

Commonwealth Health Research Board
Meeting Minutes for May 18, 2017
DRAFT

Members in Attendance:

Members Absent:

Cynda A. Johnson, M.D., M.B.A., Chair
L. Matthew Frank, M.D., Vice Chair
Kenji M. Cunnion, M.D., M.P.H.
Robert W. Downs, Jr., M.D.
Thomas W. Eppes, Jr., M.D.
John R. Onufer, M.D.
Julia A. Spicer

Others in Attendance:

Anne C. Pace, M.P.A.
Raya Mandler, Ph.D.
Merrill Mitler, Ph.D., M.P.H.
James O'Donnell, Ph.D.
Arnold Revzin, Ph.D.

CHRB Administrator
Scientific Consultant
Scientific Consultant
Scientific Consultant
Scientific Consultant

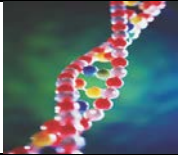
Carla R. Collins

Senior Assistant Attorney General
Office of the Attorney General
Virginia Commonwealth University
Virginia Commonwealth University
Virginia Commonwealth University
Virginia Commonwealth University
Virginia Commonwealth University
University of Virginia
Christopher Newport University
Washington and Lee University
Old Dominion University
Eastern Virginia Medical School
Eastern Virginia Medical School
Eastern Virginia Medical School

Nicholas Farrell, Ph.D.
Jennifer Koblinski, Ph.D.
Gretchen Neigh, Ph.D.
Linda Phillips, Ph.D.
Babette Fuss, Ph.D.
Weibin Shi, Ph.D.
Kathryn Cole, Ph.D.
Kyle Friend, Ph.D.
Michel Audette, M.D.
Frank Castora, Ph.D.
Randy Coleman, Ph.D.
Elena Galkina, Ph.D.

Call to Order:

Chair Cynda A. Johnson, M.D., M.B.A. called the meeting to order at 10:00 a.m. The meeting was held at the Jepson Alumni Center, Rosenbaum Room, University of Richmond, 49 Crenshaw Way, Richmond, Virginia 23173. A quorum was present for the transaction of business throughout the meeting. After the meeting was called to order, the Board discussed the recent passing of Carlos E. Caban, Ph.D., M.P.H., one of the CHRB's scientific consultants. A moment of silence commenced in his honor. His contributions to the CHRB's work were invaluable and he will be dearly missed.



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The Board then discussed the instructions for presentations, including the manner in which questions would be asked of the presenters and the time limitations for each presentation.

Approval of Minutes:

Dr. Johnson moved to revise and then approve the revised Minutes from the April 13, 2017 meeting to include the following entry under the heading of “Proposed CHRB Grant Guidelines FY 2018/2019, Proposed CHRB Policies and Procedures, Proposed CHRB Grant Agreement and Proposed CHRB Bylaws [to be voted on at the May 18, 2017 meeting and effective July 1, 2017]” and inserted before the section entitled, “Other Business to Come Before the Board”: “The Board discussed amending the Bylaws to delegate authority to the CHRB’s Administrator to request additional information from a grant applicant during the review of a Concept Paper or Full Proposal as part of the Administrative and Technical Compliance Review Process. The Board discussed its desire to ensure that scientific reviews are not denied applicants solely based upon minor technical issues with an application that could be resolved by a phone call from the Administrator to the applicant. The Board then decided by consensus to defer further discussion of any proposed revisions to any of the CHRB’s governing documents until the May 18, 2017 meeting due to time constraints at the current meeting.”

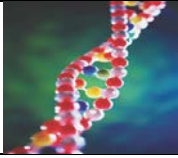
The meeting minutes, as revised, were then unanimously approved by the Board upon Dr. Cunnion’s second of Dr. Johnson’s motion.

