

IPSS Publications Committee

Policy

Version 4.0 May 2022



The rules established by this committee are to shape, guide and protect all IPSS members and the data collected

October 2021

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Current Publications Committee

Chair: Tim Bernard

Vice-Chair: Christine Fox

Members:

Lauren Beslow

Ryan Felling

Michael Noetzel

Mubeen Rafay

Laura Lehman

Ryan Felling

Dimitrios Zafeiriou

Mukta Sharma

Nick Stence (Neuroimaging Representative)

Overview of Publications Committee

The Publications Committee (PC) was established for the purpose of enabling the timely publication of IPSS research publications whilst ensuring the maintenance of ethical standards, the primacy of patient privacy and fair distribution of authorship for academic contributors.

As the ultimate mission of the IPSS is to expand knowledge on childhood stroke through publications, it is the primary responsibility of the PC to oversee all IPSS-related research and data requests. Any use of IPSS data, specifically for the generation of publications, must be reviewed and approved by the PC prior to submission for public dissemination. In addition, because of the inherent connection between future research directions and future publications, the Publications Committee will review proposals for ancillary studies and additional funding, and provide recommendations to the Executive Committee.

The Publications Committee will be responsible for investigating and adjudicating conflicts regarding data ownership, authorship, and intellectual property.

I. Scope of the Publications Policy

This policy covers papers, abstracts, and presentations that involve IPSS data collected as a part of the IPSS. These policies will remain in force irrespective of IPSS funding.

II. Goals

The overall goal of the IPSS Publications Policy is to recognize all contributing IPSS members through authorship on IPSS papers. All investigators who contribute to the IPSS either intellectually or by patient enrollment will be encouraged to participate in writing groups, and the publications committee will strive to ensure fair representation of co-investigators in the different groups. New and/or Junior investigators, for whom authorship is critical for academic promotion, will be considered a priority. The committee will register all incoming proposals, and keep an updated list of currently approved proposals along with authorship positions for those

proposals. Comprehensive lists of analysis plans and writing projects in process along with their progress reports will be circulated to all members of the Publications Committee at regular meetings.

The specific goals of the publications committee are to:

1. Provide clearly defined and comprehensive guidelines for the creation, development, and dissemination of publications resulting from the IPSS
2. Encourage timely preparation of high-quality publications and presentations from IPSS sites
3. Provide appropriate academic recognition to participants who make significant contributions to the research activities of the IPSS
4. Provide fair, transparent clearly defined and comprehensive guidelines on levels of authorship and eligibility for authorship for such publications
5. Mentor and provide assistance to authoring members as needed (e.g. advice on need for statistical analysis, assistance for members whose first language is not English, provision of pointers on how to prepare articles for submission to peer reviewed journals).
6. Provide recommendations to the Executive Committee regarding issues of data ownership and ancillary studies (see “Policies for Ancillary Studies and Proposals for Additional Funding”).

III. Glossary of Terms

For the purposes of this policy the following list of terms may be defined as follows:

- 1. IPSS Investigators**—Refers to those Co-Investigators who will collectively be referred to on the title page with the phrase “on behalf of the IPSS Investigators,” and will be listed individually in an appendix to the manuscript.
- 2. Site or local site-** refers to any one of the participating (*actively enrolling*) IPSS institutions (defined as enrolling at least 1 subject in the preceding 5 years)
- 3. Site Principal Investigator (Site PI)**-Refers to the principal investigator(s) responsible for the safe and ethical conduct of the IPSS at any one of the enrolling IPSS institutions listed above
- 4. Publication or paper-** Refers to written publications in journals, books, proceedings, published abstracts or posters and electronic environments (websites, web logs, and or electronic journals) or any other public presentation of data from the IPSS
- 5. Manuscript** – Refers to unpublished papers, papers in progress and abstracts or proposed poster or oral presentation submitted to a scientific meeting.
- 6. Research Request**—Refers to a formal request for data for the purposes of a paper, abstract, presentation, grant proposal, or any other proposed use
- 7. Submitting Investigator**—Refers to the IPSS Investigator who is submitting a Research Request
- 8. Writing Committee**-Refers to the body of investigators (N = 15 or less) who collaborate in scientific thought and writing to develop a manuscript for publication
- 9. Primary Authors**—Refers to those authors whose names will be listed on the title page of a manuscript, and whose names will appear in Pub-Med; the members of the Writing Committee will typically constitute the primary authors

