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October 2, 2006

Mr. Edward H. Hammond, Director
The Sunshine Project
PO Box 41987
Austin, TX 78704

Dear Mr. Hammond:

Enclosed please find the IBC meeting minutes requested in your letter of 15 March, 2006.

"The University of Notre Dame IBC HAS / HAS NOT implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report Biotechnology Research in an Age of Terrorism (the "Fink Committee" report)."

While specific written policies have not been implemented, the IBC annually monitors activities in Notre Dame laboratories and would not approve these areas of research.

I trust the materials are in good order. If you have further questions please contact Dr. Richard A. Hilliard, IRB Administrator directly at 574-631-5386 or Hilliard.1@nd.edu.

Sincerely,

Michael T. Edwards
Director, Office of Research

UNIVERSITY OF NOTRE DAME
Meeting of the Institutional Biosafety Committee
October 13, 2004

MINUTES

Attended by: Nora Besansky, John Adams, Joseph O'Tousa, Lisa Bognar, Robert Zerr, and Richard Hilliard. Heather Kuehnle from the St. Joseph County Health Department was a visitor at the meeting.

The meeting was convened at 1:00 p.m.. January 22, 2003 minutes were approved.

1. Protocols reviewed: See attached
2. Other Business
 - a. Lisa updated the committee on Chem Hazards procedures and procurement process.
 - b. Heather agreed to serve as one of the outside members of the committee.
3. Meeting adjourned at ~ 2:00 p.m.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10/13/2004**

- 05-001** 1. Expression and purification of human matrix metalloproteinases (MMPs) and tissue inhibitor of metalloproteinases (TIMPs) 2. Penicillin-Binding Proteins, Mechanism and Inhibition 3. Resistance to B-Lactam Antibiotics 4. Ribosomal Function and Antibiotic Design

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-2 or **Deferred for Additional Information**

Personnel with potential exposure to vaccinia vector need to be vaccinated.

- 05-002** Protein Binding Domains on Eukaryotic 5s rRNA and rDNA

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** exempt or **Deferred for Additional Information**

- 05-003** The Insect BAC Library Initiative and Evolutionary Genomics of Red Oaks

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 or **Deferred for Additional Information**

Names of lab personnel covered by this protocol needs to be forwarded to IBC.

- 05-004** 1. Structure-Function Studies on Plasminogen and Plasmin 2. Blood Coagulation Protein-Metal Ion-Lipid Binding

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-2 or **Deferred for Additional Information**

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10/13/2004**

05-005 In Vitro Protein Evolution to Improve Beta-Sheet Folding and Stability
CAREER: Conformations of Beta-Sheet Folding Intermediates: The Discrimination Between Productive Folding and Evolution

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 **or** **Deferred for Additional Information**

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05-006 Dietary and Therapeutic Intervention for Prostate and Breast Cancer

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-2 **or** **Deferred for Additional Information**

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05-007 Regulation of Cytoplasmic Dysein Targeting

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 **or** **Deferred for Additional Information**

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05-008 Various *Anopheles* projects

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1/BL-2 **or** **Deferred for Additional Information**

Transformed mosquitoes kept in BL-2 insectary.
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**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10/13/2004**

05-009 **Genetically Engineered Mosquitoes**

Hazardous/Infectious Materials protocol

Approval Date 10/13/2004 **Biosafety Level** BL-2/BL-3 **or** **Deferred for Additional Information**

Infected mosquitoes kept in BL-3 facility. Are provisions in place to house mosquitoes during the renovation of room 304?

05-010 **Molecular Evolutionary Genetics of Mosquitoes - multiple projects**

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 **or** **Deferred for Additional Information**

05-011 **Vitamin D, Calcium Homeostasis and Cancer**

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-2 **or** **Deferred for Additional Information**

Containment under BL-2 requires PI to restrict access to laboratory. Door to hallway must be kept closed.

05-012 **Molecular Biology of Mosquitoes**

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 **or** **Deferred for Additional Information**

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10/13/2004**

05-013 Molecular Biology of Mosquitoes

Hazardous/Infections Materials protocol

Approval Date 10/13/2004 **Biosafety Level** BL-2 or **Deferred for Additional Information**

Are provisions in place to house mosquitoes during renovation of 304 to BL-3 facility?

