Canadian Consortium on Neurodegeneration in Aging

Biological Samples Access Committee

Policy and Procedures for accessing biological samples

Version 1.0 approved by the CCNA Research Executive Committee on August 18, 2016

Version 1.1 Revised on September 26, 2018 (new PDAC policy)

Version 1.2 Administrative changes only – August 14 2020

1. Background

The purpose of this document is to present the Policies and Procedures governing the access to biological samples collected and stored by the Canadian Consortium on Neurodegeneration in Aging (CCNA). A limited quantity of irreplaceable biological samples will be available for refereed research purposes. The present Policy and Procedures are subject to change as they undergo interim evaluation by the CCNA Biological Samples Access Committee (BSAC) and Research Executive Committee (REC).

One of the goals of CCNA is the collection of biological specimens, including blood, urine, saliva and cerebrospinal fluid (CSF), from study participants. An accounting of the biological specimens available to the research community through CCNA will be maintained in the CCNA LORIS database (located at the Montreal Neurological Institute) and a summary of availability will be provided upon request to the CCNA Central Administration (ccna.admin@ladydavis.ca) As a starting point, a standard set of analyses of these samples has been determined by the *CCNA Biosamples Platform*, and these analyses will be carried out routinely as part of the CCNA study. *CCNA's Biosamples Platform* also determined the amount of biospecimen to be collected from each CCNA study participant. The resulting data will be documented and made available to CCNA investigators through the LORIS database. Access to these data will be adjudicated by the CCNA Publications and Data Access Committee (PDAC).

Researchers interested in gaining access to biological samples collected from CCNA study participants are required to apply for use of this limited resource to carry out analyses that:

- Are not included in the routine measurements established by CCNA's *Biosamples Platform*; and
- Demonstrable scientific promise and significance.

The process for allocation of this finite sample resource and the review of applications for samples will be managed by the BSAC.

It is not a requirement that researchers be associated with CCNA to be granted access to these samples. Samples requested may be used for identification of new biomarkers or for validation studies, including replication of findings. The use of CCNA biological samples for technology development or for comparisons among different technologies is not a priority for CCNA and will be considered only under exceptional circumstances. Requests describing other types of utilization of the CCNA biosamples will be handled on a case-by-case basis.

It is the BSAC and CCNA policy that an application made by a researcher for biological samples must include specific information and justification pertaining to:

- The exact amount of sample required;
- Any clinical or biomarker data requested for the proposed project in addition to the biospecimens. If data are requested, applicants will be asked to carefully review the CCNA PDAC policy (**Appendix 1**), included in the application and available at http://ccna-ccnv.ca/policies/ as they will be obligated to sign it before accessing data and samples, should their application be successful. The BSAC will liaise with the CCNA PDAC to discuss data access and coordinate requests;
- Certification of appropriate regulatory certificates, e.g., ethics, biohazard etc.; and
- Access to appropriate and current biological storage facilities that meet all regulatory requirements.

Upon BSAC approval of an application, and confirmation of compliance to regulatory requirements as listed above, CCNA will send the requested specific biosamples to the researcher along with information on data access, if applicable.

Researchers will be requested to update the BSAC on the status of the planned research at six-month intervals, with a formal progress review to occur every year. Any remaining biological material must be declared to the BSAC, with details about specific amounts. Unused biosample material remains in custody of CCNA. Future research carried out with remaining biosample material will be subject to conditions specified by CCNA.

It is also CCNA policy that when researchers have finished sample analyses, and subject to a one-year embargo to enable publication of the results, they must submit the results (e.g., raw biomarker data) to CCNA Central Administration (ccna.admin@ladydavis.ca) for uploading to the CCNA LORIS database. If necessary, and upon request from the researchers and approval from the BSAC, the one-year embargo period may be extended for an additional six months. Note that once these biomarker data have been entered into the CCNA database, they will become available to other researchers who wish to use them in their research.

2. BSAC Responsibilities

2.1. Establish policy and procedures for the disposition and allocation of the biological samples that are obtained from participants in CCNA studies. This includes the following features:

- Review and revision of these procedures as required;
- Development and updating of the application procedures;
- Monitoring of the availability of samples;
- Decision making about the disposition of specific samples as their supply changes; and
- Reporting on sample disposition to the CCNA Research Executive Committee (REC) through CCNA Central Administration (ccna.admin@ladydavis.ca).

