



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
September 27, 2007
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in the Building 426 Conference Room with the following members in attendance:

Ms. Theresa Bell, Secretary	Dr. Henry Hearn
Dr. Randall Morin, Chair	Dr. David Garfinkel
Ms. Alberta Peugeot	Dr. Mike Baseler
Dr. Bruce Crise	Dr. Stephen Hughes
Ms. Dianna Boissey	Mr. Lucien Winegar
Dr. Dan McVicar	Dr. Stephen Creekmore
Dr. Jeanne Herring	

Members not in attendance: Dr. Melinda Hollingshead

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Thomas, Ms. Gail Housaman, Ms. Robin Pickens

The July 2007 and August 2007 minutes were distributed for review at the meeting. A vote for final approval will be taken by email next week.

New Business

07-45 (Marshall) "Metastasis Suppression Function of NM23-H1 in an Animal Model of Breast Cancer"

- This project uses commercial plasmids to transfect NM23-H1 and NM23-M1 into the 4T1 luciferase cell line.
- No unusual concerns were identified in the animal model.

Dr. Creekmore made a motion to approve as written, Dr. Crise seconded, and all were in favor.

07-54 (Kopp) “Processing and Cryopreservation of Blood and Blood Products from Cancer Patients receiving Irradiated Whole Tumor Cell Vaccines and BCG Vaccination”

- The greatest risk is the handling of clinical specimens. Associated risks are addressed in the attached SOPs and policies. Use of standard precautions for handling this material, appropriate clinical protocol enrollment, and non immune-compromised individuals working with the material should reduce the risk level of handling clinical specimens.
- The tumor-cell vaccine (ONY-P1) has been tested for adventitious agents, is made non-replicative by radiation, and tested for sterility post-production; therefore, this material does not seem to pose any particular hazards.

Dr. Creekmore made a motion to approve with the above modifications, Dr. Hughes seconded, and all were in favor.

07-44 (Peugeot) “Collection of Human Samples for Pre-employment, Annual, Surveillance Programs, and the Research Donor Program”

- The language of the SOP should be corrected to reflect that pipetting blood is conducted in the biosafety cabinet.

Dr. Baseler made a motion to approve with the above modifications, Dr. Creekmore seconded, and all were in favor. Ms. Peugeot abstained from the vote.

07-48 (Muegge) “Reprogramming of Murine Cells”

- MMLV pBABE is a classic recombination virus and must be addressed.
- PI must acknowledge that other things may be present in the murine cell lines that may infect humans (what comes back out of cell – B5f) – may not come out as ecotropic.
- Is the full complement of the genome present?
- PI must acknowledge use of an oncogene (c-myc) and those inherent hazards.
- Work is conducted at BSL2.

Dr. McVicar made a motion to approve with the above modifications, Dr. Crise seconded, and all were in favor.

07-53 (Gorelick) “Serological Diagnostic Testing of Non-human Primates for the Presence of Potentially Adventitious Viral Infections”

- Heat inactivation at 56°C may not be sufficient without use of Triton detergent. According to the data provided, the heat inactivation test failed for some of the samples.

- PI must acknowledge there is still a risk, and use a BSL-2 practices and procedures, not BSL-1.
- All dilutions and pipetting are to be performed in a BSC, not on the open benchtop.

Dr. Baseler made a motion defer approval, Dr. Creekmore seconded, and all were in favor. Ms. Peugeot abstained from the vote.

07-58 (Gonzalez) “Dimethylbenz(a)anthracene Carcinogenesis using Knockout Mice”

- This registration involves administration of a carcinogen to KO mice.
- The animal staff must understand that this carcinogen is very potent and be trained on the hazards.
- An SOP must be provided.

Dr. Crise made a motion to approve with the above modifications, Dr. McVicar seconded, and all were in favor.

07-47 (Hussain) “Role of Nitric Oxide in the Development of Lung Cancer in LSL-k-rasG12D Mice” (CONFIDENTIAL)

- This registration involves use of virus in mice.
- Part C Pathogen and Toxin Research has not been submitted.
- Mice should be sacrificed in the BSC if it is within seven days of infection, not 48 hours.
- Aseptic technique is to be used.
- Aerosol hazards must be indicated on the animal cage cards. Change cages in BSC or under other containment.
- How animals are being dosed should be addressed in Part C and/or in the SOP.
- A fluorescein experiment is recommended.
- Will those doing the work have previous experience?
- Clarification is needed if the cages are disposable cages, and disposed of in house?
- Virus can be aerosolized; all procedures must occur in a BSC.

Dr. Crise made a motion to defer approval, Dr. McVicar seconded, and all were in favor.

07-50 (Steeq) “Effect of Pigment Epithelium-Derived Factor Expression on Brain Metastatic Breast Cancer Progression”

- PI should acknowledge the protein biological consequences.
- The statement in B8B1 is not accurate – there is some toxicity with EGFP, but this is a very minor issue.

Dr. Hughes made a motion to approve with the above modifications, Mr. Winegar seconded, and all were in favor.