CLOSED SESSION: FY 2017/2018 CHRB Grant Process Step Three: Presentation of 5 Full Proposals to the Board

Chair Cynda A. Johnson, M.D., M.B.A. moved that the Board go into closed session pursuant to Virginia Code § 2.2-3711 (A) (7), § 2.2-3711 (A) (30), and § 2.2-3705.6(17) for the purpose of

consultation with legal counsel and briefings by staff members or consultants pertaining to actual or probable litigation, where such consultation or briefing in open meeting would adversely affect the negotiating or litigating posture of the Board, and consultation with legal counsel employed or retained by the Board regarding specific legal matters requiring the provision of legal advice by such counsel regarding:

records submitted as a grant or loan application, or accompanying a grant or loan application.....to the extent such records contain proprietary business or research-related information produced or collected by the applicant in the conduct of or as a result of study or research on medical, rehabilitative, scientific, technical, technological, or scholarly issues, when such information has not been publicly released, published, copyrighted, or patented, if the disclosure of such information would be harmful to the competitive position of the applicant. Virginia Code § 2.2-3705.6 (17).



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The motion was seconded by Dr. Downs. The motion was voted upon and passed unanimously.

Chair Cynda A. Johnson, M.D., M.B.A. moved that the Board reconvene in open session. Dr. Onufer 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, Section 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 was taken. Each approved this certification.

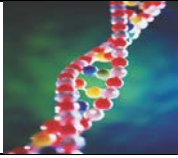
For the record, it is noted that Dr. Downs recused himself from the presentation of the proposal for #236-08-17, all discussions concerning it, and the vote concerning it to avoid even the mere appearance of impropriety.

CLOSED SESSION: FY 2017/2018 CHR B Grant Process Step Three: Presentation of 4 Full Proposals to the Board

Chair Cynda A. Johnson, M.D., M.B.A. moved that the Board go into closed session pursuant to Virginia Code § 2.2-3711 (A) (7), § 2.2-3711 (A) (30), and § 2.2-3705.6(17) for the purpose of

Consultation with legal counsel and briefings by staff members or consultants pertaining to actual or probable litigation, where such consultation or briefing in open meeting would adversely affect the negotiating or litigating posture of the Board, and consultation with legal counsel employed or retained by the Board regarding specific legal matters requiring the provision of legal advice by such counsel regarding:

records submitted as a grant or loan application, or accompanying a grant or loan application.....to the extent such records contain proprietary business or research-related information produced or collected by the applicant in the conduct of or as a result of study or research on medical, rehabilitative, scientific, technical,



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technological, or scholarly issues, when such information has not been publicly released, published, copyrighted, or patented, if the disclosure of such information would be harmful to the competitive position of the applicant. Virginia Code § 2.2-3705.6 (17).

The motion was seconded by Dr. Downs. The motion was voted upon and passed unanimously.

Chair Cynda A. Johnson, M.D., M.B.A. moved that the Board reconvene in open session. Dr. Downs 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, Section 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;

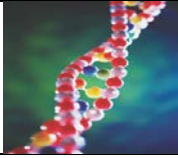
NOW, THEREFORE, BE IT RESOLVED, that the Commonwealth Health Research Board certifies that, to the best of each member's knowledge, (i) only public business matters lawfully exempted from open meeting requirements by Virginia law were discussed in the closed meeting to which this certification resolution 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 was taken. Each approved this certification.

Results of Closed Sessions:

Based upon individual polling of the members, Dr. Johnson made a motion to deny reconsideration requests from grant applicants #207-05-17 and #208-01-17. Dr. Cunnion seconded the motion. The motion was voted upon and passed unanimously.

Dr. Onufer made a motion that the following 6 Principal Investigators receive a CHRHB grant award for FY 2017/2018. Dr. Downs seconded the motion. The motion was voted upon and passed unanimously. Administrator Pace will contact the following Principal Investigators regarding the outcome of the Board's decisions. She will also provide reviewer comments [from the Full Proposal submission] to those Principal Investigators who will not receive a grant award.