- 10. Secondary Co-investigators-** Members who are not part of the writing group but who contribute patients to the current dataset. Secondary Co-investigators will not be listed in the authorship line but will be included in the Appendix of manuscripts
- 11.** Junior/New member – trainee (fellow) or early-stage investigator as defined by NIH (10 years from last residency/fellowship *unless* that investigator has already been promoted to the rank of Associate Professor or equivalent OR an investigator who otherwise meets criteria for senior member but has been with the IPSS for less than 3 years
- 12.** Senior member – investigator at least 10 years from last residency/fellowship, or at the rank of Associate Professor or equivalent, and has participated in the IPSS for at least 3 years
- 13.** Content expert – investigator as designated by Publications Committee for a specific manuscript, may not be actual IPSS member
- 14. Ancillary Study** – A study that involves participants in the IPSS and requires procedures or measurements that are not included in the protocol or data collection form

Historic Terms (prior to 2014)

- 15. Primary Paper** - Refers to major flagship papers associated with the IPSS, related to the 4 IPSS objectives outlined in the IPSS Protocol
- 16. Secondary Paper** - Refers to publications that explore hypotheses outside the scope of the Primary Papers, but use data collected as part of the main study
- 17.**

Publications Committee Membership

There are 9 IPSS members that constitute the Publications Committee (PC), consisting of 7 voting members and 2 alternates. The committee strives for 1 member from outside North America and 1 junior investigator, defined as <5 years participating with the IPSS. A quorum (at least 5 members) is required to ensure representation in decision making; if there are contentious issues, all members will be asked to vote. If it proves difficult to obtain a quorum regularly, the number of committee members will be increased appropriately.

Membership Terms & Responsibilities

The qualifications and responsibilities of the Publications Committee chair and members are described in, but not limited to the list below:

Position: Publications Committee Chair (x1)

Length of term: **2-4** years, subject to term extension on as needed basis

Qualifications:

- Chair must have served as a Publications Committee member for at least 1 term (2 years) before becoming Chair.
- Ideally the chair will be rotated in from the Vice Chair position (see below)
- Chair must meet all qualifications for Publications Committee members (see below)

Responsibilities:

- Fulfill all responsibilities of Publications Committee members
- Organize agenda for and lead discussions during conference calls
- Update Publications Committee members on status of manuscripts, new submissions, accepted publications, data requests received, etc.
- Seek volunteer for/designate a Primary Liaison for each request submitted to the Publications Committee
- Provide Publications Committee report during IPSS meetings
- Serve as a member of the Executive Committee for the length of term
- Provide Publications Committee update reports to Executive Committee and seek input as needed for controversial or substantive issues
- Mentor Vice Chair to assume Chair position

Position: Publications Committee Vice-Chair (x1)

Length of term: **2 - 4** years, subject to term extension on as needed basis

Qualifications:

- Must meet all criteria for Publications Committee member
- Must have served as member of Publications Committee

Responsibilities:

- Fulfill Publications Committee member responsibilities
- Fulfill Publications Committee Chair responsibilities in their absence
- Consider position of Chair at end of year 2 (mid-term) to determine interest and feasibility of assuming role
 - *If not interested in progressing into Chair position, will wrap up term and nominate new Vice-chair (to ensure continuity)

Position: Publications Committee Members (x5)

Length of term: 4 years, subject to term extension on as needed basis

Qualifications:

- Must have a thorough understanding of Publication Committee policy
- Must have a good understanding of IPSS goals, procedures and membership; therefore the individual must be a member of the IPSS for at least 1 year prior to becoming a Publications Committee member
- Provide an intellectual contribution to the IPSS, defined by (3 of following 4 criteria):
 - Enrollment of patients or,
 - Participating in IPSS meetings or,
 - Participation in writing committees or,
 - Participation in special interest IPSS subgroups

