

**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES**

APRIL 18, 2012

CALL TO ORDER / ANNOUNCEMENTS

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 8)

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

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

Paula Mathis, Clinical Staff - Occupational Health Services

APPROVAL OF MINUTES FROM MARCH 20, 2012 MEETING

The minutes from the March 20, 2012 meeting were approved as written.

A motion and second were made. (For: 9; Against: 0; Abstain: 1 (Lucien Winegar – not at March meeting))

ACCIDENT REVIEWS – No accidents to report

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Christopher Westlake 12-28: Analysis of membrane trafficking gene expression and function in zebrafish The goal of these studies is to deliver morpholino and cDNA for small GTPase Rab proteins and associated membrane trafficking regulators into Zebrafish embryos. More specifically, this technology will be used to investigate the expression and function of membrane trafficking regulators involved in cilia formation and ciliary signaling and the association with human diseases of the primary cilium, referred to as ciliopathy. Lead review conveyed to the committee that minimal hazards exist with the proposed research. Shalini Oberdoerffer moved to approve the registry. Theresa Bell seconded the motion. For: 10 Against: 0 Abstain: 0

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Dinah Singer 12-32: *Breeding and maintenance of mice* BREEDING ONLY - Notification to committee

Hyun Park 12-37: *Breeding and maintenance of mice* BREEDING ONLY - Notification to committee

RENEWALS

Alan Perantoni 12-22 (04-23): *Determinants of kidney differentiation and tumorigenesis* This renewal consists of several projects. Project 1: To generate permanent murine renal mesenchymal stem cell lines for further biochemical analyses; Project 2: To use the information derived from Project 1 to develop cell lines from human Wilms tumor tissues, which originate in the same progenitor as studied in Project 1; Project 3: To define the interaction of Stat1 in Wilms tumorigenicity using established human renal tumor cell lines; and Project 4: To optimize conditions for the growth and differentiation of human mesenchymal stem cells in bone regeneration. From the initial submission, the paperwork was substantially revised during pre-review and all safety concerns had been addressed. Theresa Bell moved to approve the registry. Steve Creekmore seconded the motion. For: 10 Against: 0 Abstain: 0

Sandra Ruscetti 12-27 (09-10): *In Vivo Studies to Test the Effectiveness of Pharmacological Agents Against Retroviral-induced Leukemia and Neurological Disease in Rodents* The objective of the research to be conducted under this renewal registry is to test the effects of pharmacological interventions on retrovirus-induced rodent models for leukemia and neurological disease. Lead reviewers commended the PI for a well-written document which made for an easy pre-review. The committee questioned the mentioned 'informed consent' in Part A3 and requested further clarification. Steve Hughes moved to conditionally approve the registry pending clarification on the consent form. Steve Creekmore seconded the motion. For: 10 Against: 0 Abstain: 0 (Follow-up note: PI was contacted regarding 'informed consent'. This was not a form which staff completed, but rather meant that the staff were informed by the PI regarding the hazards described in the IBC registry and were provided adequate training. PI revised text prior to release of approval.)

Brad St. Croix 12-29 (09-11): *Generation of DNA vectors for functional analysis of various endothelial markers* The six projects contained within this renewal registry primarily involve basic cloning of endothelial genes into various vectors designed or the propagation and expression of tumor endothelial markers (TEMs) in either E. coli or mammalian cells. Projects involved with the lentiviral and adenoviral vector constructs are used for in vitro assays only, while other projects involve the use of animals. The committee felt that it was not clear as to what happens to tissues and/or cells once harvested from the animals. Shalini Oberdoerffer moved to defer the registry pending clarification on the aforementioned concern. David Betzner seconded the motion. For: 10; Against: 0; Abstain: 0

Elaine Jagoda 12-36 (09-28): *General Protocol for Testing Molecular Imaging Agents (Radiopharmaceuticals of Short-lived Radionuclides and optical probes) in Rodents* The goal of these studies is to develop new imaging probes including primarily radiopharmaceuticals for Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT) and fluorophore conjugates for optical/fluorescent imaging. After the imaging probes have been developed, preclinical testing in rodents is necessary to determine the *in vivo* distribution and specific uptake of the agent at the target sites before preceding with studies in higher animals and finally to humans. For the first several projects planned, well characterized human cancer cell lines