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Institution	Principal Investigator	Grant Title
Eastern Virginia Medical School	Frank Castora, Ph.D.	<i>The role of differentially expressed mitochondrial energy production genes as regulators of amyloid precursor protein processing in Alzheimer's Disease.</i>
Christopher Newport University	Kathryn Cole, Ph.D.	<i>Anticancer Drug Design: Structure and Function of New HDAC8-Depsipeptide Complexes</i>
Virginia Commonwealth University	Nicholas Farrell, Ph.D.	<i>Targeting Triple Negative Breast Cancer.</i>
Washington and Lee University	Kyle Friend, Ph.D.	<i>Investigating enzyme activity-independent defects in metabolic disorders</i>
Virginia Commonwealth University	Babette Fuss, Ph.D.	<i>Regulation of myelin repair: the role of the actin cytoskeleton.</i>
University of Virginia	Weibin Shi, Ph.D.	<i>Characterization of reticulocalbin 2 as a major gene contributing to atherosclerosis</i>

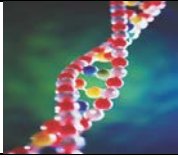
Dr. Downs made a motion to approve second year funding for Bin Xu, Ph.D., Virginia Polytechnic Institute and State University and to delegate authority to the Administrator, in collaboration with the Scientific Consultant, legal counsel, and the CHRB Chair, Cynda A. Johnson, M.D., M.B.A., to negotiate, draft, and execute the Grant Agreement Amendment required to implement the Board's conditional approval of continued funding for Jia-Qiang He, Ph.D., Virginia Polytechnic Institute and State University. Ms. Spicer seconded the motion. The motion was voted upon and passed unanimously.

CLOSED SESSION: FY 2017/2018: Personnel and Budget Discussion

Chair Cynda A. Johnson, M.D., M.B.A. moved that the Board go into closed session pursuant to Virginia Code §§ 2.2-3711 (A)(7) and 2.2-3711 (A)(1), for the purpose of

consultation with legal counsel and briefings by staff members or consultants pertaining to actual or probable litigation, where such consultation or briefing in open meeting would adversely affect the negotiating or litigating posture of the Board, and consultation with legal counsel employed or retained by the Board regarding specific legal matters requiring the provision of legal advice by such counsel regarding a personnel matter pursuant to Virginia Code § 2.2-3711(A)(1).

The motion was seconded by Dr. Downs. The motion was voted upon and passed unanimously.



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Chair Cynda A. Johnson, M.D., M.B.A. moved that the Board reconvene in open session. Dr. Onufer 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, Section 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 was taken. Each approved this certification.

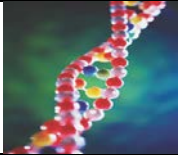
Results of Closed Session:

Dr. Onufer moved that the Board approve the proposed FY 2017/2018 CHRB Administrative Budget in the amount of \$244,464.94, including the amounts designated for DOA's fiscal services and the OAG's legal services as set forth below. The motion was seconded by Dr. Downs. The motion was voted upon and passed unanimously.

[1] The approved CHRB Administrative Budget includes \$18,464.22 for fiscal services provided by the Department of Accounts (DOA) to the CHRB. A breakdown of the DOA fiscal fee is provided in Attachment A. The contents of Attachment A are incorporated here by reference as if fully set forth here. Dr. Downs moved that the Board delegate the authority to the CHRB Chair, Cynda A. Johnson, M.D., M.B.A., to execute the MOU between the DOA and the CHRB on the Board's behalf. Dr. Cunnion seconded the motion and it passed unanimously.

[2] The approved CHRB Administrative Budget also includes \$10,000 for legal services provided to the Board by the Office of the Attorney General (OAG). The Memorandum of Agreement between the CHRB and the OAG was presented, reviewed, discussed, unanimously approved by the Board, and executed by the CHRB Chair, Cynda A. Johnson, M.D., on behalf of the Board.

[3] The approved CHRB Administrative Budget includes approval of a fulltime status for the CHRB Administrator and a 1% salary increase. The Board, via motion made by Dr. Onufer, seconded by Ms. Spicer, and unanimously approved, delegated authority to Chair Cynda A. Johnson, M.D. and authorized her to complete a performance review of the CHRB



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Administrator and to develop any contracts or contract amendments necessary to establish the scope of work, compensation, and terms and conditions governing the Administrator, including the terms referenced above.

[4] The approved CHRB Administrative Budget also includes funding for four scientific consultants. The Board, via motion made by Dr. Onufer, seconded by Dr. Downs, and unanimously approved, delegated authority to Administrator Pace and Assistant Attorney General Collins to develop any contracts or contract amendments necessary to establish the scope of work, compensation, and terms and conditions governing the scientific consultants as independent contractors of the CHRB and delegated authority to the CHRB Chair, Cynda A. Johnson, M.D., to execute all contracts or contract amendments between the CHRB and the scientific consultants on the CHRB's behalf. The Board specified that the contracts for the scientific consultants will include a confidentiality clause and a conflict of interest clause.