2.2. Review of applications from CCNA and non-CCNA researchers for studies that propose to use CCNA biological specimens using the following criteria:

- Significance for advancing clinically useful biomarkers of neurodegenerative disease;
- Scientific quality of the proposal, including longitudinal design to fully exploit the value of CCNA biological specimens, and the availability of preliminary data demonstrating feasibility;
- The proposal does not duplicate biomarker measurements already being performed and available in the CCNA LORIS database. Applicants will be able to access the list of ongoing CCNA studies using participant's biological samples upon request to CCNA Central Administration (victor.whitehead@ladydavis.ca). In some cases, the BSAC will consult and coordinate with *CCNA's Biosamples Platform*, and/or *CCNA's Team 9: Developing New Biomarkers* (Team Leaders: Drs. Roger Dixon, University of Alberta and Pierre Bellec, Université de Montréal) to clarify any potential overlap with specific proposed measurements or proposed studies. Coordination with *CCNA Genetic Samples: DNA Sequencing and Genotyping Platform* (Platform Leaders: Drs. Peter St. George-Hyslop and Katherine Siminovitch, University of Toronto) may also be required in relation to genetic analysis or genotyping (e.g., novel polymorphism analysis);
- Prospective investigator(s) commit to data sharing as specified by the CCNA PDAC policy;
- The investigator(s) and environment can support high quality and timely analyses. Research funding that would ensure that the studies can be carried out successfully should be in place, or a plan to obtain funding based on the development of preliminary data should be in place; and
- The investigator agrees that the requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* will be adhered to in carrying out the proposed project and will ensure that a human ethics certificate has been obtained from the appropriate Research Ethics Board and any other required certificates as applicable (e.g., biohazards in accordance with The Laboratory Biosafety Guidelines of the Medical Research Council of Canada (2004), and animal ethics in accordance with the guidelines of the Canadian Council on Animal Care) are in place before carrying out the proposed project;
- The investigator will adhere to and comply with all applicable laws and regulations regarding protection of personal information, including provincial legislation concerning privacy and personal health information; and
- The investigator certifies that the biological specimens will not be sold, transferred to a third party, or in any way used for commercial purposes.

2.3. Make recommendations to the CCNA REC which will make the final decision on sample allocation. BSAC recommendations to the REC will fall in one of the four following categories:

- **Approve the application**: BSAC recommends that the CCNA REC approve the application and directs the Biorepository and Bioanalysis Centre to release specimens to the investigator;
- **Conditionally approve the application**: Minor modifications to the proposal are required prior to final approval;
- **Hold the application**: BSAC recommends that the application requesting biological samples be held for future re-evaluation. This intermediate category reflects applications thought to be meritorious, but of unclear significance with respect to expected future applications for these limited resources. Applications in this category will be re-evaluated in each session and possibly moved to the category above or below; or

- **Reject the application**: A brief reason for this decision will be provided or suggestions may be made for revision and resubmission of the proposal.

It should be noted that even after a positive BSAC recommendation, the CCNA REC may choose to withhold the release of biological specimens for programmatic considerations. If an application is rejected, an appeal in writing providing additional information can be made to the CCNA REC, through CCNA Central Administration. This will be sent back to the BSAC for further consideration and new recommendation to the REC.

3. Procedure for applying for access to biological specimens

3.1. Applications will be made to the CCNA BSAC, through CCNA Central Administration (ccna.admin@ladydavis.ca), on the CCNA Biological Samples Request Form (**Appendix 2**). This will include a brief description of the scientific question, rationale, measurements to be made, clinical data requested, justification for sample numbers and sample sizes, specific amount of biofluid requested (with justification), funding available to conduct the study, and plan for data analysis and dissemination. Manuscripts accepted for publication, published manuscripts, unpublished relevant materials, and submitted grants will be considered as appendix material. It is advisable that researchers submit a preliminary request for samples to ensure sample availability prior to the submission of a full application;

3.2. Applications will indicate whether access to clinical data associated with the biological specimens will also be requested. In that case, the BSAC will liaise with the CCNA PDAC to discuss data access and coordinate requests;

3.3. Applications will be reviewed by at least two members of the BSAC and discussed in teleconference with the full committee. *Ad hoc* reviewers will be added to the review teleconference as required. Consultation with CCNA's *Biosamples Platform* and/or CCNA Team 9 will take place as required to seek input on potential overlap in proposed measurements;

3.4. Decisions and comments on individual requests will be communicated to the CCNA REC quarterly. The CCNA REC will communicate their final decision to the applicants, through CCNA Central Administration;

3.5. The CCNA REC reserves the right to limit the sample size of the biological specimens and to authorize only partial allocation of the specimens requested;

3.6. Once an application for biological specimen allocation is approved, an abstract describing the project will be posted on the CCNA members portal of LORIS; and

3.7. Biological specimens will be provided free of charge, but the applicant will be responsible for shipping and handling fees.

4. Conflict of interest

The BSAC will follow the same Conflict of interest (COI) policy as CCNA International Scientific Advisory Board (ISAB) members (Appendix 3). Reviewers must declare any real or perceived COI with any application and in cases where a COI is acknowledged, they will recuse themselves from any review, discussion, or decision about that application.

