

**FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES**

FEBRUARY 19, 2013

CALL TO ORDER / ANNOUNCEMENTS

The FNLCR Institutional Biosafety Committee was convened at 12:20 pm in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 8)

- | | |
|---|--|
| <input type="checkbox"/> Michael Baseler (regrets) | <input checked="" type="checkbox"/> Stephen Hughes |
| <input checked="" type="checkbox"/> Theresa Bell | <input checked="" type="checkbox"/> Sarah Hooper |
| <input checked="" type="checkbox"/> Rev. David Betzner | <input checked="" type="checkbox"/> Bhargavi Kondragunta |
| <input checked="" type="checkbox"/> Stephen Creekmore (arrived at 12:35pm) | <input type="checkbox"/> Serguei Kozlov (regrets) |
| <input checked="" type="checkbox"/> Bruce Crise | <input type="checkbox"/> Dan McVicar (Chair) (regrets) |
| <input checked="" type="checkbox"/> Eric Freed | <input type="checkbox"/> Randall Morin (regrets) |
| <input checked="" type="checkbox"/> Melinda Hollingshead (arrived at 12:33pm) | <input checked="" type="checkbox"/> Raja Sriperumbudur |
| | <input type="checkbox"/> Lucien Winegar (regrets) |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

Dr. Rachel Bagni

APPROVAL OF MINUTES FROM JANUARY 15, 2013 MEETING

The minutes from the January 15, 2013 meeting were approved as written. A motion and second were made. (For: 8 ; Against: 0; Abstain: 0)

ACCIDENT REVIEWS

None to report

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Jianwei Zhu 12-85: Manufacturing of a VRP-TRP2 Vaccine for a Phase I Clinical Trials Per instruction from BRB/NCI, the work scope of this project was changed. Instead of producing TRP2/VRP starting from cell culture, BDP will only conduct vialing the purified bulk and testing the final drug product. BDP will receive the purified bulk that is tested RCA-free. BDP will not handle the plasmid, no cell culture, and no purification as originally planned. Consequently, the current application of the IBC #12-85 is not suitable for the new work scope and was withdrawn.

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Randy Stevens 13-07: Measurement of Lymphocyte Proliferation in Human Peripheral Blood Mononuclear Cells Stimulated with Recombinant Anthrax Protective Antigen The purpose of this new project is to study T-lymphocyte memory in human anthrax survivors. First, peripheral blood mononuclear cells (PBMCs) from survivors of anthrax disease will be stained with monoclonal antibodies which recognize various cell surface markers. Next, the PBMCs will be labeled with the cell proliferation dye carboxyfluorescein diacetate succinimidyl ester (CFSE), then stimulated with recombinant protective antigen (rPA) of *Bacillus anthracis*. Finally, the PBMCs will be fixed with 1% paraformaldehyde prior to analysis of a flow cytometer. Proliferation of memory T lymphocytes will be determined by measuring cellular fluorescence on a flow cytometer, using standard flow cytometry techniques. There were minimal questions during the pre-review. Lead reviewers requested that the PI add a statement to not permit immunosuppressed individuals from conducting the research without clearance from Occupational Health. The committee had no additional concerns or questions. Steve Hughes moved to approve the registry. Bhargavi Kondragunta seconded the motion. For: 8; Against: 0 Abstain: 0

Jeff Strathern: 13-10: RNA polymerase pilot study-BREEDING ONLY Notification to committee

RENEWALS

Rachel Bagni 13-05 (12-54 (06-20)): Production and Isolation of Recombinant Adenoviruses and Adeno Associated Viruses (rAAV) The Viral Technology Group (VTG) will engage in the production of recombinant adenoviruses and/or AAV as a service to investigators at the NCI. Recombinant adenoviruses and/or AAV expressing foreign genes will be produced by introduction of cloned adenovirus and/or AAV vector DNA into continuous human cell lines. The virus will subsequently be purified, titered and shipped to the requesting investigator. All reagents, materials, clones and virus stocks are stored in the respective room where production occurs thereby reducing the chance that any material may inadvertently be used in an incorrect manner resulting in replication competent adenovirus. In addition, adeno-associated virus related production work is carried out at different times of the day and the cultures are maintained in separate stacks of incubators. Lead review posed the question to full committee as to whether the adenoviral prep should be tested for replication competent adenovirus (RCA) prior to giving it back to the investigator. After much discussion, the committee concurred that the RCA testing should not be a requirement since the risks of handling of the material would be no different. However, if an investigator requested for the RCA testing to be done, Dr. Bagni does have the capabilities to provide that service. Theresa Bell motioned to approve the registry without requiring RCA testing. Melinda Hollingshead seconded the motion. For: 10; Against: 0; Abstain: 0