OPEN SESSION: Review and Discussion of CHRB Grant Related Documents

Administrator Pace reviewed the following proposed grant related documents with the Board with a focus on significant changes. By motion made by Dr. Downs and seconded by Dr. Onufer, the Board unanimously approved the CHRB Grant Guidelines and Application Instructions, the CHRB Policies and Procedures, the CHRB Grant Agreement and the CHRB By laws as revised by the Board. [A summary of significant changes appears below; however, the reader is encouraged to review the approved governing documents posted on the CHRB's website.]

CHRB Grant Guidelines and Application Instructions FY 2018/2019 [effective July 1, 2017]

[1] **Revised wording under Introduction:** Support to aid in obtaining preliminary data that may enable an investigator in obtaining support for a major research project.

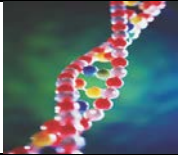
[2] **Added language under Grant Application Instructions and Grant Application Review Process under Step Three: Full Proposal Presentation to the CHRB:** The presentation should elaborate on the information contained in the Full Proposal, specifically focusing on the scientific merit of the proposal, the manner in which it will be accomplished, and how it will improve the health of citizens of the Commonwealth of Virginia.”

[3] **Clarification of language under Key Dates for 2018/2019:** Clarified that Concept Papers and Full Proposals must be submitted electronically through the CHRB's Grant Application Management Electronic System (GAMES).

[4] **Under Application Instructions: Submitting the Concept Paper under How many applications can be submitted:** Increases from 10 to 12 Concept Papers from a single agency, non-profit organization, or institution of higher education per funding cycle.

[5] **Added language under Application Instructions under Document Titles for Cover Page and Scientific Project Summary, Research Plan and Attachments:** However, the CHRB Administrator may request additional information, concerning the Cover Page and/or Attachments, or information contained within the research plan that relates to the Cover Page or in the Attachments, for clarification.

[6] **Added language to existing language under Attachment 9: Subcontract, MOU:**



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Although the applicant is not required to submit copies of such documents with the Concept Paper, please note that the Concept Paper must **state that a memorandum of understanding or affiliation agreement will be in place with the Co-Investigator's institution or organization before the CHRBR makes the first payment if a grant award is made.**

[8] Added language: 7. Disclosure of Conflict of Interest

The Applicant must disclose professional, personal or financial relations with entities (Pharma, industry, academic institutes, etc.) that are related to the current application if, while not included in the grant, they could nonetheless directly influence the direction of the study, could benefit from the funds, or be later publicly associated with studies funded by the CHRBR. If there are no conflicts, or potential conflicts of interest issues related to the CHRBR Grant Application, then a statement to that effect should be provided.

Examples:

[1] The PI proposes to study tobacco related lung cancer and is currently funded by the tobacco industry

[2] The PI proposes to study a potential new oncological drug (not yet FDA approved) and currently also is paid by the pharma company that developed the drug to promote the drug in commercial venues

[3] A post-doc who has just left the PI's lab moved to the department of one of the Board's members and is still collaborating with the PI.

[9] Added language to the Budget Rationale:

The budget rationale **should** also be used to explain any special circumstances related to the project participants **or activities such** as salary increases, calculation of fringe benefits, what fringe benefits are included as it relates to IRS student exemption **and significant costs (more than \$10,000 per year) for particular service or supply items.**

[10] Added language as to why we request current and pending grant applications for professional Project Participants: **Grant/Contract funding, dollars and time commitments on research contracts could be important information.**

[10] Added language: Added wording that a bio sketch is not acceptable and that, **"Note that no Pre-Masters or Pre-Doctoral Graduate Student can participate in a CHRBR-funded project at greater than 20% effort."**

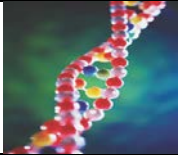
[11] Added language to Attachment 6 Checklist: **Your check mark indicates that you have reviewed your Concept Paper/ Full Proposal to ensure that all items on the checklist have been included with your Submission.**

