Publications Policy for the P-ICECAP Trial

Purpose

To define guidelines for preparing, reviewing, submitting and maximizing productivity of high-quality peer-reviewed publications for the P-ICECAP Trial.

Responsible Individuals

Trial PI, Trial PI designee, designees from the SIREN Clinical Coordinating Center (CCC), SIREN Data Coordinating Center (DCC), P-ICECAP Executive Committee including Publications Committee, and the Scientific Program Director from NIH.

Study-Specific Publication Procedure – Publications Committee

The goal of this policy is to maximize productivity of high-quality peer-reviewed publications. For each trial carried out in collaboration with SIREN, a Publications Committee will be formed immediately after the Notice of Award is obtained. The charge of this Committee is to encourage paper production, ensure timely publication of data, maintain a high standard for the quality of papers, determine appropriate authorship and to review new study concepts, and recommend and prioritize publications when appropriate. This Committee will be chaired by the Trial PI and include individuals selected by the Trial PI who were instrumental in drafting the study protocol and conducting the research. The Committee will also include a member of the SIREN Clinical Coordinating Center (CCC), a member of the SIREN Data Coordinating Center (DCC) and the Scientific Program Director from NIH. At a minimum one site PI will also serve on the Publications Committee and an appropriate individual will be chosen for each study.

Manuscript proposals and completed papers will be submitted to the Publications Committee at two time points. First, concept proposals that include the designation listed below as primary, secondary, etc., list of authors and their qualifications for authorship, a statement that no others deserving authorship have been omitted, the scientific rationale for the paper, and the data needed will be submitted. After approval, the final paper will be reviewed prior to journal submission to ensure that statements made at the time of the paper proposal were carried forward in manuscript formation; the Committee will also verify acknowledgement of grant sources, contributing sites and personnel, and the SIREN network and ensure that the final manuscript meets the highest standards regarding scientific rigor, thoroughness, clarity, and full disclosure of conflicts of interest.

Publication Priority

Papers will be divided into primary, secondary, tertiary and quaternary manuscripts defined as follows. These designations are important to the Publications Committee since primary and secondary papers should be published early and authored by the Trial PI and colleagues.

Primary: Primary papers are pre-specified as including the primary outcome data of the trial as described in the grant application.

Secondary: Secondary papers are defined as containing the secondary, prespecified data as described in the grant application.

Tertiary: Tertiary papers are post-hoc analyses that relate to the central hypotheses being tested but may not have been pre-specified in the grant application.

Quaternary: Quaternary papers utilize the dataset for data that do not relate to the hypotheses of the study or descriptions of the trial not otherwise specified.

The Trial PI and his or her designees have the first rights to publish collective study data per the Publications Committee approval. It is expected that within six months of analysis availability, the manuscript presenting the primary study results will be sent to the Publications Committee by the PI. All studies carried out by SIREN must submit their primary data for publication regardless of the study results. The Trial PI and her or his designees will designate lead authors and workgroups to publish secondary papers.

Other trial investigators are encouraged to propose and publish tertiary and quaternary papers and are permitted protected data publication rights for one year following publication of the primary manuscript. The Publications Committee will retain oversight of the collective data and decision-making authority with respect to the collective data for one year after publication of the primary study results. Within one year of the publication of the primary manuscript, the public use datasets will be created by the DCC and submitted as directed by the funding institute(s).

Individual study investigators will be given one year from trial initiation to specify publications that he/she or his/her designee wishes to author using the collective data. After this time interval, ideas submitted to the Publications Committee will be evaluated on a first-come, first-served basis.

Authorship

It is important to team science that authorship be inclusive. The contributions of all participating study teams should be recognized by including the statement “for the P-ICECAP Investigators.” at the end of the named authors list, or in lieu of named authors, for all primary and secondary publications. An appendix must then

be included that lists the contributing investigators. It is the responsibility of the corresponding author to communicate to the journal, prior to publication, the intention that this list be indexed in PubMed, as the journal may not do this otherwise. It is recommended that the list include the team members at the trial leadership and coordinating centers, followed by each enrolling site. List enrolling sites in order by the number of subjects they enrolled and provide this number for each site. For each enrolling site, recommend listing, at a minimum, all site Principal Investigators and Primary Study Coordinators with their roles. Consideration may also be given to selective listing other site investigators (such as site neurologists) and study team members under some circumstances after discussion between the trial Publication Committee and the P-ICECAP Executive Committee.

