

Commonwealth Health Research Board Meeting Minutes for December 13, 2011

DRAFT

Members in Attendance:

Robert S. Call, Chairman
George E. Broman, Vice Chairman
Matthew Frank
Fred Hadeed
Cynda Ann Johnson
S. Lawrence Kocot
Karsten Konerding

Members Absent:

Others in Attendance:

Anne Pace, Administrator
Carla Collins, Assistant Attorney General,
Office of the Attorney General

James O'Donnell, Scientific Consultant
Carlos Caban, Scientific Consultant

Call to Order:

Chairman Dr. Robert S. Call called the meeting to order at 10:00 a.m. The meeting was held at the Virginia Hospital and Healthcare Association [VHHA], 4200 Innslake Drive, Glen Allen, Virginia 23060. Dr. Call introduced Dr. Cynda Ann Johnson, the newest member to the Board. Dr. Call also recognized and thanked Mr. Kocot for ten years of service with the Board. A gift was presented to Mr. Kocot from the Board. With seven members serving on the Board, a quorum was present throughout the meeting.

Approval of Minutes:

Dr. Call moved to approve the minutes of the May 17, 2011 and June 29, 2011 meetings with the following correction to the May 17, 2011 minutes submitted by Dr. Broman:

Page 6, INSERT: The Board's next meeting will be Tuesday, June 29, 2011 at the Science Museum of Virginia followed by the Grants Workshop.

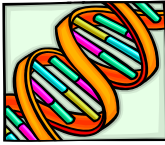
Mr. Kocot seconded the motion. The motion was voted upon and passed unanimously.

CHRB Financial Reports

Administrator Pace presented the CHRB administrative fiscal information:

FY 2010/2011 FINAL CHRB Expenses [July 1, 2010 through June 30, 2011]

The FY 2010/2011 CHRB administrative budget totals \$97,065.89. The fiscal year 2010/2011 began on July 1, 2010 and ended on June 30, 2011. Expenditures for FY 2010/2011 totaled \$97,031.30, with the largest expenses being related to salaries, fiscal services, and management services.



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FY 2011/2012 YTD CHRBR Expenses [through November 30, 2011]

The FY 2011/2012 CHRBR administrative budget totals \$165,500. The fiscal year 2011/2012 began on July 1, 2011 and ends on June 30, 2012. Expenditures for FY 2011/2012 through November 30, 2011 totaled \$65,615.83 with the largest expenses being related to salaries and management services.

FY 2012/2013 CHRBR Grant Process Step One: Concept Paper Submissions

Dr. Call moved that the Board go into closed session pursuant to Virginia Code § 2.2-3711 (A) (30) for the purpose of discussion or consideration of grant application records exempt from the Virginia Freedom of Information Act pursuant to subsection 17 of § 2.2-3705.6. The motion was seconded by Mr. Hadeed. The motion was voted upon and passed unanimously.

Dr. Call moved that the Board reconvene in open session. Dr. Broman seconded the motion. The motion was voted upon and passed unanimously. The Board adopted the following resolution by roll call vote.

CERTIFICATION

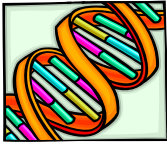
WHEREAS, the Commonwealth Health Research Board has convened a closed meeting on this date pursuant to an affirmative recorded vote and in accordance with the provisions of The Virginia Freedom of Information Act; and

WHEREAS, § 2.2-3712 of the *Code of Virginia* requires a certification by this Board that such closed meeting was conducted in conformity with Virginia law;

NOW, THEREFORE, BE IT RESOLVED, that the Commonwealth Health Research Board certifies that, to the best of each member's knowledge, (i) only public business matters lawfully exempted from open meeting requirements by Virginia law were discussed in the closed meeting to which this certification resolution applies, and (ii) only such public business matters as were identified in the motion convening the closed meeting were heard, discussed, or considered by the Board.

A roll call vote of members present approved this resolution unanimously.