05-014 Genetic Analysis of Retinal Degeneration

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 or **Deferred for Additional Information**

05-015 QTL Mapping of Diapause and Host Recognition Traits in *Rhagoletis*

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** exempt or **Deferred for Additional Information**

05-016 Studies of Antifreeze Proteins in Arctic and Nearctic Insects

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 or **Deferred for Additional Information**

PI indicates that BL-2 is employed by lab.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10/13/2004**

05-017 Genetics of Drug Cross Resistances and Virulence in Malaria Parasites

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-2 or **Deferred for Additional Information**

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05-018 Minimal Inhibitory Coincentrations of Antibiotics

Hazardous/Infectious Materials Protocol

Approval Date 10/13/2004 **Biosafety Level** BL-2 or **Deferred for Additional Information**

If VRSA colonization from nasal swabs is identified, Risk Management and the Health Center needs to be notified in addition to the CDC.

05-019 Molecular Analysis of Apical Organelles of Plasmodium

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-2 or **Deferred for Additional Information**

Are provisions in place to house mosquitoes during of renovation of room 304 to BL-3 facility?
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05-020 Molecular Analysis of Apical Organelles of Plasmodium

Hazardous/Infectious Materials Protocol

Approval Date 10/13/2004 **Biosafety Level** BL-2/BL-3 or **Deferred for Additional Information**

Infected mosquitoes kept under BL-3 containment.
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Recombinant DNA Registration Document

Approval Date	10/13/2004	Biosafety Level	BL-2	or	Deferred for Additional Information
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Hazardous/Infectious Materials Protocol

Approval Date	Biosafety Level	or	Deferred for Additional Information	X
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Radioisotopes covered under PIs Radiation Safety protocol. Laboratory personnel must take the refresher course on Radiation Safety.

Committee not clear on how *T. gondii* being used. Description of procedures needed. Is there an SOP for inadvertent exposure to parasite?

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1/BL-2 **or** **Deferred for Additional Information**

Mammalian cell transfection under BL-2 containment.
Personnel needs to be listed on protocol.

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 or **Deferred for Additional Information**

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10/13/2004**

05-025 **Tissue Culture Cells and Human Hepatocytes**

Hazardous/Infectious Materials Protocol

Approval Date 10/13/2004 **Biosafety Level** BL-2 **or** **Deferred for Additional Information**

Human hepatocyte work done under BL-2 containment.

05-026 **Flexibility-Activity Relationships in Human Pin1**

Recombinant DNA Registration Document

Approval Date 10/13/2004 **Biosafety Level** BL-1 **or** **Deferred for Additional Information**

UNIVERSITY OF NOTRE DAME
Meeting of the Institutional Biosafety Committee
April 5, 2005

MINUTES

Attended by: Nora Besansky, John Adams, Joseph O'Tousa, Lisa Bognar, Robert Zerr, Roland Chamblee and Richard Hilliard. Phil Iapalucci from Audit and Advisory Services was a visitor at the meeting.

The meeting was convened at 2:00 p.m.. October 13, 2004 minutes were approved as submitted.

1. Protocols reviewed: See attached
2. Other Business
 - a. Phil Iapalucci presented an update on the current inventory of Select Agents. Of 162 surveys sent out, 160 have been returned. Will send follow-up to these two PIs. It was agreed that surveying labs every two years would be sufficient. New faculty will be identified and surveyed in the interim period.
 - b. Lisa presented the ND Biosafety Manual. Discussion centered around training. Training can be accomplished via personal presentations either by RM&S or possibly by trained lab personnel. On-line training will be developed.
3. Meeting adjourned at ~ 3:00 p.m.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
4-5-2005**

05-027 **Molecular Recognition by Molecules of the Cellular Immune System**

Recombinant DNA Registration Document

Approval Date 4-5-2005 **Biosafety Level** BL1 or **Deferred for Additional Information**

While BL1 containment is apparent, PI needs to include justification of requested level in question 5.

05-028 **Inhibition of Interleukin-12 in Leishmania Infected Macrophages
Interleukin-12 in Leishmania Infected Human Dendritic Cells**

Recombinant DNA Registration Document

Approval Date 4-5-2005 **Biosafety Level** BL2 or **Deferred for Additional Information**

Protocol approved at BL2 as submitted.

05-029 **Inhibition of Interleukin-12 in Leishmania Infected Macrophages
Interleukin-12 in Leishmania Infected Human Dendritic Cells**

Hazardous/Infectious Materials Protocol

Approval Date 4-5-2005 **Biosafety Level** BL2 or **Deferred for Additional Information**

Protocol approved at BL2 containment as submitted.

05-030 **Pyrethroid Spray Sheet Collection**

Hazardous/Infectious Materials Protocol

Approval Date 12-20-2004 **Biosafety Level** or **Deferred for Additional Information**

Questions regarding personal protective equipment were addressed by PI.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
4-5-2005**

05-031 Enhanced Ethanol Production by Genetically Engineering Yeast to Reduce Volatile By-Production Formation

Recombinant DNA Registration Document

Approval Date 4-5-2005 **Biosafety Level** BL1 or **Deferred for Additional Information**

Protocol approved at BL1 containment as submitted.

