regular solid waste, potentially saving the university \$10,000 or more per year.
- K. Donovan and P. Watts agreed to work with Bob Snyder in developing a plan of action regarding the re-location and potential certification of the autoclave.
- D. Davies suggested that an interim policy on the handling of RMW be submitted as soon as possible to Biology, Chemistry and Anthropology to notify them of the most critical RMW issues while the "RMW Guidelines" are being re-defined.
- K. Donovan agreed to draft a memo to the above-mentioned departments.

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en de transporte de la companya de la co • D. Davies also suggested that Science Stores be asked to purchase plain autoclave bags that are not "biohazard"-labeled for use in sterilizing regular (non-RMW) trash.

#### 4) New protocol (K. Sauer BSL-1)

- K. Donovan distributed copies of K. Sauer's protocol, "Whole Genome Approach to Identify Vaccine Candidates Against *Burkholderia mallei*"
- Protocol did not require IBC approval and was intended for review only.

#### 5) New IBC Forms

- K. Donovan noted that the IBC form CMP-4, "Registration of Research Involving Biohazardous Materials" needs to have the contact information on the last page revised. The "RETURN TO" will be changed to Kelly Donovan and the "COPY TO" will be changed to Karl Wilson. S. Gilje offered to make these changes.
- K. Donovan noted that there is no form or consistent process for approval and/or denial of
  protocols. G. James will send Kelly an electronic version of an IRB form letter to be modified for
  use by the IBC.
- K. Donovan noted that no new protocols have been submitted (other than K. Sauer's noted above) and only a few renewals have been received this year.

## 6) New Business

#### Biosafety Manual

- K. Donovan presented a Biosafety Manual that has been developed for use by the university.
- A PDF will be provided to all IBC members for review and will require official approval by the IBC. (K. Donovan asked members to look specifically at definitions, roles and responsibilities in the first section of the manual.)
- Discussion of the manual will be on the agenda for the next IBC meeting.

#### ITC waste management

- G. James asked how the new ITC building is planning to manage its biohazardous waste.
- S. Gilje said that this problem is being addressed, but the current plan is to transport it to Science 3 for disposal.

#### Garruto lab safety

- P. Watts shared an issue raised by Joanne Pfeil (Molecular Biology Technician) about personnel from Dr. Garruto's lab being seen in hallways in protective laboratory clothing (booties, masks, gloves, etc.), as well as the problem of leaving the lab door to the hallway propped open.
- K. Donovan stated that he has brought these issues to Dr. Garruto's attention on several occasions, but the problems continue.
- A discussion about who is ultimately responsible for student safety violations ensued.
- D. Davies stated that Dr. Garruto's lab should have a higher standard for safety based on the nature of his research, compared to other researchers in the building.
- S. Gilje noted that the IBC could withdraw its approval for Dr. Garruto's research if these safety violations continue.
- K. Donovan will issue a formal verbal warning to Dr. Garruto, indicating that if these violations continue, the IBC will consider withdrawing its approval for his research activities.
- K. Wilson asked for motion to adjourn at 10:06am; so moved by G. James; seconded by S. Gilje.
- The next committee meeting will be scheduled for September, 2005.

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### Minutes of August 23, 2006 Meeting Science III, Room 214

Present: Karl Wilson, Kelly Donovan, Gary James, Pamela Watts, Sharon Aswad, Jillian Harrington,

David Davies (arrived midway through meeting)

Absent: Karin Sauer, Stephen Gilje

### 1) Approval of minutes from June 16, 2005 meeting

• G. James moved to approve minutes. Minutes were unanimously approved.

#### 2) Current Committee Review

- Present members were introduced to Jillian Harrington, Director of Compliance and Risk Management.
- The current committee member list was reviewed. The following members need to be renewed: Gary James, Pamela Watts and David Davies.

#### 3) Old Business

## Regulated Medical Waste & ITC Waste Management

- The RMW "update" developed by P. Watts is posted on the EH&S website and is to serve as an addendum to the "Guidelines for the Handling and Disposal of Regulated Medical Waste" until the guidelines are updated and approved by the IBC.
- The RMW subcommittee (K. Donovan and P. Watts) is to continue to review and re-define the "Guidelines" for IBC approval. J. Harrington will work with subcommittee on this.
- J. Harrington mentioned the desire to certify an autoclave for RMW handling.
- There was some discussion of how RMW is to be handled by the new Innovative Technologies Complex (ITC).

#### **IBC Forms & Biosafety Manual**

- IBC registration form CMP-4 has been updated as suggested in June 16, '05 IBC meeting.
- K. Donovan noted that a disapproval/approval form for protocols is still needed.
- The Biosafety manual is still in the process of being updated.

#### Garruto Lab Safety

 K. Donovan has met with laboratory personnel for training and reviewed key concerns discussed during the June 16, '05 IBC meeting (wearing of protective clothing in the hallways, lab doors propped open, etc.).

#### 4) Review of open projects and new protocols

- Merriweather/IBC#150 (a Biosafety Level 1 project)
- Garruto/IBC#151 (a Biosafety Level 2 project)
- McGee/IBC#152 (renewal of IBC#119)
- K. Wilson/IBC#153 (renewal of IBC#137)
- Laramee/IBC#154 (Biosafety Level 2; not yet approved by Human Subjects Research Review Committee)

S. Aswad moved to approve above protocols; motion seconded by G. James and unanimously approved by committee.

#### 5) New Business

#### **Ethidium Bromide Contamination**

The following was discussed:

- Presence of ethidium bromide (EtBr) contamination in Science 3, Rm. 129.
- EtBr is a DNA intercalating agent (mutagenic and teratogenic) and can be absorbed through the skin so requires safe handling.
- Alternative chemicals for EtBr are more expensive and probably not any safer.
- PI's need to educate and train their students and technicians in proper handling of EtBr.
- EH&S will send memo to all faculty that use EtBr concerning proper training of students and staff and will also address EtBr in fall safety training.

#### Other

- Concern was expressed over the infrequency of IBC meetings. What is the minimum NIH requirement for IBC meetings?
- J. Harrington suggested a staff person to coordinate the IBC (scheduling meetings, follow up and posting of protocols, setting up a Blackboard site for protocol review, etc.) could be beneficial.
- G. James motioned to adjourn at 12:06; seconded by K. Donovan.