5. Intellectual Property

Should any inventions, discoveries, new uses, processes, or compounds arise directly out of studies using the biological samples obtained from CCNA, they shall be owned by the inventing party in accordance with the institutional policies of the inventing party. Inventions jointly developed shall be owned jointly by the inventing parties in accordance with the institutional policies of the inventing parties; and the parties agree to negotiate in good faith a revenue-sharing agreement which reflects the respective contributions of the parties to the creation on an invention.

6. Acknowledgment

It is required that the source of biological samples obtained from CCNA be acknowledged in all publications and scientific presentations containing data derived from these samples. The following text is a template for this acknowledgment.

"***(Some of) the biological specimens used in this research were provided by the Canadian Consortium on Neurodegeneration in Aging (CCNA), which is supported by the Canadian Institutes of Health Research and other partners.***"

Appendix 1: CCNA Publications and Data Access Committee (PDAC) policy

Appendix 2: CCNA Biological Samples Request Form

Appendix 3: CCNA ISAB Terms of Reference and Conflict of Interest policy

Appendix 1

CCNA Publications and Data Access Committee (PDAC) policy

Canadian Consortium on Neurodegeneration in Aging

Publications and Data Access Committee Policy

Version 1.2

Approved by the CCNA Research Executive Committee on September 26, 2018

1. Principles

1.1. This document outlines the guiding principles and rules of engagement for the Publications and Data Access Committee (PDAC) policy ("the Policy") developed by the Canadian Consortium on Neurodegeneration in Aging (CCNA) PDAC, a sub-committee of the CCNA Research Executive Committee (REC). It delineates how the Policy will be operationalized to ensure the appropriate use and dissemination of CCNA data and appropriate credit for said use and dissemination;

1.2. The Policy is necessary to protect the reputations, interests and work undertaken by all CCNA investigators, their institutions, the Canadian Institutes of Health Research (CIHR) and other CCNA funding partners, and to foster and maintain trust between CCNA investigators and research participants;

1.3. The Policy aims to be fair, transparent and explicit, while enabling decisions and publications in a timely manner. Based on input from the CCNA Themes, Teams and Platforms Leaders, it will anticipate the majority of publication types and common publication scenarios but the REC will retain the right to make decisions, after consultation with the PDAC, for unforeseen publication scenarios;

1.4. The PDAC will develop and oversee the implementation of the Policy. Intended publications using CCNA acquired data must be reviewed by, and discussed with, the PDAC although this discussion need not require an in-person meeting of all parties (i.e., it could be conducted by email, telephone, WebEx etc.);

1.5. CCNA investigators will be encouraged to collaborate with other CCNA researchers in the use and analysis of CCNA acquired data, unless the relevant expertise is not available within the CCNA research community;

1.6. The PDAC will consist of a Chair and up to 10 CCNA Principal Investigators (PIs), who will be rotated as required; and

1.7. The PDAC will report to the CCNA REC.

2. Aims

2.1. The Policy is intended to maximize the impact and publicity for CCNA and to publish in a way that recognises the individual efforts throughout the length of the study;

2.2. CCNA will collectively be held accountable for any publication using CCNA acquired data until such time that the dataset has been publically archived; and

2.3. The Policy also provides a mechanism by which the CCNA REC and CCNA Central administration can maintain a central record of research outputs which is required for reporting to CIHR and other funding partners.

3. Expectations

3.1. It is anticipated that one/two major, high profile, CCNA publications that summarize the overall findings of the study will be written by the CCNA PIs, under the oversight of the CCNA Named Principal Investigator (NPI) and the REC. These major publications will be highly integrative with a broad authorship in accordance with the International Committee of Medical Journal

Editors (ICMJE) authorship criteria (http://www.icmje.org/recommendations/);

3.2. It is also anticipated that each Team, under the direction of their respective Theme Leaders, Platform and Cross-cutting Program Leaders, will write two to five major CCNA publications reporting the Team/Platform/Cross-cutting Program findings;

3.3. Co-investigators may also wish to take the lead on more detailed and specific scientific papers in selected Teams and Platforms. There may be multiple levels of other publications authored by some/all CCNA co-investigators on subsets of data, imaging and fluid biomarker correlations and more detailed analysis of the individual assessments. This will be the opportunity for CCNA PIs to conduct more detailed analyses, and for some investigators to have the opportunity to take lead roles or to work as part of a writing team. The CCNA REC also wants to acknowledge the hard work of the junior CCNA investigators, who should have the opportunity to author CCNA related publications. However, subsidiary papers must not undermine the impact or content of the major CCNA papers; and

3.4. It is anticipated that all CCNA publications will be in line with the CIHR, NIH, and European Association of Science Editors guidelines for reporting on sex differences, and where appropriate gender differences, in human participants, cell lines, and experimental animals. Briefly, these guidelines include the following recommendations:

3.4.1. Exercise care in the terminology used to describe research methods and explain results in order to avoid confusing sex with gender;