Named authors should follow logical criteria for authorship consistent with the spirit of ICMJE guidelines. All investigators who make a creative, substantive contribution to the research should be listed as authors. This includes those who creatively participated in the concept, design, obtaining funding, conduct, analysis and/or drafting of the manuscript. Typically, this is the trial leadership including Trial PIs, Trial Statistician, and Trial Executive Committee, the Trial's Coordinating Center Liaisons, and the Trial's NIH Scientific Program Director. The NIH Scientific Program Director should be a co-author on the primary publication if this is allowed by NIH. Those with oversight responsibilities external to the trial such as members of the DSMB and external medical safety monitors, and other contributors outside of the trial, should be thanked and recognized in the acknowledgement section. (Site PIs enrolling a specified number of patients may also be included as authors if they meet authorship criteria)

The first author for publications should be the individual who was most fully responsible for the concept, design, funding, conduct, analysis and drafting of the manuscript. The last author should be the senior member who contributed the most to the items listed above. The order of the remaining authors should follow from their relative contribution to the manuscript. All relevant individuals should receive a copy of the manuscript in a timely fashion and be offered the option to request that their name be listed, moved in order, or removed from authorship. All grievances should be conveyed to the Publications Committee by the first author and Trial PI with a recommendation for resolution. The Publications Committee has the final word with respect to authorship decisions.

Citation of Common Data Elements

The NIH encourages research teams to cite their use of CDEs for both dissemination and tracking purposes. As such**, authors should** indicate in the Methods or Acknowledgements section that the study "used the NINDS Common Data Elements (http://www.commondataelements.ninds.nih.gov/)" and if appropriate refer to the following citation in the References section: "Grinnon ST, Miller K, Marler JR, Lu Y, Stout A, Odenkirchen J, Kunitz S. National Institute of Neurological Disorders and Stroke Common Data Element

Project - approach and methods. Clin Trials 2012;9:322-9. PMID: 22371630". If possible, also list "NINDS Common Data Elements" as a keyword when submitting the manuscript.

Acknowledgement of Funding

Each publication reporting research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institutes of Health under Awards **U24NS100659 and U24NS100655**. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, the network will notify the NIH awarding IC in advance to allow for coordination.

Compliance with the NIH Public Access Policy

In accordance with PL. 110-161, all publications must comply with the mandatory NIH Public Access Policy. Compliance is the responsibility of the authors but may be delegated to the publisher. For more information, see NOT-OD-08-033 and the Public Access website.

Study-Independent Publication Procedures (SIREN operations and methods papers)

Members of the SIREN CCC, DCC and site PIs may wish to publish methods papers that describe the network's function, or papers that are otherwise wholly independent from the trials conducted. These paper proposals and final manuscripts will be submitted to the P-ICECAP and SIREN Publications Committees. The SIREN General Publications Committee includes the SIREN CCC PIs, the SIREN CCC Publications Director, the SIREN DCC PIs and a NIH Program Director. This committee does not have authority over individual study Publications Committees. Papers published from this group will not address topics in the studies' specific aims and will require authorship and review by the PIs of the studies whose data are used in these methods papers.

Individual Site Investigator Publication Rights

Individual institutions shall retain ownership of all data that they generate. Institutions shall grant to P-ICECAP non-exclusive license to use data for educational and research purposes. Site investigators who wish to publish their own institution's data will be able to proceed with such publication, provided that the site PI has first sought approval for multi-site publication in accordance with the procedures set out under the study-specific publication procedure. Individual site investigator publications can be delayed for one year after the primary publication has been published or two years after the study has ended (database lock), whichever comes first.

Adherence to Policy

Participation in P-ICECAP requires adherence to the publication policy described in this SOP, even though Hub PIs retain ownership of the data collected at their sites. Authors who publish articles that are not compliant with this policy must contact the journal and retract the publication.