Responsibilities:

- Participate in monthly conference calls. If unable to do so, must e-mail comments on discussion topics
- Attend IPSS meetings where possible
- Encourage and facilitate the generation of IPSS publications
- Review data requests (abstracts, manuscripts, ancillary study proposals), data policy revisions and new candidate expressions of interest
- Act as a liaison for delegated request
- When serving as a liaison, conduct critical review of data/analysis request, lead the Publications Committee discussion on the request, and communicate with submitting member the recommendations from the Publications Committee
- Mentor and assist IPSS writing group members as needed (e.g. advice on research methods, statistical analysis, and assistance for members whose first language is not English, provision of pointers on how to prepare articles for submission to peer reviewed journals) and follow-up as needed.
- Ensure timely review by other committee members
- Provide recommendations to the Executive Committee regarding issues of data ownership and ancillary studies

Rotation of Membership

Members of the IPSS will be invited to apply for committee membership on a rolling basis, to serve for a minimum of **4 years**. No more than 2 members will be rotated on and off within a given year to allow for continuity. The Publications Committee (PC) will issue a call to the general IPSS membership for interested members and develop a list of candidates. The Publications Committee will then vote from the list of potential candidates.

The following criteria are considered when electing the new PC member:

- Patient enrollment throughout duration of involvement
- Patient enrollment in prior year
- Meetings attendance
- Lead author of IPSS research publication
- Co-author of IPSS research publication
- Member of sub-group activities
- Member of active/former sub-study
- Experience with publications in stroke

The member with the most votes will be invited to join the Publications Committee. The Publications Committee will make every attempt to ensure non-North American representation; a targeted call for a non-North American member will be issued when needed. If the Publications Committee cannot identify a non-North American volunteer to replace a departing non-North American member, a North-American volunteer may be elected.

Data Use

All manuscripts, abstracts, posters, and slides to be presented at national and international meetings, must be approved by the Publications Committee prior to submission or presentation.

Data Ownership

Any data entered into the IPSS is owned by the co-investigator(s) who collected and entered the data. By entering the data into the IPSS database, co-investigators give implicit permission for the IPSS to analyze the collective data for presentation at scientific or IPSS meetings, manuscripts, and grant applications and progress reports. Rules on authorship, detailed in this policy document, will apply to ensure that all investigators who have shared data will receive appropriate credit for their contribution upon publication of any collective data.

Data Requests

Analysis of IPSS data for abstracts, posters, or manuscripts may not commence until an analysis plan has been approved through the process described below. It is the responsibility of the first author to follow the guidelines listed below.

Notes:

The process will proceed as follows:

1. Investigators who wish to analyze IPSS data must first submit a **Research Proposal** to the Publications Committee (**see Appendix I**). Verbal expressions of interest at IPSS meetings and contact with individual members of the Publications Committee do not constitute formal request nor prevent submission of competing proposals.
2. A liaison will be assigned to each request received by the Publications Committee. This liaison responsibilities include:
 - a. Performing a comprehensive review of the request and seeking revisions as needed; Timely feedback by the rest of the committee
 - b. Lead discussion on the request during Publication Committee conference calls,

- c. Communicate the decision of the Publications Committee to the submitting investigator, and
 - d. Follow-up with the submitting investigator should further action (potential conflicts, overlapping projects, problems of feasibility, more detailed information including tables) be recommended by the Publications Committee
3. The Publications Committee will review the request within **3 months** of its submission, and may opt to approve, approve with pending modifications, or reject the abstract, poster, slides or manuscript. The submitter has 3 months to re-submit the proposal.
 - a. Five (5) members of the Publications Committee need to approve the request. If there are not 5 members that can approve due to conflicts of interest and affiliation with the designated projects, members of the Executive Committee will serve as committee member(s) for the purpose of the review.
4. Once the Data Request has been approved, an e-mail will be sent out to the general IPSS membership notifying them of the new initiative and inviting them to contact IPSS Central if they would like to participate in the writing group
5. The submitter (or first author) will then be required to sign an **IPSS Data Use Agreement Form** (see Appendix II) prior to release of the IPSS data.