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which overexpress the target (HGFR, EGFR, or ACE) will be used for xenograft models. The pre-review addressed all biosafety concerns and SAIP will be conducting the majority of the experiments in their facility due to the needs for imaging. Melinda Hollingshead moved to approve the registry. Mike Baseler seconded the motion. For: 11 Against: 0 Abstain: 0

Perwez Hussain and Hiro Okayama 12-39 (09-39): AOM and DSS induced colon tumorigenesis in genetically engineered mice for miR-2 BREEDING ONLY - **Notification to committee**

Brad St. Croix 12-45 (09-11): Genetically engineered models to study tumor angiogenesis BREEDING ONLY - **Notification to committee**

Dennis Klinman 12-46 (07-56): Breeding Program BREEDING ONLY- **Notification to committee**

OUTSTANDING ITEMS

- Trinchieri/Noer – IBC 11-66 (formerly 10-60) Flow cytometry core lab: On March 29, 2012, Theresa Bell re-evaluated the lab space to determine suitability with current draft NIH Guidelines for Cell Sorters. Final versions of the IBC paperwork were also received on 03/22/12. The committee voted to formally notify the PI of their concerns regarding the space limitations of the current flow cytometry core based on the NIH Guidelines. It is the opinion of the IBC that operations in the core would be significantly enhanced by modifications to the existing space. Specific problems include the transient entry of investigators into the sorting rooms for verification of the sorting parameters, multiple ingress and egress from the room by operators for access to key equipment such as the fluorescent microscope, inadequate space for the donning and disposal of PPE required for safe operation of the core, and the necessity for PAPR or respirator use by core staff who are not actively sorting hazardous materials. EHS and IBC are willing to provide as much guidance as needed to facilitate improvements in the setup of this core space toward the goal of a convenient and more efficient operation of the facility. Steve Hughes motioned to make the formal notification to the PI. Shalini Oberdoerffer seconded the motion. For: 11; Against: 0; Abstain: 0.
- Jairaj Acharya 12-06 (06-03 and 06-16): Transport studies in mouse embryonic fibroblasts (MEFs) using Vesicular Stomatitis Virus G Protein A and Functional Analysis of Enzymes of Sphingolipid Metabolism – In February - deferred back to full committee. Revised paperwork received by the IBC Administrator on 04/18/12 and was forwarded to lead reviewers for comment. To be reviewed by full committee in May.
- Ding Jin 12-17 (09-25): Transcription Regulation in E. coli (K12) and H. pylori – Deferred at March meeting. Dan McVicar met with PI and Dr. Ji Ming Wang after the meeting to discuss the delay of in vivo research memorandum that would be distributed (04/02/12) and what the committee was requesting from each PI to ensure proper safety measures were in place to reduce the chance of an accidental exposure. As of the posting date, no revised paperwork or new registrations for the *in vivo* work were received by the IBC Administrator; therefore, the *in vivo* research continues to be in a holding-status.
- Scott Durum 12-23 (09-06): Effects of cytokine-expressing bacteria on the development, progression and treatment of inflammatory bowel disease and colon cancer (L. lactis) Third request to respond to pre-review questions sent to PI on 04/05/12. As of the posting date, no

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revised paperwork was received by the IBC Administrator. (Post-meeting note: Dan McVicar was to contact PI directly regarding the IBC registry and lack of response)

- Ji Ming Wang 12-30: Use of normal human blood cells for studies of inflammation and cancer in vitro Deferred at March meeting. PI revised registry/SOP. Updates sent back to lead review. As of the posting date, no new registration for the *in vivo* work was received; therefore, the *in vivo* research continues to be in a holding-status as does the paperwork for 12-30. The committee wanted *all* registries received/updated prior to releasing approval for any of them.

AMENDMENTS

Eighteen amendments were processed and approved between the March and April IBC meetings.

OTHER BUSINESS

- NIH/OBA antibiotic resistance (H. Young) – see letter of interpretation posted on SharePoint
- Dual Use research
- IBC Membership - Dr. Bhargavi Kondragunta –VPP technology development group
- IBC web-registration update
- Human cell lines and animal biosafety level determinations

ADJOURNMENT

The meeting was adjourned at 1:30 pm.

Next meetings:

May 15, 2011

June 19, 2012