L² Diagnostics, LLC
PO Box 8175
New Haven, CT 06530-0175

20 March, 2007

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

Dear Sir:

Pursuant to the request by The Sunshine Project under the Public Access Provisions of the NIH guidelines requesting copies of L2 Diagnostics, LLC Institutional Biosafety Committee minutes, enclosed are all the meeting minutes from May 1, 2003 to present:

1. Institutional Biosafety Committee Minutes from June 28, 2005.
2. Institutional Biosafety Committee minutes from December 12, 2006.

Respectfully,

Jonathan Alderman
Chairman, L2 Diagnostics
Biosafety Committee

L² Diagnostics, LLC
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Minutes of Biosafety committee meeting held June 28, 2005, 5:00-6:00pm

Attendees:
Ruth Montgomery
Jon Alderman
Barbara Kazmierczak
Cara Case
Mark Blazejak
Michel Ledizet
Kali Kar
Ray Koski
Karen Anthony
Member(s) absent: Michael Cappello
Guest(s): Nathalie Bonafe

New Business:

RK: brief West Nile virus project descriptions in layman terms
ML: brief Antithrombotic and Immunosuppresant project descriptions in layman terms

Brief self-introduction of attendees

JA: Power Point presentation- role of IBC

General question:
MB: Would all work be done here?
RK: Half done at L2 and half at Yale or Connecticut Agricultural Experiment Station (CAES)

Protocol Review:

ML leaves the room
1. Therapeutic activity of a novel tick immunosuppresant

JA: Any questions, concerns, the protocol is open for discussion?
BK: Is Salp15 purified protein toxic to mucus membranes
RK: No known toxicity associated with the protein, plus it is an immunosuppressant
Project approved

2. Preclinical development of the tsetse thrombin inhibitor
JA: Any questions, concerns, the protocol is open for discussion?
All: None
JA: Motion to approve and seconded.
JA: Protocol approved.

Project approved

RK leaves the room

3. Recombinant subunit WNV vaccine development, Vaccination against WNV, Small molecule inhibitors of WNV infection, Protection against WNV by RNA interference.

JA: Any questions, concerns, the protocol is open for discussion?
BK: Small molecule inhibitors of WNV infection: Are virus-like particles infectious and how much viral genome used to construct particles?
KA: Virus-like particles are non-infectious. Less than 2/3 of WNV genome is used.
RM: If need to add new bacterial, insect or mammalian cell lines in protocols, does the committee have to meet again?
JA: Not necessary for committee to reconvene. But L2 needs e-mail or written approval from committee to add or modify any protocols.
JA: Any other concerns?
All: None
JA: Motion to approve and seconded.
JA: Protocols approved.

4. Eastern Equine Encephalitis (EEE) Vaccine and Immunotherapy

JA: Any questions, concerns, the protocol is open for discussion?
BK: Is EEE really a risk group 2?
ML and KA: Yes, it is classified as such in BMBL manual
BK: How much virus genome is used and where and how the genome will be manipulated?
ML: Less than 2/3 genome is used. Viral genome will be isolated at CAES and pcr will be performed there. Only gel purified pcr fragment will be brought to L2.
JA: Any other concerns?
All: No
JA: Motion to approve and seconded.
JA: Protocol approved.

5. Antibody prophylaxis and therapy of flavivirus infection

JA: Any questions, concerns, the protocol is open for discussion?
BK: Infectious dengue genome a concern?
KA: L2 has dengue genomic RNA; however it would not be propagated in mammalian cell lines to generate infectious particles. The genomic RNA will be used only as a template to pcr amplify the genes of interest.
JA: Any other concerns?
All: No
JA: Motion to approve and seconded.
JA: Protocol approved

Approximately 6:00 pm meeting adjourned.

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Minutes of Biosafety committee meeting held Dec 12, 2006, 5:15-6:15pm

Attendees:
Ruth Montgomery
Jon Alderman (Chairperson)
Barbara Kazmierczak
Mark Blazejak
Michel Ledizet
Nathalie Bonafe
Kalipada Kar
Raymond Koski
Karen Anthony
Member(s) absent: Cara Case
Guests: Martin Mattessich
Paul Kaplan
Ada Vaill

Brief self-introduction of attendees

JA: L2 was certified as BSL II by CT state in August 18, 2006
KA: Described process of BSL II certification

KA: L2 filed annual report with NIH Office of Biotechnology Activities. Next report due by May 18, 2007

Protocol Review:

1. Glioma therapeutics targeting glioma pathogenesis-related protein
NB: Brief project introduction
NB leaves the room
JA: Any questions, concerns, the protocol is open for discussion?
JA: Need biosafety approval for immunizing rabbits to raise antisera
KA: Rabbit immunization done by contractor- Cocalico Biologicals
JA: Include Cocalico Biologicals assurance number with protocol
BK: error on P4 section 2b – work does **not** involve DNA from human or animal **pathogens**
RK: BSL requirement of cell lines used?
KA: All cell lines obtained from ATCC designated as BSL I
BK: Enclose product information sheet for each cell line with protocol
RK: Protocol should be classified as 'exempt' since no DNA from human or animal pathogens used
NB: Incorporates suggested changes into protocol
Project approved by committee

BK: Are there any new employees added to existing protocols? If so, the protocols should be updated. How are new employees trained?

KA: Existing protocols haven't yet been updated to include new employees but this will be implemented immediately. New employees are required to complete an online biosafetey course, and the training record is documented.

JA: 'Sunshine Project' introduction- request to release minutes of biosafety committee meetings to Sunshine Project committee.
JA will review NIH policy and Freedom of Information Regulations and will determine when and how to release the minutes.

New protocol:

Glioma therapeutic targeting glioma pathogenesis-related protein.

Active protocols:

Recombinant subunit West Nile virus vaccine development
Vaccination against West Nile virus
Small molecule inhibitors of West Nile infection
Antibody prophylaxis and therapy of flavivirus infection
Protection against West Nile virus by RNA interference

No longer active protocols:

Therapeutic activity of a novel tick immunosuppressant
Preclinical development of the tsetse thrombin inhibitor
Eastern Equine Encephalitis vaccine and immunotherapy

6:15 pm meeting adjourned.