Presentation of Single Centre Data

Because the data is ultimately owned by the individual, studies utilizing single center data would not require 'permission' from the IPSS Publications or Executive Committee.

Notes:

IPSS Writing Committees

Writing Committees will be established to develop a research idea into an abstract and/or manuscript(s). The investigators in the writing group will constitute the primary authors for the resultant publications.

Research ideas are initially presented to the Publications Committee using the IPSS "Research Request Template" (as outlined above), which encourages Submitting Investigators to consider feasibility and statistical planning.

- Primary IPSS papers – As major flagship papers associated with the IPSS, these proposals are generated exclusively by an IPSS member, intended for open authorship from the IPSS group (examples include data lock projects, but also others in between)
- Secondary IPSS papers – Two types: 1) Adjunctive papers are proposed by an outside research group that has its own unique expertise (may have an IPSS member, but may not) and will be assigned to Working Groups. 2) Working group papers are manuscripts with a focus that the PC deems within the scope of a working group, often requiring additional data for analysis.

Writing Committee Composition

IPSS writing committees are made up of ≤ 15 Investigators (ideally, 10) who work collaboratively to write a paper. This group is determined using the PC point system (below), as

well as desire to include multiple active members in authorship. These first and senior author are determined by the group as a whole (the group is encouraged to organize a phone meeting, with support by the IPSS Coordinator); the Investigator(s) who submits the research proposal will have the opportunity to serve as first or senior. The PC prefers 1 Investigator from each site per paper; however, situations may arise in which 2 are appropriate (medical students or residents from the first/senior author's institution, specialist- data analyst, for career advancement etc.). If approved by the Publications Committee, medical students or residents from the lead author's institution can be selected for the second author role, acknowledging the goal of the Publications Committee to give priority to junior IPSS Investigators. More experienced authors at the level of Associate Professor are actively encouraged to use this opportunity to mentor less experienced colleagues and might therefore expect to be last, rather than first, author.

Authorship Guidelines:

1. If studies are not the work product of a specific working group, the Publications Committee will decide if the project should be assigned to one or more specific working groups and become a working group paper.
2. For working group papers/adjunct papers, initial invitations will be sent to the specified working groups. If there is room for additional authors then invitation will be sent outside the working groups, with the expectation that interested authors will join one of the specified working groups.
3. Writing groups with 10-15 authors, 3 spots will be held for junior/new authors; for smaller writing groups, PC will determine number of held spots for junior/new authors. The remainder of the spots can be determined by the points system and need for content expert

4. One to two content experts may also be added at the discretion of the PC.
5. Author selection:
 - a. Authors have not exceeded the maximum number of papers as allowed by their current point accumulation.
 - b. Junior/new and senior members will be selected by point total separately, in the proportion specified above.
 - c. Authors with specific expertise or interest may be given preference at the discretion of the PC by majority vote.
6. PC will maintain a list of those who expressed interest but not selected for writing groups so that they will have priority for future opportunities. Authorship will be based on points, as well as an attempt to have authorship opportunities for all members, when available.
7. If additional data are required for a Writing Group paper, the Writing Group may make submission of these data a requirement for authorship when appropriate.

The Publications Committee will assign the final writing group, while first author and senior author will be determined by the group itself. Generally, one of the investigators who proposed the paper should be acknowledged by being first or senior author. Upon receipt of the data, the lead author will be responsible for overseeing the timely generation and development of the related manuscript, in accordance with the timelines detailed below.

If requests from IPSS members to join the Writing Group are not granted, they should be notified and provided with a rationale.

Writing Group Formation

The IPSS membership will be extended the invitation via email to join the writing group(s). IPSS members will have **3 weeks** to express their interest (via letter of intention) in participating by notifying IPSS Central, in order to allow equal and fair opportunity for all members. At beginning of Week 3, a reminder will be sent to IPSS Investigators. At week 4-8 (week of Publications Committee meeting), writing group candidates are discussed amongst the PC based on their points according to the point system (capturing contribution/activity within the IPSS). See *Authorship for more details*. Once the committee determines the writing group members, there will be a phone conference held to discuss analysis and manuscript updates.

