



## **Canadian Consortium on Neurodegeneration in Aging**

### **Publications and Data Access Policy**

**Version 1.0**

***Approved by the CCNA Research Executive Committee on August 7, 2015***

## **1. Principles**

- 1.1. This document outlines the guiding principles and rules of engagement for the Publications and Data Access policy ("the Policy") developed by the Canadian Consortium on Neurodegeneration in Aging (CCNA) Publications and Data Access Committee (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/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;
- 3.4. It is anticipated that the first publications will be written in the spring of 2016, although technical papers or protocol descriptions might be publishable earlier. A declaration of priority papers by PIs is expected by April 2016; and
- 3.5. It is anticipated that all CCNA publications will be in line with 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:

- 3.5.1. Exercise care in the terminology used to describe research methods and explain results in order to avoid confusing sex with gender;
- 3.5.2. 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;
- 3.5.3. Where appropriate, it should be reported if sex and/or gender differences are expected;
- 3.5.4. 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;
- 3.5.5. 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;
- 3.5.6. Where appropriate, meaningful sex/gender based analyses should be reported regardless of positive or negative outcomes; and
- 3.5.7. 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 reviewed and may be revised by the PDAC, 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 and platform leaders;
  - 4.1.3. Changes in the CCNA research sites; or
  - 4.1.4. Changes to relevant CCNA policies and procedures.

#### **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 Sample Access policy (for samples) overseen by the PDAC and the CCNA Sample Access Committee (CSAC), 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 will be granted automatically upon request of access. CCNA investigators must provide a project/publication summary prior to pursuing said project;
- 5.6. For non-CCNA investigators, CCNA data will be embargoed for one (1) year after the entire cohort has been completed, uploaded into LORIS, quality-controlled and cleaned, and subsequently locked;
- 5.7. After the embargo period, non-CCNA investigators may be granted access to CCNA acquired data upon submission of background materials and of a project outline

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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;

5.8. 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

5.9. 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](http://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 Institute 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 a 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 c/o Pascale Léon, Managing Director and Chief Operating Officer, CCNA (pascale.leon@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: \_\_\_\_\_