Curing Coma Campaign Policies

1. Mission Statement

The Curing Coma Campaign (CCC) was developed by the Neurocritical Care Society (NCS) with the goal of improving the lives of patients with Disorders of Consciousness (DoC) and coma resulting from severe acute neurological conditions. The plan is to accomplish this by advancing the science of coma and DoC through new research endeavors and advancing the clinical care of patients through education and outreach. This is recognized as a "grand challenge" that will bring together many collaborators across these domains and will only succeed if there is open and enthusiastic cooperation in research, education, and outreach endeavors. It is the stated principles of the CCC that aspects that derive from the work done collaboratively be available for open use by CCC participants, be recognized as collective work of the CCC, and that CCC participants receive appropriate credit for their work and participation. It is anticipated that aspects may potentially arise in several different domains including research data, publications, educational or other outreach product development, and intellectual property from inventions. Each CCC participant is expected to abide by the principles in this Policy document as allowable based on restrictions from their primary employer (most often a university).

2. Roles and Responsibilities

Many individuals are involved in the CCC in a variety of different roles. Each specific role has unique duties, obligations and responsibilities. This includes members who serve on the CCC scientific steering committee, scientific advisory committee and working groups, CCC modules, and sites and individuals who enroll patients in research studies and registries. This Policy document is intended to apply uniformly across all participants. The specific governance structure of the CCC is described below.

- **a. CCC Project Executive Committee (the "CCC-EC")**. The CCC-EC (also known as Mission Control) will have a minimum of six (6) members, is responsible for overall direction of the CCC and is the final arbitrator for decisions and dispute resolution for CCC issues.
- **b.** CCC Project Scientific Steering Committee (the "CCC-SSC"). The CCC-SSC consists of all of the members of the CCC-EC plus a minimum of six (6) additional members. The CCC-EC has the power to make any changes to the size, membership and duties of the CCC-SSC. Members of the CCC-SSC are responsible for the overall scientific direction and strategy for the CCC.
- c. CCC Project Scientific Advisory Committee (the "CCC-SAC"). The CCC-SAC consists of all members of the CCC-SSC as well as additional members convened at the initiation of the CCC (Vancouver 2019 NCS meeting) and added as necessary. Members of the CCC-SAC are responsible for attending periodic calls and meetings of the entire CCC-SAC to review status, re-assess research, and help frame the long-range scientific agenda of the CCC. Specific scientific working groups will be developed out of the CCC-SAC and will include members beyond the CCC-SAC as needed to accomplish the mission of the CCC.

- **d. CCC Project Modules.** The CCC includes distinct operational modules (eight (8) at the initiation of the CCC), each having a specific focus related to execution of the various aspects of the mission of the CCC. Each Module has two co-leads who are responsible for ensuring active participation of Module members and completion of Module responsibilities as defined in the CCC Manual of Procedures. Each Module should include a minimum of five (5) members including co-leads.
- e. Member Sites. Individual institutions may contribute to the CCC through studies that involve submission of data at the individual patient-level, provider-level, or overall institution. Each Participant Site will have a designated Principal Investigator (PI) who will be responsible for coordinating CCC research activities at that institution.
- **f. CCC Project Collaborator ("Collaborator").** Individuals may participate in the mission of the CCC in a variety of ways that may include membership in the above noted committees, as a member of a scientific working group or module, or as a member site for the CCC to contribute research data or participate in educational or outreach activities. Every individual participant who contributes to a CCC Project, and/or CCC Project work products, is deemed a Collaborator.
 - i. In addition to their other roles and obligations, each Collaborator agrees that as a participant in the CCC, the Collaborator will be open with ideas and will share results of their individual research efforts related to coma with the various CCC Committees, including: data, conclusions, intellectual property conceived, and publications.