3.4.2. If only one sex is included in the study, the title as well as the abstract should specify the sex of animals or any cells, tissues, and other material derived from these, and the sex of human participants;

3.4.3. Where appropriate, it should be reported if sex and/or gender differences are expected;

3.4.4. How sex and gender were taken into account in the design of the study should be clearly stated, including reporting of representation of males and females;

3.4.5. Data should be routinely presented disaggregated by sex. For animal studies, the numbers of animals from each sex must be indicated. For human studies, the number and percentage of men and women who participated in the research study should be reported;

3.4.6. Where appropriate, meaningful sex/gender based analyses should be reported regardless of positive or negative outcomes; and

3.4.7. The reasons for lack of any sex or gender considerations should be justified and if there is no strong scientific rationale for the exclusion of one sex, this should be covered as a limitation.

4. Revisions of the CCNA Publications and Data Access policy

4.1. The Policy will be formally reviewed annually by the PDAC and the REC to confirm alignment with the CCNA's overall mission, objectives and policies and procedures;

4.2. The Policy will be reviewed and may be revised by the PDAC at any other time, for approval by the REC, if there are:

4.1.1. New members, departing members, or significant changes in the responsibilities of a

current member of the CCNA REC or PDAC;

4.1.2. Changes to key committee or core CCNA membership including Theme, Team, Platform and Cross-cutting Program Leaders;

4.1.3. Changes in the CCNA research sites; or

4.1.4. Changes to relevant CCNA policies and procedures or other aspects of CCNA, as deemed relevant by the PDAC or the REC.

5. Data use and analysis

5.1. A distinction is made between publication and data analysis.

5.1.1. The Policy does not in itself restrict analysis of CCNA data, which might be with a view to publication but which might also be for training purposes, quality control, exploratory analysis, methods development or other reasons; and

5.1.2. Where data relate to the specific protocol or overall aims of CCNA, publications may not be made independent of CCNA or be outside of the Policy.

5.2. The clinical, neuropsychological, imaging, biomarker and genomic data from each clinical site or laboratory within CCNA will be managed and uploaded centrally to the LORIS database. Other types of data, such as those derived from *in vitro* or *in vivo* model systems will also be uploaded to the LORIS database. Access to data and tissue samples for analysis is subject to this Policy (for data) and to the CCNA Biological Sample Access Committee (BSAC) Policy (for samples) overseen by the PDAC and the BSAC, respectively.

5.3. Internal analyses at each participating CCNA site may be undertaken as follows:

5.3.1. Internal analyses of locally acquired data must be overseen by a CCNA site PI; and

5.3.2. Local analyses of CCNA data may be undertaken for quality control, training or exploratory purposes, but the publication of these should adhere to this Policy. This is to prevent redundant analyses or competitive publications between CCNA members. Local analyses that may be of interest and relevance to the broader CCNA membership can be brought to the attention of other members.

5.4. Linked projects: It is recognized that some data and samples may be duplicated between CCNA and local non-CCNA studies e.g., DNA sequencing data, structural images, neuropsychological scores;

5.5. Access to and analyses of CCNA acquired data by CCNA investigators, stored into LORIS and as part of the COMPASS-ND study, will be granted automatically to CCNA investigators upon request of access. CCNA investigators will provide a project/publication summary to CCNA Central Administration (ccna@ladydavis.ca) **by December 31, 2017**, prior to pursuing projects based on COMPASS-ND data. This will constitute a writing plan for CCNA for the first 12 month after the COMPASS-ND cross-sectional data have been collected, uploaded into LORIS and locked. This 12 month period is hereby referred to as "the quarantine period". The list of "Protected planned projects and publications" will be posted on LORIS and on the CCNA website by January 15, 2018;

5.6. All CCNA investigators are expected to honour the priority of the list of "Protected planned

projects and publications" prepared by CCNA Teams and Platforms that designed the study and developed specific questions in order to answer their Team's of Platform's hypotheses. Carrying out these specific projects and publishing their results represents a large portion of the deliverables specified in the CCNA grant application;

5.7. Any CCNA investigator who wish to analyze and subsequently publish data related to a question already listed in the "Protected planned projects and publications" must apply to join the designated CCNA Team's writing group or wait until the quarantine period has passed;

5.8. There is no quarantine period to study and publish on research questions not recorded in the "Protected planned projects and publications" list. However, all CCNA investigators intending to study and publish on such research questions must submit to the PDAC, via CCNA Central Administration (ccna@ladydavis.ca) and at the earliest possible time before engaging in a specific project, a summary of the project envisioned to ensure that there is no overlap or duplication with a previously proposed project. Data requests must be submitted to ccna@ladydavis.ca using the CCNA Data Request Form (available upon request);

