



REPLY TO  
ATTENTION OF

**DEPARTMENT OF THE ARMY**  
WALTER REED ARMY INSTITUTE OF RESEARCH  
WALTER REED ARMY MEDICAL CENTER  
WASHINGTON DC 20307-5001

February 28, 2007

Edward Hammond  
The Sunshine Project  
1920 Stuart St  
Berkeley CA 94703

Dear Mr. Hammond:

Please find attached the 25 January 2007 meeting minutes of the Walter Reed Army Institute of Research/Navy Medical Research Center (NMRC) Institutional BioSafety Committee (IBC).

No fees are requested for receipt of these minutes.

Please feel free to contact me with requests for additional documents. Thank you.

Sincerely,

A handwritten signature in blue ink, appearing to read "Debra L. Yourick".

Debra L. Yourick, Ph.D.

Associate Director

Research, Marketing and Policy Dev.

503 Robert Grant Ave.

Silver Spring, MD 20910-7500

Voice: 301-319-9471

Fax: 301-319-9810

cc: Michelle Johnson-Lancaster, IBC Coordinator  
Office of Biotechnology Activities  
National Institutes of Health

MCMR-UWF-C

25 January 2007

MEMORANDUM THRU Chair, WRAIR/NMRC Institutional BioSafety Committee

FOR: Members of the IBC

SUBJECT: Quarterly Committee Meeting

In Attendance: Dr. David Lanar (Chair), Dr. Ann Stewart, Dr. Malabi Venkatesan, Dr. Brian Bell, CAPT Tom Richie, CAPT Stephen Savarino, CDR Marcus Larkin (NMRC – Director of Safety), CPT Amy King (WRAIR – Director of Safety Office), Dr. Phil Coyne (Unaffiliated with the Institute – community representative), Ms. Lisa Ware.

1. Dr. Lanar explained that the WRAIR has been out of compliance with the NIH Institutional Biosafety Committee guidelines with regards to meetings and minutes. – Solution: we will now meet on a quarterly basis (more if needed), minutes will be taken and such minutes will be made available to the public upon request.
2. The group reviewed the slide presentation made available on the OBA web site detailing the requirements for IBCs in the NIH guidelines. All agreed that except for the actual face-to-face meetings and minutes that the WRAIR/NMRC IBC was in compliance with the NIH Guidelines in both review of required research within the WRAIR/NMRC and membership of the IBC.
3. For the record it was restated what the review process for Memorandum of Understanding and Agreement (MUA) will be at the WRAIR/NMRC:
  - a. Dr. Lanar will review the MUA and discuss it with the Principal Investigator for clarity.
  - b. Dr. Lanar will forward the edited copy to two members of the IBC for review. A special consultant could be chosen for review if one of the IBC members was not completely qualified to review the MUA.
  - c. After comments are received by these members, a compiled copy will be sent to all members for approval by email vote.
  - d. The MUA will be presented to the entire committee at its next quarterly meeting for a voice vote. At that time any public comments could be received, considered and addressed by the committee.
4. Review requirements for protocols by the IBC: It was noted that recombinant DNA work that will go into humans is subject to the NIH Recombinant DNA Advisory Committee (RAC), however vaccines are exempt from RAC review. Therefore, to date, the Institutes' research has not been subject to RAC review. The important point is outlined in the NIH Guidelines, Appendix M-V1-A.: "Human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the

vector-encoded immunogen is not expected, are exempt from Appendix M-1, *Requirements for Protocol Submission, Review and Reporting – Human Gene Transfer Experiments.*”

5. Dr. Lanar will continue to keep a database containing the information on all infectious BSL-2 and BSL-3 and select agent work done at the Institute. The database is available for public inspection by contacting Dr. Lanar ([david.lanar@us.army.mil](mailto:david.lanar@us.army.mil) or 301-319-9003).
6. CPT King will send the IBC summaries of safety inspections in Building 503 for recording in the minutes. In addition, anytime there are actions taken dealing with biosafety issues a summary report will be sent to the IBC for its inclusion into the quarterly WRAIR/NMRC IBC minutes.
7. A Biosurety/Biosecurity member will be added as a consultant to conform to NIH guidelines. Tina Lovell (Laboratory Security) and Bernie Pierce (Physical Security) have been suggested.
8. Dr. Lanar will speak with Victor Anthierrey about putting an IBC page on the WRAIR website with an MUA template and information on what research requires an MUA.

**Action Items:**

- a. The IBC will meet quarterly. The next meeting is scheduled for 26 Apr 07, 1500 hrs, and minutes will be taken and distributed to the members of the IBC.
- b. CPT King will send safety summaries to IBC as needed.
- c. Dr. Lanar will coordinate with CPT King for Building 503-wide training of PIs on the function of the IBC and on requirements to file MUAs with the IBC.
- d. Dr. Lanar will work with Mr. Anthirrey to establish a website for the IBC.

Minutes taken by: Lisa Ware, M  
Program Coordinator  
Division of Malaria Vaccine Development

Minutes Approved by: David E. Lanar  
Chairman, WRAIR/NMRC IBC

-----  
29 January 2007