Rachel Bagni 13-06 (12-83 (08-41, 06-21)): Lentivirus Production and Specimen Testing The Viral Technology Group (VTG) is involved in the generation, production and purification of recombinant HIV-1 based vectors as a service to NCI/NIH and other investigators. Recombinant HIV-1 based lentiviruses expressing a foreign gene(s) will be produced by introduction of cloned HIV-1 vector DNA along with helper virus DNA's (encoding HIV-1 structural proteins except no intact envelope gene) into continuous human cell lines. The envelope gene of Vesicular Stomatitis Virus g-protein (VSV-g) will be supplied to complement the HIV-1 envelope deletion. Subsequently, HIV-1 viral particles with a VSV-g envelope will be produced that contain the HIV-1 based vector genome. The virus particles will be purified, concentrated, titered and shipped to the requesting investigator. Additionally, this

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renewal covers epidemiological, clinical and research samples that are tested for human pathogens, microsatellite profiles, mycoplasma contamination and serological markers of viral infections. The serological techniques employed are ELISA, Luminex and MSD. The molecular techniques include nucleic acid extraction, STR analysis (DNA fragment sizing), real-time quantitative PCR and endpoint PCR. The PI indicated that lentiviral work will be conducted during different times of day from the adenoviral related production work and the cultures are also maintained in separate incubators. The committee requested the PI to add the following statements to the registry: No cell lines kept in the lab are capable of supporting HIV replication and HIV systems containing different inserts are not produced at the same time. Theresa Bell motioned to approve the registry. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 0

Deborah Morrison 13-08 (10-24): Functional Characterization of KSR The purpose of this renewal is to continue studies on the biological function of kinase suppressor of Ras (KSR), a conserved component of the Ras signal transduction pathway. Investigators will generate DNA constructs for the expression of wild type and mutant KSR proteins in tissue culture cells, and also generate a targeting vector for eliminating KSR expression in the mouse. Lead reviewer and full committee had no additional questions or concerns. Eric Freed motioned to approve the registry. Raja Sriperumbudur seconded the motion. For: 10; Against: 0; Abstain: 0

Norma Diaz-Mayoral 13-09 (P020799WKA02): Lab Operations for the Cell Processing Laboratory The Cell Processing Laboratory in the Applied/Developmental Research Directorate, provides support to NCI and other NIH institute clinical trials and research projects by: (1) separating whole human blood into subfractions such as plasma; (2) extracting DNA and RNA from whole blood & subfractions; (3) verifying pre-processed specimen inventory upon receipt & storing frozen and fixed human tissue; (4) arraying DNA onto test platforms for other investigators; and (5) preparing human blood, human tissue, DNA and RNA for domestic and international shipments. Neither the DNA nor the RNA are tested, amplified, or recombined in this laboratory under any protocol. Once samples have been processed, they are aliquotted into labeled cryovials for cryopreservation. No additional concerns regarding this renewal registry were expressed by the lead reviewers or full committee. Bhargavi Kondragunta motioned to approve the registry. Raja Sriperumbudur seconded the motion. For: 10; Against: 0; Abstain: 0

OUTSTANDING ITEMS - None

AMENDMENTS

Twelve amendments were processed and approved between the January and February 2013 meetings.

OTHER BUSINESS

- Per request of the committee members who are located at the ATRF, the capability to video conference into the meeting was made available at the February meeting.
- Reminder to committee: IBC web registration beta-testing comment period open through February 28, 2013
- Reminder to committee: Changes to NIH Guidelines for Synthetic Nucleic Acid Molecules become effective in March 2013

ADJOURNMENT

The meeting adjourned at 12:55pm.

Next meetings:

March 19, 2013

April 16, 2013