Dr. Broman made a motion that the following 27 concept papers be developed into full proposals. Dr. Konerding seconded the motion. The motion was voted upon and passed unanimously. Administrator Pace will contact the principal investigators for each of the concept papers identified below regarding the CHRBR's request for a full proposal submission. Administrator Pace will also provide reviewer comments to those principal investigators from whom full proposal submissions will not be requested.



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Concept Paper #	Submitting Institution/ Organization
207-04-12	UVA
247-06-12	GMU
274-15-12	EVMS
207-09-12	UVA
207-13-12	UVA
221-01-12	ODU
236-05-12	VCU
247-04-12	GMU
274-01-12	EVMS
274-08-12	EVMS
274-09-12	EVMS
274-11-12	EVMS
274-13-12	EVMS

Concept Paper #	Submitting Institution/ Organization
804-03-12	Carilion Medical Center
207-11-12	UVA
208-03-12	VT
208-14-12	VT
236-02-12	VCU
236-04-12	VCU
236-11-12	VCU
236-13-12	VCU
247-01-12	GMU
247-05-12	GMU
247-07-12	GMU
804-01-12	Carilion Medical Center
208-01-12	VT
236-09-12	VT



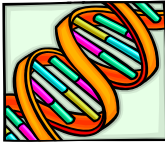
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Progress of Ongoing CHRB Grant Awards

Administrator Pace provided an update regarding ongoing CHRB Grant Awards. First and second interim reports' due dates are reflected in the chart below.

PI	Institution/ Organization	Grant Title	First Interim Report Due	Second Interim Report Due
Justin R. Anderson, Ph.D.	Radford University	Characterization of La Crosse virus receptors in mosquito tissues	March 31, 2011	January 31, 2012
John Harrington, M.D.	Children's Hospital of The King's Daughters	Treatment of Behavior Disorders among School-Aged Children with Autism Spectrum Disorders (ASD)	March 31, 2011	January 31, 2012
Molly Hughes, M.D., Ph.D.	University of Virginia	Development of Novel Antimicrobial Agents for Multi-Drug Resistant Bacterial Pathogens	March 31, 2012	January 31, 2013
Kylene Kehn-Hall, Ph.D.	George Mason University	BTK induction by HIV: implications for therapeutics	March 31, 2012	January 31, 2013
Mary Jayne Kennedy, Pharm.D.	Virginia Commonwealth University	Evaluation of mitochondrial gene sequence variants as biomarkers of aminoglycoside-induced renal injury in newborn infants	March 31, 2011	January 31, 2012
Frank Lattanzio, Ph.D.	Eastern Virginia Medical School	Development of a well Tolerated, anti-angiogenic agent to treat drug resistant cancers	January 31, 2012	NA
Masoud Manjili, Ph.D.	Virginia Commonwealth University	Sequential common gamma chain cytokines can expand tumor antigen-reactive T cells that are resistant to cancer-associated immune suppression & generate long-lasting memory responses against HER2/neu	January 31, 2012	NA
Aylin Rizki, Ph.D.	Virginia Commonwealth University	The role of MRE11/RAD50/NBS1 in ER/PR/HER2 Negative Breast Pre-Cancer Progression	January 31, 2012	NA
Jennifer Stewart, Ph.D.	Virginia Commonwealth University	Generation of Mice Deficient in Vesicular Monoamine Transporter-1: Potential Links to Schizophrenia	March 31, 2011	January 31, 2012
Claretta J. Sullivan, Ph.D.	Eastern Virginia Medical School	Atomic force microscopy in sepsis research: a new look at bacterial membrane vesicles	March 31, 2011	January 31, 2012
Arthur Weltman, Ph.D.	University of Virginia	Effects of exercise intensity on postprandial glucose disposal and endothelial function in prediabetic adults	March 31, 2011	January 31, 2012



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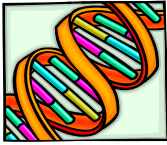
Other Business to come before the Board:

