

NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
MARCH 18, 2014

CALL TO ORDER / ANNOUNCEMENTS

The NCI@F Institutional Biosafety Committee was convened at 12:04 pm in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 8)

- | | |
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| <input checked="" type="checkbox"/> Katalin Baranji (regrets) | <input checked="" type="checkbox"/> Stephen Hughes |
| <input checked="" type="checkbox"/> Michael Baseler (regrets) | <input checked="" type="checkbox"/> Sarah Hooper |
| <input checked="" type="checkbox"/> Theresa Bell | <input type="checkbox"/> Serguei Kozlov (regrets) |
| <input checked="" type="checkbox"/> Rev. David Betzner | <input type="checkbox"/> Dan McVicar (regrets) |
| <input checked="" type="checkbox"/> Stephen Creekmore | <input type="checkbox"/> Raja Sriperumbudur |
| <input checked="" type="checkbox"/> Bruce Crise | <input type="checkbox"/> Lucien Winegar (regrets) |
| <input checked="" type="checkbox"/> Eric Freed | <input checked="" type="checkbox"/> Enrique Zudaire |
| <input type="checkbox"/> Melinda Hollingshead (regrets) | |

Non-Voting

- Walter Hubert
- Karen Barber
- Sheryl Ruppel

APPROVAL OF MINUTES FROM FEBRUARY 18, 2014 MEETING

The minutes from the February 18, 2014 meeting were approved as written. A motion and second were made (For: 10; Against: 0; Abstain: 0)

ACCIDENT REVIEWS - Mouse bite on pinky finger from a naïve mouse while changing mouse cages. No biologicals.

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Christophe Redon – 14-09: Role of histone H2AX in metastasis. Histone H2AX plays a key role in DNA double-strand break repair, maintaining genome stability, and deterring tumorigenesis and cancer progression. Data from genome-wide gene expression profiling from H2AX knockout mouse cell line in our lab reveal a novel critical function for histone H2AX in cell motility and invasion. Bruce Crise motioned to approve and Steve Hughes 2nd. For: 10; Against: 0; Abstain: 0

RENEWALS

Anne Monks – 14-10: Manipulation of potential drug-target, or drug-modulated genes with recombinant DNA technology including use of lentiviral based delivery system and the CRISPR/CAS9 technology to knock down and overexpress genes. To register the use of recombinant DNAs to

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understand the critical nature of specific targets identified in the response of novel anticancer agents, including use of lentiviral based delivery system to express shRNA (to knock down), or overexpress specific genes identified as potentially critical to the response of novel anticancer agents. Conditional approval pending mock observation. Eric Freed motioned to approve and Steve Creekmore 2nd. For: 10; Against: 0; Abstain: 0

OUTSTANDING ITEMS

Zhi-Ming (Thomas) Zheng – 14-04: Tumor Virus RNA Biology. This is a study of tumor viruses including human papillomavirus and Kaposi sarcoma-associated herpes virus in attempt to understand how these tumor viruses infection lead to the development of cancer. Mock observation will need to be rescheduled. PI to separate out the virus and animal work into two registrations. Deferred to full committee pending submittal of new documentation: For: 10; Against: 0; Abstain: 0

Yinling Hu – 14-01 (09-12) – Role of Ikk α in Cancer and Inflammation. The importance for the development of squamous cell carcinomas in human and mice and for inflammation and immune function. PI to submit an ASP for the intratracheal injections with adenovirus into animals. The current IBC registration 14-01 should only cover the genetically modified animals and the in vitro keratinocyte work. A NEW IBC registration should be submitted to address the intratracheal animal injection work. The committee deferred to April meeting. For: 10; Against: 0; Abstain: 0

Larry Anderson – 14-02 (09-45) – clinical and Pre-clinical pharmacology analytical methods. To develop and use methods of analysis to gather information on the disposition and actions of potential new anti-tumor agents in biological systems. Deferred to sub committee pending clarifications: For: 10; Against: 0; Abstain: 0

John Gilly 14-06 (10-16) – Use of HEK 293 cells for alphavirus vaccine production. Clarifications regarding the hazards of the pump if failed need to be addressed. Decontamination procedures for manual filling need to be clarified. Questions have been developed and forwarded to the chair. A meeting with the PI will be scheduled. The committee deferred to April meeting. For: 10; Against: 0; Abstain: 0

Dimitar Dimitrov 13-38 (04-04, 08-20): Developing anti-viral vaccines and human antibodies against infectious diseases and cancer antigens by using recombinant membrane proteins of HIV, Nipah, Hendra, Dengue viruses and cancer antigens. Committee requested additional clarifications and a Vaccinia-specific SOP as well as a lab visit. Post-meeting, Theresa Bell learned that the lab was relocating and suggested that the space that will be used for the Vaccinia work should not be evaluated until the move has been completed. No Vaccinia work is being performed at this time. **Continue deferral until lab move and observation is completed.** For: 8; Against: 0; Abstain: 0

George Pavlakis – 13-80 (New): Use of Lymphodepletion and Adoptive Cell Transfer in the Evaluation of Cancer Vaccine in Mouse Models. This registration is for the use of recombinant vaccinia virus as a vaccine vector against melanoma using the mouse model. Two representatives from the lab were present to discuss the IBC concerns. There were questions during the pre-review. The committee requested that the PI provide a section B for recombinant work and a lab specific SOP that addresses Vaccinia. Theresa Bell motioned to approve and Bruce Crise second. For: 10; Against: 0; Abstain: 0

AMENDMENTS

Twenty six amendments were processed and approved between the December and January IBC meetings.

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OTHER BUSINESS

ADJOURNMENT

The meeting adjourned at 2:30 pm.

Next meetings: *April 22, 2014* *May 20, 2014*