[12] Added language: Attachment 9: Although the applicant is not required to submit copies of such documents with the Concept Paper, please note that the Concept Paper must **state that a memorandum of understanding or affiliation agreement will be in place with the Co-Investigator's institution or organization before the CHRBR makes the first payment if a grant award is made.**

[13] Added language under nonsubstantive changes: Percentage of effort **and salary requests** for specific project participants if the change is for no more than 5% [e.g. 35% to 30% effort] and is for research participants other than the Principal Investigator. **The resulting salary increase may not cause the revised budget to exceed the amount approved by the CHRBR.**

No change in percentage of effort or **salary** between the Concept Paper and Full Proposal submissions is allowable for the PI.

[14] Added language under Principal Investigator: A PI may serve as a PI in one submission and as a **Co-investigator, Consultant, Collaborator or Advisor/Mentor** in another **CHRBR project** as long as the Applicant Institution or Organization agrees to permit it and the percentage of effort is reasonable given all of the other time commitments. **The other time commitments must be clearly set forth in each submission.**



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[15] Yes, an undergraduate student can participate in a CHRB grant project:

[1] during off-semester or summer time **for pay** at up to 100% effort, or

[2] as part of a research course during the academic year **at no greater than 10% effort**. The research participation may be permitted as part of an undergraduate student's required research activity.

[16] Added language to clarify that Health Insurance is an allowable cost for graduate students: Health Insurance **for graduate students**

[17] Added wording under IRB/IACUC related costs or fees for CHRB Funding:

No, **Costs associated with IACUC review of animal research protocols or IRB review of human research protocols are not allowable costs.**

Added wording under IRB/IACUC related costs or fees for Institution Matching Funds:

No, **Costs associated with IACUC review of animal research protocols or IRB review of human research protocols are not allowable costs. However, matching funds can be used for secretarial, janitorial, etc. expenses.**

CHRB Policies and Procedures [effective July 1, 2017]

[1] Added language to existing language under Subcontracting with other Institutions and Organizations: Although the applicant is not required to submit copies of such documents with the Concept Paper, please note that the Concept Paper must **state that a memorandum of understanding or affiliation agreement will be in place with the Co-Investigator's institution or organization before the CHRB makes the first payment if a grant award is made.**

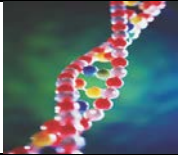
[2] Revised language: Requests for reconsideration of decisions made by the CHRB during the grant application review process can be made by the Principal Investigator and the Applicant Institution or Organization only where there are **demonstrated factual errors in the review of the Concept Paper or the Full Proposal**. For example, if the review states **that** the investigator has no expertise in the area of research proposed, but the proposal clearly identifies several related publications by the investigator, a request for reconsideration can be made and the CHRB may exercise its discretion to reconsider its review of that application.

In the written request **for reconsideration**, the Principal Investigator **and the Applicant Institution or Organization** must identify the specific factual errors that **the Board allegedly made and that constitute the basis for reconsideration of the Board's decision**. **If the request for reconsideration does not contain this information, the request for reconsideration may be denied.** The reconsideration request is not an opportunity to provide additional information to supplement the original Concept Paper or, if applicable, the Full Proposal submission.

Requests for Reconsideration Regarding Termination or Revocation of Grant Award or Portion Thereof

If, during the Grant Period of an Awarded Grant, the CHRB terminates or revokes a grant, or any portion thereof, for failure to comply with any of the CHRB's *Grant Guidelines and Application Instructions*, any of the CHRB's *Policies and Procedures effective July 1, 2017*, or any requirement set forth in the Grant Agreement, the Principal Investigator and the Grantee Institution or Organization may submit a written request to the CHRB for a reconsideration of the CHRB's decision to terminate or to revoke the funding; provided, however, that such a request for reconsideration may be made only if alleged errors in the facts upon which the CHRB **allegedly** based its decision to terminate or to revoke the grant award, or any portion thereof, have been demonstrated to the satisfaction of the CHRB.