Physicians Dispensing Drugs: The Virginia Board of Pharmacy issued a Guidance Document [110-29, Revised February 2011] entitled, Physicians Dispensing Drugs. Due to concerns regarding the Guidance Document's potential impact upon the CHRB and research proposals utilizing controlled substances, the CHRB's Administrator requested a statement from the Virginia Board of Pharmacy regarding the licensing and/or registration requirements with which such researchers must comply. Mr. J. Samuel Johnson, Jr., Pharmacist and Deputy Director of the Virginia Board of Pharmacy, provided a response which was subsequently clarified by the Board of Pharmacy's Executive Director. The CHRB's Chair, Dr. Call, and its Administrator requested legal advice from Assistant Attorney General Collins, as well. Assistant Attorney General Collins concluded that the Guidance Document does not have any direct impact upon the CHRB. Generally speaking, the Executive Director of the Board of Pharmacy explained that in lieu of requiring a physician intending to dispense investigational drugs to his own patients from obtaining a practitioner-of-the-healing-arts-to-sell-controlled-substances license, the Board of Pharmacy has permitted such a physician to obtain a Controlled Substances Registration for dispensing purposes. She further explained that if a physician is solely administering investigational drugs in Schedules II through VI to his own patients, he may administer these drugs pursuant to his current active medical license and DEA registration. If a researcher is not a licensed physician and does not otherwise have authority to possess controlled substances, he must obtain a Controlled Substances Registration from the Board of Pharmacy.

Financial Disclosure Forms due January 15, 2012: Administrator Pace referred members to the financial disclosure forms provided to them at the meeting. Members should complete the forms, sign, and return them to Administrator Pace who will forward the completed forms to the Office of the Secretary of the Commonwealth.

Commonwealth Risk Management Plan: Administrator Pace provided members with the correct copy of the Commonwealth of Virginia Risk Management Plan for the CHRB. Don W. LeMond, Director of the Department of the Treasury, sent a letter which "confirms that the Commonwealth Health Research Board, to include its board members and any officers or employees are covered for liability by the Commonwealth Risk Management Plan subject to its terms and conditions". Administrator Pace provided a copy of that letter to each Board member.

Dr. Broman asked whether the CHRB should provide feedback, regarding the issues or questions that the Board would like to have addressed, to Principal Investigators whose project proposals advance at each stage of the grant review process. Dr. Caban responded that the National Institutes of Health [NIH] always sends a summary of the review for each submission. However, he and Dr. O'Donnell also explained that the NIH's grant process differs from the CHRB's. The NIH reviews each proposal only once. If the CHRB provided comments to each applicant from whom a full proposal was requested, the Principal Investigators would use the information to improve their submissions at a subsequent stage of review during the same grants competition cycle. This would seem to provide an unfair competitive advantage vis-à-vis those who submitted concept papers; yet did not advance at a subsequent stage of the process. Dr. Konerding noted that certainly if the CHRB provided feedback to any applicant, it would have to do so for all applicants at every stage of the competition. It was noted that when oral presentations are made to the CHRB, the CHRB may ask questions concerning the proposals.



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Following discussion, the consensus of the CHRB was that no feedback would be provided to Principal Investigators whose project proposals advance during the grant review process. Dr. Frank suggested that, in preparing for presentations to the Board, all Principal Investigators should discuss briefly any success of past research which is relevant to the pending proposal.

Next meeting:

Dr. Call moved that the meeting be adjourned. The motion was seconded, voted upon, and passed unanimously by the Board. The meeting adjourned at 12:10 p.m.

The Board's next meeting will be Tuesday, April 10, 2012 at either the Medical Society of Virginia or the Virginia Hospital and Health Care Association. The meeting will begin promptly at 10:00 a.m. At this meeting, as part of the 2012/2013 grant review process, the Board will review the recommendations of the review panel and determine which full proposals should be presented to the Board.

For planning purposes, please note that presentations to the Board are scheduled for Tuesday, May 15, 2012 at either the Medical Society of Virginia or the Virginia Hospital and Health Care Association.