5.9. After the quarantine period, any CCNA investigator can undertake/publish research on any question that has not been addressed yet. To do so, the CCNA investigator must submit to the PDAC, via CCNA Central Administration (ccna@ladydavis.ca), a summary of the project/publication proposed. The PDAC will verify that the project has not already been submitted by a CCNA Team of Platform and, as such, is not listed in the "Protected planned projects and publications";

5.10. For non-CCNA investigators, CCNA data will be quarantined for 12 month after the entire cohort has been completed, uploaded into LORIS, quality-controlled and cleaned, and subsequently locked;

5.11. After the quarantine period, non-CCNA investigators may be granted access to CCNA acquired data upon submission of background materials and of a project outline supporting their data access request. They will only be granted access to data related to the project outlined. Where there is an actual or potential conflict of interest, the non-CCNA investigator should discuss the case with the PDAC;

5.12. CCNA partners will have the same access to CCNA acquired data as non-CCNA members, although they may ask CCNA investigators to pursue projects on their behalf; and

5.13. If there is disagreement or uncertainty about granting access to data, the case may be referred to the CCNA REC.

6. Publication and authorship

6.1. Manuscript publication

6.1.1. All manuscripts must be reviewed by the PDAC before they can be submitted. This review will ensure that confidentiality is protected; that the publication will not bring the study into disrepute; and that the publication is a fair representation of CCNA and of

the contribution of investigators. It will also provide advice and feedback to authors where it may be helpful;

6.1.2. Members of the PDAC may delegate the review of manuscripts to one individual in their research team but the member has responsibility for their comments and for reporting their decision back to the PDAC on time;

6.1.3. All authors considering publications of research funded by CCNA are to submit a brief outline to the PDAC. The corresponding author(s) shall forward a late draft of their publication to the PDAC at least four weeks prior to the intended submission. A late draft implies a document that is approaching readiness for submission, and which would ordinarily be circulated among co-authors. The late draft will not vary substantially in its use of data, principal analyses or theoretical content from the final submitted version, i.e., the final version should be easily recognized from the late draft, while permitting authors to correct, clarify and amend the paper in its final stages;

6.1.4. The PDAC will review all such material within three weeks of acknowledging its receipt, and confirm approval to submit for publication, subject to any necessary amendments, to the lead author(s). It will be the responsibility of the lead author(s) to (i) notify the REC (through CCNA Central administration) of the acceptance of any manuscript and forward a copy of the final version, together with details of the name of the journal where the manuscript has been accepted, and (ii) to ensure that all conditions with respect to publication have been met and appropriate acknowledgements are included;

6.1.5. The PDAC will not review or veto non-CCNA publications, but the non-CCNA PI should describe the nature and scope of the data and analysis, to satisfy the PDAC that the non-CCNA publication is not a duplication of the aims and methods of CCNA funded research; and

6.1.6. Publications will be Open Access within six months of publication, in accordance with CIHR policies. http://www.cihr-irsc.gc.ca/e/46068.html.

6.2. Conference participation (including presentations, posters, and conference papers)

6.2.1. All authors considering submitting conference abstracts based on data from the CCNA study will need to obtain the support of at least one CCNA PI. Responsibility for the presentation materials lies with this PI, who must give final approval of materials to the lead author(s) before the conference. The lead author(s) shall notify the CCNA Central administration of the acceptance of any conference abstracts with the date of the meeting and presenting author;

6.2.2. The lead author(s) shall forward a late copy of any poster presentation and final abstract to the PDAC; and

6.2.3. It will be the responsibility of the lead author to notify the PI of the intended date of publication of any abstract arising from the CCNA study and to ensure that all conditions with respect to publication have been met and appropriate acknowledgements are made.

6.3. Authorship requirements and formats

6.3.1. It is anticipated that one/two major high profile CCNA publications that summarize the

overall findings of the study will be written by the CCNA PIs under the lead of the CCNA NPI and REC. It is also anticipated that each Team and Platform Leader, under the direction of their respective Theme Leaders, will write two to five major CCNA publications reporting the Team/Platform findings. These major papers will be highly integrative with a broad authorship;

6.3.2. Where journals permit, these papers will list as authors all PIs and all other researchers who have made a scientific and/or clinical contribution, sufficient to justify authorship under the ICMJE criteria. The order of authors will be decided by the PIs under the direction of the PDAC, with any disputes referred to the REC. The principles underlying authorship order will be i) in approximate distribution by centre balancing contribution to different stages of investigation, analysis, writing and ii) otherwise alphabetic order except first and last author; and

6.3.3. Some journals limit the number of authors. In this case, the authorship will be decided by the CCNA PIs most responsible for the work under the oversight of the PDAC to include the individual(s) who have contributed most to writing the manuscript, the PIs representing each participating centre, and a limited number of other authors by nomination and discussion with the PDAC. In this instance a final corporate author reflecting the CCNA collaboration will be considered e.g., "and the CCNA study group".