3. Publication and Authorship Guideline.

The purposes of these publication and authorship guidelines are three-fold: (1) to maximize production of manuscripts from the work of the CCC; (2) to ensure that those who do the work and the writing receive credit for their contributions; and (3) to acknowledge that the CCC is a large collaborative body whose success as a whole and on many individual projects is related to work across the CCC for which broad recognition is appropriate. Peer-reviewed manuscripts are expected to arise from work of the CCC and this is strongly encouraged in order to disseminate the work of the CCC and advance the science relevant to coma and DoC. The overall goals of the CCC publication guideline are to ensure that manuscripts are published in a timely manner and that CCC Collaborators receive credit for their participation in a manner commensurate with their work on the specific manuscript and its place within the CCC as a whole. Additional goals are to encourage more junior members to serve leadership roles in CCC authorship and to advance equity and diversity in authorship.

a. This guideline addresses three major types of manuscripts. Primary manuscripts are those that arise directly from work conducted by and led through the Curing Coma Campaign. Secondary manuscripts are those in which the Curing Coma Campaign participates as a collaborative group in a project led by another group. Tertiary manuscripts are those in which data collected as part of the Curing Coma Campaign is provided for external analysis. All data presentations, including abstracts, oral presentations, and posters, are encompassed by the term "manuscript."

- **b.** The CCC-EC will serve as the Publications Oversight Committee. All publications arising from the CCC will be reviewed by the CCC-EC prior to submission for publication. This role may be revisited and transferred to another group within the CCC as publications become more frequent.
- **c. Primary manuscripts** may arise from the work of specific working groups and modules within the CCC or other groups. The following process will be followed for development of CCC Primary Manuscripts.
 - a. Prior to development of a publication, the responsible working group or module will create an author list of named authors based on contributions to the work and the manuscript as well as a proposal for authors to be included under the heading *Curing Coma Campaign collaborators*. Identification of a junior CCC member as first author and manuscript architect is encouraged.
 - i. This authorship list, including the first author, senior author, primary manuscript architect (if different than the first or senior author), and those to be included as *CCC collaborators*, will be reviewed and approved by the CCC-EC. Adjudication or review may be requested by the CCC-EC with the SSC, SAC, working group, or module leaders in order to clarify authorship contributions. The overall intent is to be inclusive, not exclusive, with authorship.
 - ii. Primary Authorship, denoted as those on the first line(s) of the authorship attribution in a journal and in indexing services, will be based on appropriate effort as defined in the guidelines published by the International Committee of Medical Journal Editors (ICMJE). Primary authors should meet all four of the following criteria:
 - 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
 - 2. Drafting the work or revising it critically for important intellectual content; AND
 - 3. Final approval of the version to be published; AND
 - 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- **d.** Primary manuscript authorship credit will be granted to the primary authors *with the Curing Coma Campaign collaborators as an author*. Following the list of primary authors, all publications arising from the Curing Coma Campaign will bear the following attribution: "and the Curing Coma Campaign collaborators" listed in a table or supplementary table provided as part of the manuscript submission. The intent of this is to broadly recognize the contributions to various aspects of the CCC that make group and individual work possible.

- i. Depending on the nature of the article, this list of collaborators will include members of all or specific CCC committees, scientific working groups, and modules and, if the manuscript involves data collected from participating CCC sites, representatives of each contributing site as well.
- ii. It may be appropriate to recognize a specific CCC scientific working group or module as authors, with the listing of all CCC collaborators (per d.i. above) as an acknowledgement in a supplementary table. This will be determined by the primary authors and the CCC-EC at the time of manuscript development.
- iii. For manuscripts that involve data contributed from specific institutions (Member Sites), the manuscript corresponding author will coordinate with the PI of each contributing institution to obtain a list of personnel at that site who should be named as a collaborator for the specific manuscript. This list will be at the discretion of the Participant Site PI, but should include key personnel directly involved in the conduct of the study at the site.
- iv. Prior to submission of any Primary Manuscript for peer review, the CCC-EC will re-review the authorship list with the manuscript corresponding author.
- e. Secondary manuscript authorship will be determined by the principle organization performing the work with whom the CCC is collaborating. An attribution "and the Curing Coma Campaign collaborators" will be strongly encouraged and follow the above process.
- **f.** As a condition of use of CCC data for tertiary manuscripts, at least one named author from the CCC will be required as well as the attribution "and the Curing Coma Campaign collaborators" according to the above process.
- **g.** These publication and authorship guidelines will be reviewed after the publication of the first three Curing Coma Campaign primary manuscripts in which they were used, in order to assess whether these guidelines are achieving their intended goals or should be revised.