[3] Added language under Request for Budget Reallocation: **Funding not spent in Year 1, for two-year grant awards, will carry over from Year 1 into Year 2 in the same budget line item as Year 1. A budget reallocation request is required for any changes from Year 1 to Year 2 if funds are requested to be**



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carried over to a different budget line item. Any proposed budget reallocations that request increases in salary and fringe benefits for any project participants, above and beyond what was approved in the original budget, must be funded with institutional matching funds.

[4] Added language under nonsubstantive changes: Percentage of effort **and salary requests** for specific project participants if the change is for no more than 5% [e.g. 35% to 30% effort] and is for research participants other than the Principal Investigator. **The resulting salary increase may not cause the revised budget to exceed the amount approved by the CHRBR.** No change in percentage of effort or **salary** between the Concept Paper and Full Proposal submissions is allowable for the PI.

[5] Added language: Yes, an undergraduate student can participate in a CHRBR grant project:

[1] during off-semester or summer time **for pay** at up to 100% effort, or

[2] as part of a research course during the academic year **at no greater than 10% effort.** The research participation may be permitted as part of an undergraduate student's required research activity.

[6] Added language under Change in Institutional Official:

The Grantee Institution or Grantee Organization must provide the CHRBR with a new letter of authorization for the new Institutional Official and/or authorized representative and **an Addendum to the original grant agreement signed by the Principal Investigator and co-signed by the appropriate Institutional Official or the Organization's authorized representative.** The letter of authorization **and the endorsed the addendum to the original grant agreement** must be provided to the CHRBR no later than 4:00 p.m. of the business day following the first day the new Institutional Official, or authorized representative, serves the Grantee Institution or Grantee Organization in that capacity.

[7] Under PDF Copies may be accepted as Originals in the Circumstances specified: With the exception of the Grant Agreement, **an Addendum to the original Grant Agreement, and an Amendment to the original Grant Agreement,** if a written request or response is required by these Policies and Procedures from the Principal Investigator or Grantee Institution or Organization, an electronic PDF copy of the original, **containing** original signatures, . . .

[8] Added language to the Disclosure of Conflict of Interest and added examples:

The Applicant must disclose professional, personal or financial relations with entities (Pharma, industry, academic institutes, etc.) that are related to the current application if, while not included in the grant, they could nonetheless directly influence the direction of the study, could benefit from the funds, or be later publicly associated with studies funded by the CHRBR. If there are no conflicts, or potential conflicts of interest issues related to the CHRBR Grant Application, then a statement to that effect should be provided.

Examples:

[1] The PI proposes to study tobacco related lung cancer and is currently funded by the tobacco industry

[2] The PI proposes to study a potential new oncological drug (not yet FDA approved) and currently also is paid by the pharma company that developed the drug to promote the drug in commercial venues

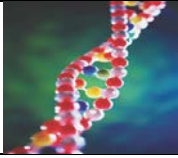
[3] A post-doc who has just left the PI's lab moved to the department of one of the Board's members and is still collaborating with the PI.

[9] Under CHRBR Grant Award Scientific and Fiscal Reporting Requirements:

For one-year grant awards: Each Grantee Institution or Organization receiving a one-year CHRBR grant award is required to submit interim scientific and fiscal progress reports at seven months **[January 31st for expenses incurred through December 31st].**

For two-year grant awards: Each Grantee Institution or Organization receiving a two-year award must submit interim scientific and fiscal progress reports at nine **[March 31st for expenses incurred through February 28th]** and nineteen months **[January 31st for expenses incurred through December 31st].**

[10] Under Audit Requirements and Access to Records: The CHRBR also reserves the right to



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require the return of all funds paid if: (b) The PI and/or Grantee Institution or Organization, **without the CHRBR's pre-authorization and approval**, alters the research plan as approved by the CHRBR. The PI and Grantee Institution or Organization must agree to these terms and conditions as part of the Grant Agreement **and any Addendum or Amendment thereto**.

[11] Added language: Copies of Concept Papers and Full Proposals that do not result in a Grant Award are not released to the public **unless the CHRBR is required by law or a lawful Order of a court to do so**.