6.4. Subsidiary publications

6.4.1. Co-investigators may also wish to lead on more detailed scientific publications on selected data groups. There may be many publications authored by some/all CCNA co-investigators on subgroups of data, imaging correlations and more detailed analysis of the individual assessments;

6.4.2. This will be the opportunity for local PIs to do more detailed analyses, and to enable several people to take lead roles or to work as part of a writing team;

6.4.3. Junior research staff across several sites should also have the opportunity to author papers;

6.4.4. For subsidiary publications/presentations, the lead author(s) will identify those individuals who have made a significant contribution and propose the order in which their names should appear in the author list. Approval for manuscript publications and poster publications authorship will be given by the PDAC;

6.4.5. Subsidiary publications must not undermine the impact or content of the principal publications;

6.4.6. No advanced approval is required for authorship list for conference presentations, but the principles of authorship and recognition for contributions to publications should be upheld;

6.4.7. The developers of new methods that underpin CCNA should be named authors on either the first three publications that use the method, or on all publications that benefit from the method within three years of the method's first use, unless an argument can be made against this guideline; and

6.4.8. The developer(s) is strongly encouraged to publish the method soon after its development. This will be subject to the same publication process as above.

7. Publicity

7.1. Press releases must refer to CCNA. Any parties considering dissemination (including press releases) of the details of the research and/or results should notify the PDAC (via CCNA Central administration) of such intent and submit a draft for approval;

7.2. The PDAC will review all such outlines within 14 days of acknowledging its receipt, and notify of approval, subject to any necessary amendments, to the lead author;

7.3. In situations where a faster response is required (e.g., unexpected press interest), the request should be made directly to the CCNA NPI (with cc to the CCNA Central administration) for executive decision;

7.4. It will be the responsibility of the lead author to notify the CCNA Central administration of the intended date of any such publication and to ensure that all data conditions with respect to publication have been met and appropriate acknowledgements are made (see section 8 for details); and

7.5. All members of CCNA must adhere to publications embargos.

8. Acknowledgements

8.1. The public web address for the CCNA study may be given as www.ccna-ccnv.ca;

8.2. Statements and acknowledgements to be included in publications

8.2.1. Funding of the CCNA by CIHR and other funding partners must be acknowledged;

8.2.2. Exact wording may vary depending on the journals and the type of publication, but a default statement is: *The Canadian Consortium on Neurodegeneration in Aging is supported by a grant from the Canadian Institutes of Health Research with funding from several partners.* The CCNA Central administration will ensure that the relevant CCNA funding partners are acknowledged in the manuscript when reviewing the document before it is submitted to journals;

8.2.3. A statement of ethical approval should be included in all papers e.g., *This study received local approval from the participating centre(s)' Research Ethics Committee or Institutional Review Board*;

8.2.4. Other acknowledgements may refer to local or national bodies that have significantly funded or contributed to the research or the funding agencies for PIs in the case of additional CCNA leveraged grants, e.g., from private foundations; and

8.2.5. Some journals request an author note to outline the contributions of all the authors. The wording of such as statement should be drafted by the lead authors, discussed and agreed by all co-authors, with oversight and arbitration where necessary by the PDAC.

Signed acceptance of the CCNA Publications and Data Access Policy

After reading this document, please sign and return an electronic copy to the CCNA Central Administration (ccna@ladydavis.ca) to confirm that you agree to its content.

Name (please print): _____

Institution: _____

Team/Platform/Cross-cutting Program number and title: _____

I, the undersigned, acknowledge that I have read and understood this document and agree with its terms and conditions.

Signature: _____

Date: _____

Appendix 2

CCNA Biological Samples Request Form

CCNA Canadian Consortium on Neurodegeneration in Aging

CCNV Consortium canadien en neurodégénérescence associée au vieillissement

CCNA Biological Sample Request Form

Administrative information

Applicant information

Project Leader's Information		
Name:	Affiliation/Organization:	
Address:	City:	Province:
Email address:	Phone Number:	

Project Information	
Project title:	
Short title (5 words or less):	
References relevant to proposed project:	
1	
2	
3	
4	
5	

CCNA information (if applicable):
CCNA Team/Platform/Cross-cutting program name/number:
Team/Platform/Cross-cutting program leader name:

Collaborator information

List all collaborators with this proposal		
Main collaborator:	Name:	Affiliation:
	Email address:	
Other cllaborator:	Name:	Affiliation:
	Email address:	
Other collaborator:	Name:	Affiliation:
	Emailaddress:	

Proposed timeline

Date of project initiation (mm/dd/yyyy):
Date of project completion (mm/dd/yyyy):

Purpose of request

☐	New study
☐	Existing study

Type of biological sample requested (Please refer to inventory for availability – all aliquots are 0.5ml)

☐	Blood		
☐	Serum	Number of aliquots requested:	Diagnostic information (as per inventory):
☐	Plasma	Number of aliquots requested:	Diagnostic information (as per inventory):
☐	Buffy coat	Number of aliquots requested:	Diagnostic information (as per inventory):
☐	Saliva	Number of aliquots requested:	Diagnostic information (as per inventory):
☐	CSF	Number of aliquots requested:	Diagnostic information (as per inventory):
☐	Other	Number of aliquots requested:	Diagnostic information (as per inventory):

Do you have funding for the proposed study?