05-032 Transgenic Engineering of Aedine Mosquitoes Using the piggyBac Transposon

Recombinant DNA Registration Document

Approval Date 4-5-2005 **Biosafety Level** BL1 or **Deferred for Additional Information**

Question 4 indicates that PI will express sense and antisense transcripts that interfere with the replication of Dengue fever virus in mosquito cells and tissues. Will any live mosquitoes be infected? Please clarify.

05-033 Assays of the Effectiveness of Antisense and Ribozyme Inhibition of Dengue Virus Replication

Hazardous/Infectious Materials Protocol

Approval Date 4-5-2005 **Biosafety Level** BL2 or **Deferred for Additional Information**

Approval is just for BL2 experiments. When the BL3 facility is completed and certified, the IBC will review the BL3 portion of the protocol.

05-034 The Pathological Consequences of the Plasminogen System
Expression of Murine Wild Type and Mutant PA-1 Protein

Recombinant DNA Registration Document

Approval Date 4-5-2005 **Biosafety Level** BL1 or **Deferred for Additional Information**

Protocol approved at BL1 containment as submitted.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
4-5-2005**

05-035 Identification of Lens Development Genes

Recombinant DNA Registration Document

Approval Date 4-5-2005 **Biosafety Level** BL1 **or** **Deferred for Additional Information**

Protocol approved at BL1 containment as submitted.

UNIVERSITY OF NOTRE DAME
Meeting of the Institutional Biosafety Committee
October 20, 2005

MINUTES

Attended by: Nora Besansky, John Adams, Joseph O'Tousa, Mark Suckow, Lisa Phillips, Robert Zerr, and Richard Hilliard.

The meeting was convened at 1:30 p.m.. April 5, 2005 minutes were approved as submitted.

1. Protocols reviewed:
See Attached Sheet

3. Meeting adjourned at ~ 3:00 p.m.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10-20-2005**

06-001 Tumor Induction in Lobund-Wistar Rats

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** 2 **or** **Deferred for Additional Information**

Use of MNU in FLSC 406 carried out under level 2 containment per FLSC guidelines.

06-002 *Anopheles gambiae* project

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1/2 **or** **Deferred for Additional Information**

BSL1: routine lab work.
BSL2: transformed mosquitoes in BSL2 insectary.
More specificity needed regarding transposons being used.

06-003 Genetically Engineered Mosquitoes

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** **or** **Deferred for Additional Information**

More specificity needed regarding transposons being used.
Infected mosquitoes held in BSL3 facility when certified. *Plasmodium* BSL3 SOP on file. Need to be appended to protocols when submitted.

06-004 Molecular Evolutionary Genetics of Mosquitoes

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved as submitted.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10-20-2005**

- 06-005** 1. Expression and purification of human matrix metalloproteinases (MMPs) and tissue inhibitor of metalloproteinases (TIMPs) 2. Penicillin-binding proteins, mechanism and inhibition 3. Resistance to B-lactam antibiotics 4. Ribosomal function and antibiotic design

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 2 or **Deferred for Additional Information**

Approved as submitted.

- 06-006** Investigations of Antibiotic Resistance and Development

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** 2 or **Deferred for Additional Information**

Procedures for transportation across campus developed in conjunction with RM&S.
SOP for animal use developed with FLSC and appended to protocol.

- 06-007** The Insect BAC Library Initiative, Evolutionary Genomics of Red Oaks, The Nasonia Genome Project

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 or **Deferred for Additional Information**

Approved as submitted

- 06-008** Molecular Biology of Mycobacteria

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1/2/3* or **Deferred for Additional Information**

BSL1: *E. coli* laboratory strains
BSL2: *Mycobacterium avium*, *M. bovis*
BSL2: *M. tuberculosis*. Pending completion and certification of BSL3 facility in Galvin Life Sciences.
M. tuberculosis BSL3 SOP has been developed and on file. Needs to be appended to protocol at submission.

Hazardous/Infectious Materials Protocol

***Mycobacterium avium*, *M. paratuberculosis*, *M. bovis* BSL2**

Answer to question 2 does not address the nature of the inserted sequences. Addressed in question 4.

Sindbis and dengue virus-infected cell cultures will be held in BSL3 facility upon completion and certification. BSL3 SOP for this work has been developed and on file. Needs to be appended to protocol upon submission.

Use of human tissues requires BSL2. Because of the potential for aerosolization during drilling and sawing of bone specimens, these procedures need to be conducted under hood or other isolation apparatus.