[12] Added language to clarify that Health Insurance is an allowable cost for graduate students: Health Insurance **for graduate students**

[13] Added wording under IRB/IACUC related costs or fees for CHRBR Funding:

No, **Costs associated with IACUC review of animal research protocols or IRB review of human research protocols are not allowable costs**. Added wording under IRB/IACUC related costs or fees for Institution Matching Funds:

No, **Costs associated with IACUC review of animal research protocols or IRB review of human research protocols are not allowable costs**. However, matching funds can be used for secretarial, janitorial, etc. expenses.

CHRBR Grant Agreement [effective July 1, 2017]

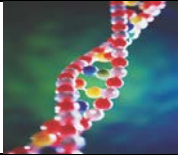
[1] Added language: The Grantee Institution or Organization, by and through the Institutional Official, or Authorized Representative, or his successor, Principal Investigator and other participants **must disclose professional, personal or financial relations with entities (Pharma, industry, academic institutes, etc.) that are related to the current CHRBR funded project if, while not included in the grant project, they could nonetheless directly influence the direction of the study, could benefit from the funds, or be later publicly associated with studies funded by the CHRBR**. These individuals must ensure any conflict or potential conflict of interest issues related to the CHRBR grant project have been reported to, and resolved by, the applicable review committee at the Applicant Institution or Organization. The PI must advise the CHRBR in writing of the manner in which the conflict, or potential conflict, of interest was resolved.

[2] Clarification Under CHRBR Grant Award Scientific and Fiscal Reporting Requirements:

For one-year grant awards: Each Grantee Institution or Organization receiving a one-year CHRBR grant award is required to submit interim scientific and fiscal progress reports at seven months **[January 31st for expenses incurred through December 31st]**. For two-year grant awards: Each Grantee Institution or Organization receiving a two-year award must submit interim scientific and fiscal progress reports at nine **[March 31st for expenses incurred through February 28th]** and nineteen months **[January 31st for expenses incurred through December 31st]**.

[3] Added language under: Request for A No-Cost Extension:

[1] The Grantee Institution or Organization, by and through the Institutional Official, or Authorized Representative, or his successor, and Principal Investigator understand and agree that no-cost extension requests must be made in writing prior to the expiration of the original period within which all CHRBR Grant funds must be expended, by the Principal Investigator, and co-signed by the appropriate Institutional Official, i.e. the Director of the Office of Research or the Office of Sponsored Programs, or Authorized Representative. Written three-month extension requests must be received by the CHRBR Administrator at least 30 days prior to the original deadline from which the extension is requested. Under compelling justification, the CHRBR may permit an extension, for up to three months, to complete the project without providing additional funds. **Approval of a three-month no-cost grant extension will require an Addendum to the original Grant Agreement signed by the**



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Principal Investigator and co-signed by the appropriate Institutional Official or the Organization's authorized representative.

[2] The Grantee Institution or Organization by and through the Institutional Official, or Authorized Representative, or his successor, and Principal Investigator further understand and agree that only under extraordinary circumstances may a no-cost extension exceeding three months, but not to exceed six months, be requested. An example of an “extraordinary circumstance” may be an incident in which a piece of equipment critical to the completion of the project becomes inoperable, and it is determined that it will take up to six months for a replacement to be fabricated. **Approval of a six-month no-cost grant extension will require an Addendum to the original Grant Agreement signed by the Principal Investigator and co-signed by the appropriate Institutional Official or the Organization's authorized representative.**

CHRB Bylaws [effective July 1, 2017]

[1] Added language: Under C. The authority delegated to the Administrator by the Board and its Chair shall include, but not be limited to, the following:

1. The authority to request additional information from a grant applicant during the administrative review of a Concept Paper or a Full Proposal;

Next Meeting:

Chair Cynda A. Johnson, M.D., M.B.A. moved that the meeting be adjourned. The motion was seconded by Dr. Downs, voted upon and passed unanimously by the Board. The meeting adjourned at 4:00 p.m.

The Board's next meeting will be **Thursday, December 14, 2017** in Richmond, Virginia at the Wilton Center or the Gottwald Science Center Conference Room at the University of Richmond. The meeting will begin promptly at 10:00 a.m. At this meeting the Board will review the Concept Papers submitted, as part of the 2018/2019 grant process, and review the panel's recommendations regarding which ones should be developed into Full Proposals. The Board then will determine which Principal Investigators will be asked to submit Full Proposals.