☐	Yes – please state all funding sources
	Start date (mm/dd/yyyy):
	End date (mm/dd/yyyy):
	Grant title:
	Name of funding agency/source
☐	No
☐	Other (e.g., grant application):

Research proposal

Please provide a description of the proposed research for which you are requesting biospecimens from CCNA
(Proposal should not exceed three pages, excluding tables, figure and references)

Background – including specific hypotheses:

Specific aims

Preliminary data

Methods

a) Inclusion/Exclusion criteria

b) Data analysis

Deliverables, timeline and future studies

Signature page

I, the undersigned, certify that, in the performance of the project for which access to CCNA biological samples is hereby requested:

1- **(if Canadian researchers):** I will adhere to the requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and will ensure that a human ethics certificate has been obtained from the appropriate Research Ethics Board and any other required certificates as applicable (e.g., biohazards in accordance with The Laboratory Biosafety Guidelines of the Medical Research Council of Canada (2004), and animal ethics in accordance with the guidelines of the Canadian Council on Animal Care).

2- **(if non Canadian researchers):** I will ensure that a human ethics certificate has been obtained from the appropriate Research Ethics Board and any other required regulatory certificates as applicable (e.g., biohazard, animal care etc.) in my country.

3- I will comply with all applicable laws, regulations and guidelines regarding protection of personal information, including provincial legislation concerning privacy and personal health information.

4- **I have read, understood, and signed the CCNA Publications and Data Access Policy (included)**

5- **I have read, understood and signed the CCNA Biological Sample Access Policy (included)**

X _____

Appendix 3

CCNA ISAB Terms of Reference and Conflict of Interest policy

Terms of Reference and Non-Disclosure Agreement for the CCNA International Scientific Advisory Board (ISAB)

Version 1.1

Minor administrative modifications approved by CCNA's Scientific Director, Dr. Howard Chertkow (September 20, 2019)

1. Name

Canadian Consortium on Neurodegeneration in Aging (CCNA) International Scientific Advisory Board (ISAB)

2. Preamble

The CCNA aims to coordinate and strengthen Canadian research on Alzheimer's disease (AD) and other neurodegenerative disorders (NDDs) by fostering innovative and collaborative research across Canada. Through a series of inter-related teams organized around research areas supported by cross-cutting programs and national platforms, the overall objectives of the CCNA are to carry out transformative research that advances our understanding of the biology, natural history, presentation, management, and consequences of AD and other NDDs, resulting in new and better forms of prevention, treatment, and coping with these diseases.

The research teams are organized under three thematic headings: 1) mechanisms and primary prevention; 2) treatment/secondary prevention; and, 3) quality of life. Cross-cutting programs supporting the overall initiative include the following programs: 1) Training and Capacity Building (TCB), 2) Knowledge Translation and Exchange (KTE), 3) Ethical, Legal, and Social Implications (ELSI), 4) Women, Sex, Gender, and Dementia (WSGD), 5) Engagement of People with Lived Experience of Dementia (EPLED), along with 6) the Indigenous Cognitive Health Program. The national platforms will facilitate research and create opportunities for collaboration. They include the following platforms: 1) Clinical Cohorts Study on Dementia Assessment (COMPASS-ND), 2) LORIS – Database and Information Technology, 3) Clinical Cohorts Study on Dementia Prevention (CAN-THUMBS UP), and 4) Neuroimaging – a National Standardized MRI Dementia Protocol.

3. Terms of Reference

3.1. Authority

The CCNA ISAB reports to the Research Executive Committee (REC) of the CCNA. The REC includes the Scientific Director (Chair), the directors and co-directors of the three themes, along with key Principal Applicants representing the platforms and crosscutting programs.

3.2. Purpose

The main functions of the ISAB include:

- Advising to ensure that the research programs and associated projects of the CCNA meet high international standards of scientific excellence;
- Offering advice to the CCNA REC to capitalize on evolving research opportunities, technologies, potential research partnerships and/or collaborations, and funding opportunities; and
- Prior to the end of the end of the third year of the CCNA initial funding period, conducting a "mid-term review" that will consist of assessing all teams, cross-cutting programs, and platforms on their progress in achieving the milestones and deliverables agreed upon and, when appropriate, providing recommendations for modifying the research plan and/or adjusting the funding allocated. Recommendations could include terminating the activities of a team, cross-cutting program, and/or platform.