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10-20-2005**

06-013 Transcription and mRNA Localization During *Xenopus* Development

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** exempt **or** **Deferred for Additional Information**

Approved as submitted as exempt

06-014 Transcription and mRNA Localization During *Xenopus* Development

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** **or** **Deferred for Additional Information**

Approved as submitted

06-015 Identification of Lens Development Genes

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved as submitted BSL1

06-016 Identification of Lens Development Genes

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** **or** **Deferred for Additional Information**

Approved as submitted

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10-20-2005**

06-017 Protein Folding Studies of P69 Pertactin and P93 Pertactin

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved as submitted at BSL1

06-018 Protein Folding Studies of Green Fluorescent Protein

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved as submitted at BSL1

06-019 Protein Folding studies of Tailspike

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved as submitted at BSL1

06-020 Protein Folding Studies of Tailspike, Pertactin and Green Fluorescent Protein

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** **or** **Deferred for Additional Information**

Approved as submitted

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10-20-2005**

06-021 Inhibition of Interleukin-12 in *Leishmania* Infected Macrophages
Interleukin-12 in *Leishmania* Infected Human Dendritic Cells
Sand Fly Genome Project and Anti-Saliva Vaccine Development

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 2 or **Deferred for Additional Information**

Approved as submitted at BSL2. BSL3 SOP on file for when BSL3 facility is completed and certified

06-022 Inhibition of Interleukin-12 in *Leishmania* Infected Macrophages
Interleukin-12 in *Leishmania* Infected Human Dendritic Cells
Sand Fly Genome Project and Anti-Saliva Vaccine Development

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** 2 or **Deferred for Additional Information**

Approved as submitted at BSL2

06-023 The Biogeography of Sympatric Speciation in *Rhagoletis*

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 or **Deferred for Additional Information**

Approved as submitted at BSL1

06-024 The Pathological Consequences of the Plasminogen System

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 or **Deferred for Additional Information**

Approved as submitted at BSL1

E. coli laboratory strains at BSL1
Mammalian cell transfection at BSL2

Approved as submitted

Approved as submitted as exempt

Approved as submitted at BSL2

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING
10-20-2005**

06-029 Contrast Agents for Micro-Computed Tomography of Microdamage in Bone

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 **Biosafety Level** 2 **or** **Deferred for Additional Information**

Use of human tissues requires BSL2. Because of the potential for aerosolization during drilling and sawing of bone specimens, these procedures need to be conducted under hood or other isolation apparatus.

06-030 Studies of Antifreeze Proteins and Related Adaptations of Arctic and Subarctic Insects
Structure/Function Studies of Antifreeze Proteins and their Enhancers from the Beetle *Dendroides canadensis*

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved at BSL1. BSL2 not required for systems being used.

06-031 Ovarian Follicle Selection Mediated by Release from MAP Kinase Signaling

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 1 **or** **Deferred for Additional Information**

Approved at BSL1

06-032 Genetics of Drug Cross Resistances and Virulence in Malaria Parasites

Recombinant DNA Registration Document

Approval Date 10-20-2005 **Biosafety Level** 2 **or** **Deferred for Additional Information**

Approved as submitted at BSL2

**INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY OF NOTRE DAME
MINUTES OF MEETING**

- 06-033** Population and Evolutionary Developmental Dynamics of Abdominal Pigmentation in Neotropical *Drosophila* and the impact of genetic Structuring on Disease Transmission in Balinese macaques

Recombinant DNA Registration Document

Approval Date Biosafety Level or Deferred for Additional Information **X**

Who is performing the blood sampling on the macaques? How will the blood be transported or will DNA be extracted prior to transporting to PI lab? Is there an IACUC protocol for work with the macaques?

- 06-034** Population and Evolutionary Developmental Dynamics of Abdominal Pigmentation in Neotropical *Drosophila* and the impact of genetic Structuring on Disease Transmission in Balinese macaques

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 Biosafety Level or Deferred for Additional Information

Approved as submitted

- 06-035** Membrane Trafficking Events in the Regulation of Organelle Biogenesis and Stability in Apicomplexan Parasites

Recombinant DNA Registration Document

Approval Date 10-20-2005 Biosafety Level 2 or Deferred for Additional Information

Approved as submitted at BSL2

- 06-036** Membrane Trafficking Events in the Regulation of Organelle Biogenesis and Stability in Apicomplexan Parasites

Hazardous/Infectious Materials Protocol

Approval Date 10-20-2005 Biosafety Level or Deferred for Additional Information

Approved as submitted