07-52 (Soman) “Bioassays and Product Characterization for Viruses, Immunotoxins, Plasmids, and Protein Products of Recombinant Cells in the Bio-Analytical Development Section of QC”

- No safety issues are addressed in this document.
- PI is to identify risks and mitigation measures for each experiment and material.
- Who is working with what, where, when, and why?
- How are materials kept from cross-contaminating (temporal and physical locations)?
- What is toxicity of the immunotoxin?
- How are aerosols contained while performing manipulations?
- PI must identify what recombinant plasmids are being manipulated, and how will they be handled
- The paper work states that they are not working with toxins, but they are working with immunotoxins. This needs corrected.
- Is there an extended host range?

Dr. Crise made a motion to defer approval, Dr. Hughes seconded, and all were in favor.

07-55 (Trinchieri) “Investigating the Inflammatory Regulation of Tumors by Genetic Modification of Tumor and Tumor Environment Mammalian Cells through In Vitro and In Vivo Delivery of Gene-Modified Adenoviral Vectors, DNA Expression Plasmids or Small Interfering RNAs”

- This registration involves the manufacturing of Adenovirus.
- Part C is not completed.
- PI must state what volumes of virus they are growing up.
- E9 – 72 hours – increase to 1 week? Versus 7 days
- Address safety measures more IV route hazards need addressed
- The statement regarding the hazards of replication competent adenovirus as minimal is not accurate.
- A statement is needed that specifies the human cell lines are not going into mice.

Dr. Crise made a motion to approve with the above modifications, Mr. Winegar seconded, and all were in favor.

07-59 (Kinders) “Evaluation of Circulating Tumor Cells as a Technology Platform for reporting Clinical Efficacy and as a source of Surrogate Tissues for Pharmacodynamic Effects of new Anti-Cancer Agents”

- PI should explain how the whole blood is fixed in the vacutainer.
- How do samples go from one container to another via a closed system?
- Samples being fixed should be described in the protocol.
- Are patients/specimens screened?
- Vaccinia vaccine will be offered, but not made mandatory because the samples are post 28-day inoculation.

Dr. McVicar made a motion to approve with the above modifications, Dr. Crise seconded, and all were in favor.

07-57 (McLellan) “Breeding ASP”

- PI should state in question A1 that all strains will be registered by using supplemental form once they have been identified.
- The IBC did not vote on approval since the lead reviewer was not present to discuss this proposal.

Renewals

07-49 (Hornung) “IML Staphylococcal Enterotoxins A and B for use in T cell Stimulations and ELISA Assays”

- Is it possible to receive the toxin already in a liquid form rather than powder form?
- A chemical fume hood is more desirable than a BSC to avoid the risk of turbulence from the laminar flow barrier; however, a glove box is ultimately recommended.
- The LD50 is very low, so PI must acknowledge the potential of getting sick from a very small dose.
- If entire contents were dispersed, what would be the worst case scenario?
- PI should address how materials will be stored safely when not in use.

Dr. Creekmore made a motion to approve with the above modifications, most importantly the engineering controls being addressed, Dr. Garfinkel seconded, and all were in favor.

07-51 (Whitby) “ATP Viral Technology Laboratory & AVP Viral Oncology Section”

- There is not enough information provided on the Herpes virus.
- The PI should organize the paperwork better by separating out the oncogenes, adenovirus, and lentivirus and address each one separately.
- The SOPs are good, but the registration form is not and should be redone.

Dr. Hughes made a motion to defer approval, Dr. Morin seconded, and all were in favor.

06-94 (Dimitrov) “HIV Entry and Neutralization”

- Many statements in the paperwork are completely wrong.
- Waste handling procedures are unclear.
- New paperwork must be submitted.

Dr. Baseler made a motion to defer approval with the above modifications, Dr. Hughes seconded, and all were in favor.

06-94 (Dimitrov) “Using Recombinant Vaccinia Viruses for Expression of Proteins in Mammalian Cells”

- It is not clear what the paperwork is describing. The paperwork must be completed properly for work to continue. All work is to be put on hold until this gets corrected.
- Collaborators need to be identified.

Dr. Morin made a motion to defer approval with the above modifications, Dr. Baseler seconded, and all were in favor.

Amendments

06-85 (Klinman)

- Information provided is unclear. PI must submit a new registration.

Dr. McVicar made a motion to defer approval, Dr. Hughes seconded, and all were in favor.

05-45 (Symer)

- No statements are made as to the hazards of recombination with transposons.
- A statement is needed regarding immunocompromised individuals working with the lentivirus and adenovirus vector systems.
- PI must explain how the two viruses will be kept separated in the lab.
- A description and a map of each vector system should be provided.
- Paperwork should state how the hazards will be mitigated?

Dr. McVicar made a motion to defer approval, Dr. Morin seconded, and all were in favor.

Outstanding Items

An update on the outstanding items was provided by Ms. Bell. Specifically noted was that the VPP and Dr. Tarr would be resubmitting their revisions to a previous registration sometime in October or November of 2007.

Other Business

- BBP Update: 46/1065 = 96% compliance
- ACUC/IBC subcommittee discussion

The meeting was adjourned at 3:07 pm.

Theresa D. Bell, MPH, CBSP
IBC Secretary
Biological Safety Officer, EHS

Ms. Cara Leitch
IBC Coordinator
Sr. Safety Specialist, EHS

APPROVED:

Randall S. Morin, Dr. P.H.
Chairman, NCI-Frederick IBC
Director, EHS

Date

xc: Dr. Reynolds
Mr. Wheatley
Dr. Arthur
Mr. Butfer