3.3. Membership

- The ISAB will be constituted of internationally recognized figures in AD and NDD research. The Chair, co-Chair (if applicable) and other members will be appointed by the CCNA REC and will reflect expertise from across relevant disciplines;
- The ISAB will not exceed 10 members, with the majority from outside Canada; and
- *Ad hoc* meeting participants, selected for their specific expertise or knowledge pertinent to the mandate of the ISAB, may be invited by the Chair/co-Chair or the CCNA REC to provide advice on a specific topic.

3.4. Terms of appointment

- Members will be appointed for three-year terms renewable for an additional three-year term to a maximum of six years if relevant, i.e., if the CCNA's activities continue into a second five-year term (2019-2024);
- A member may withdraw at any time upon written notification to the Chair/co-Chair and the CCNA REC; and
- A member may be relieved of their appointment for just cause (e.g., non-attendance, disclosure of confidential information, breach of conflict of interest guidelines) by the CCNA REC effective upon written notification.

3.5. Meetings, quorum, and other functions

- The ISAB will meet by teleconference/videoconference with the CCNA REC and Scientific Director twice a year and members will be invited to attend the annual Partners Forum/Scientific meeting of CCNA researchers;
- In the third year of the CCNA initial funding period, an in-person meeting will take place to conduct the mid-term review (see section 1.2); and
- A majority (50 percent plus one) of the ISAB shall constitute a quorum. The ISAB will strive to make decisions by consensus.

3.6. Compensation

- ISAB members will be reimbursed for reasonable travel and accommodation expenses incurred in attending meetings, in accordance to the CCNA Travel Expense Policy; and
- ISAB members will be provided with an honorarium of CDN $2,000 for the

work associated with conducting the mid-term review.

3.7. Secretariat

- A record (i.e., minutes) of the discussion and any recommendations made during meetings will be produced. Minutes will be circulated to ISAB members after each meeting. This responsibility will be assumed by the CCNA staff.

3.8. Review of Terms of Reference

- The CCNA REC will review and make changes to these terms of reference a year after the ISAB begins meeting and as needed subsequent to this.

The undersigned member of the ISAB acknowledges and agrees to the following principles regarding confidentiality and conflict of interest.

4. Confidentiality

I understand that certain types of confidential information, e.g., personal information, confidential commercial information, etc. will be disclosed to me. I therefore agree to the following:

- All materials and information supplied by, or on behalf of the CCNA, or which I receive in my capacity as a member of the CCNA ISAB, whether disclosed in written, graphic, photographic, recorded, projected, or verbal form, shall be regarded as "Confidential Information", unless this information has already been publicly disclosed;
- I shall neither disclose such Confidential Information, or any part thereof, to any third party, nor shall I use such Confidential Information for my own personal gain or benefit or for any purpose other than in connection with the activities of the ISAB. I shall protect and maintain as confidential any information divulged during the work of the ISAB;
- Confidential Information shall not be reproduced in any form;
- All Confidential Information in my possession, including electronic and word processing records, shall be securely stored at all times to prevent unauthorized access and must be transmitted using secure techniques;
- For meetings of the ISAB that are held by teleconference, I shall make every reasonable effort to ensure that a secure line is used; and
- At the end of my term on the ISAB, all Confidential Information in my possession will be returned to the CCNA offices or securely destroyed. Any loss or theft of confidential documentation shall be reported to the CCNA.

5. Conflicts of Interest

I understand that ISAB members are expected to conduct themselves in an appropriate manner, i.e., use of their positions cannot be reasonably construed to be for their private gain, or that of any persons of organization, and a real, apparent or potential conflict of interest exists when my personal or financial interests affect, or may be perceived to affect, my objectivity. Accordingly, I acknowledge that I must refrain from any conflict of interest and, indeed, its appearance. In the event that a real, apparent or potential conflict of interest arises or is discovered or recognized, I will make immediate full disclosure of the nature and scope of this conflict to the CCNA REC.

I recognize that situations giving rise to possible conflicts of interest include, but are not limited to, the following circumstances:

- I am in a position to gain or lose financially/materially from the information being shared/reviewed as a member of the CCNA ISAB;
- I have a close professional or personal relationship with a member of the REC of the CCNA; or
- I have a direct or indirect financial interest in the information being shared/reviewed.

6. Disclosure and compliance measures

Any ISAB member who becomes aware of a conflict of interest must promptly disclose the conflict to the CCNA. The CCNA will determine if it constitutes a conflict of interest and what measures – such as recusal – are required. Such disclosures and compliance measures shall be documented and retained for the record.

I, the undersigned, have read and understood the role of the CCNA ISAB members and the provisions regarding Confidentiality and Conflicts of Interest and agree to adhere to the conditions described herein and take personal responsibility for complying with these requirements

_____

Signature

_____

Name (print)

_____

Date