Authorship

Authorship on each paper will be determined based on a combination of three strategies. The first component relies on a point system to standardize authorship determinations for the site investigators. The point system was developed to recognize the individual contributions of each site PI to the manuscript development process. The second component is based on the International Committee of Medical Journal Editors (ICMJE) requirement for authorship. This criteria will help determine order of authorship. All of these criteria must be fulfilled in order to qualify for authorship under the guidelines established by the International Committee of Medical Journal Editors. Lastly, the first and senior author will provide their input on degree of contribution and adjust order of authors accordingly. IPSS investigators that have only contributed data will be acknowledged as co-investigators or secondary authors in any published manuscripts (typically in an appendix to the manuscript). A maximum number of manuscripts per writing block (as defined by PC) will be enforced in order to provide opportunities for less experienced members.

Author Contribution

The first and senior author will outline the specific roles and responsibilities of their writing group members; and are responsible for authors meeting minimal contributions. They are also responsible for any changes in writing committee composition and roles/responsibilities throughout the project. If a dispute arises about inclusion in a writing group or roles/responsibilities within the writing group, the Publications Committee will ultimately adjudicate the disagreement.

At minimum, to meet the authorship criteria detailed below, each member will be responsible for fulfilling all 4 of the ICMJE criteria:

1. Substantial contributions to conception and design, acquisition of data, and/or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.
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.

If a primary author is not providing adequate contribution to a manuscript and ICJME criteria are not met after several months, the first/senior author may exercise his/her right to strongly encourage participation or propose forfeiture of authorship. If there is still no reply from authors, the Publications Committee Chair may step in to assist, proposing a 2 week deadline for any final comments/feedback prior to reconsideration of authorship order. The Chair and senior author may disinvite the non-engaged member from authorship and remove them from the authorship byline. They will still be acknowledged as co-investigators. A middle author may be promoted to a first or senior author position where necessary. The Publications Committee

liaison for the project will remain in contact with the writing committee chair to oversee writing group activity and ensure roles/responsibilities are being met.

Table 1. ICMJE Criteria - Authorship Ranking System adopted by the IPSS

Note: ***Non-IPSS members, non-enrolling Investigators/collaborators will also follow the above point system

Points Awarded*	Criteria	Condition
2 points	Awarded for substantial contributions to study design and conception	
2 points	Awarded for acquisition of data	Data quality will be a consideration for awarding these points. Protocol violations, loss to follow-up rate, edits/audits rate, responsiveness to edits/audits and queries, overdue forms, and missing forms will all impact scoring.
1 point	Awarded for sites recruiting greater than 30 patients for the IPSS or individuals who enroll a minimum of 50% of site's patients or 5 patients (whichever is smaller). This does not include data entry only.	Center should have contributed to the content of the latest dataset to be included.
1 point	An additional point will be awarded for every tenth patient recruited beyond the first ten patients enrolled in the IPSS. Points awarded up to 20 th patient enrolled beyond initial 30 patients	A maximum of 2 points can be awarded under this criterion.
2 points	Awarded for providing a critical review of the manuscript for important intellectual content	
4 points	Awarded for producing the first draft of the manuscript (limited to the Chair and Vice-Chair of the respective Writing or Publications Committee)	
2 points	Active committee membership (Executive Committee members, Publication Committee members, Writing Committee for paper, Subgroup membership related to paper)	Committee input is related to the major outcomes of the paper

Table 2. IPSS Point System

Number of papers in a writing block	Papers Permitted per Investigator per writing block	
0-6	up to 2	0-6 = may be first or senior on 1 paper 6-12 may be first or senior on 2 papers
6-12	up to 3	
13+	up to 4	

*PC defines writing blocks and may adjust these numbers based on demand. The principle of the points system is to ensure fair opportunity among IPSS investigators; the number of papers indicated in the system are permitted but not necessarily guaranteed. The PC will utilize the points to determine which authors will have priority for authorship in manuscripts and will balance that with opportunities for all members to participate in writing groups. **Non-Author Co-investigators**

Secondary Co-investigators will follow the ICMJE guidelines for non-author contributors:

“Contributors who meet fewer than all 4 of the ICMJE criteria for authorship [(listed in preceding section)] should not be listed as authors, but they should be acknowledged.

Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are:

- Acquisition of funding;
- General supervision of a research group or general administrative support; and
- Writing assistance, technical editing, language editing, and proofreading.

Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

Timeline for Manuscript Production

1. Submit Research Request to IPSS Publications Committee
2. Within 2 months, PC and liaison will review request
3. If approved, Data Use Agreement must be signed by first author or Submitting investigator and research proposal will be posted to the IPSS membership for opportunity to join the writing group
 - a. If declined and returned for revision, the Submitting investigator has 3 months to re-submit to the PC for a subsequent review
4. After 4 weeks, the writing group sign-up is closed
5. The writing group candidates are reviewed by the PC based on point system (*details above*) and notified after confirmation. This is typically between weeks 4-8 after posting.
6. Writing group members will meet for phone conference to discuss first and senior positions, and then receive final sign-off by PC (and Exec?)
7. Once confirmed (time line for when writing group members notified?), data packages are provided to the first and senior author
8. Within 3 months of receiving the data package, groups are expected to have started analyzing the data and/or writing process
9. At the 2 month mark, the first and senior author will submit a progress report to the PC with the following details:
 1. Manuscript Title:
 2. Authorship:
 - a. Who has participated?
 - b. Who hasn't participated?
 - c. Order (we understand this may be subject to change):
 3. Preliminary results:

4. Foreseeable date of completion of first draft:
5. Comments (i.e. major data discrepancies, general updates, feedback):

10. At 8 months, a first draft of the manuscript should be completed and submitted to the liaison for review and presentation to the Publications Committee

Abstracts

Abstracts for consideration must be submitted to the Publications Committee no later than noon Eastern Standard Time (12:00pm-EST), **5 weeks** before the abstract deadline (exceptions to this deadline can be made for late-breaking science, if approved by the PC chair). The Publications Committee will conduct a critical review of the abstract and provide feedback to the submitting PI within **1 month** of the submission. Although every effort will be made to expedite this process, the submitting investigator will bear primary responsibility for submitting abstracts for review in a timeframe suitable to submission of the abstract prior to any pending deadlines, and he/she should understand that the commitment extends to the production of a full-length manuscript, following the timelines indicated above.

Acknowledgement of the IPSS

The final listing on the author line for all primary publications will be “on behalf of the IPSS Investigators” or “for the IPSS”. This list is constituted of the secondary authors. The Publications Committee, by majority vote, may advise the Executive Committee to add additional authors to the author list. If a member wants to challenge a decision about authorship, the Executive Committee will review and adjudicate any complaint. Please also recognize the main funding source for the IPSS by including the following text, “*This research was graciously supported by The Auxilium Foundation.*”

Data sharing – Disclosure Language

Please use the following language (or similar, journal dependent) in the data use disclosure statement:

“Data available on request from the authors - The data that support the findings of this study are available from the corresponding author upon reasonable request. [If author providing data is not the corresponding author, please provide contact info for that author]”

Special Considerations for the IPSS Publications Policy

1. Use of the summary data and information available on the IPSS website for presentations need not be approved by the IPSS Publications Committee.
2. The Publications Committee may, by majority vote, withdraw any abstract or manuscript from submission
3. The IPSS Publications Committee reserves the right to make final determinations over conflicts or disputes about authorship ranking.
4. **Pooled Analyses with non-IPSS Centers (ANCILLARY?):** Occasionally investigators may be interested in using IPSS data for pooled analyses with data from other non-IPSS studies. These research proposals, even if they overlap with previously approved analysis plans, should be submitted under a separate Research Request for approval, and are subject to the same guidelines for approval, use of IPSS data, and review as all other IPSS analysis plans. At least one IPSS Principal Investigator must be included as a co-author on any abstracts or manuscripts coming out of the analyses. All abstracts, posters, slides and manuscripts are subject to the same review process as all IPSS analyses, and it is the responsibility of the IPSS Primary Investigator on the analysis plan to notify the other researchers of this condition, and to facilitate the review and approval process according to the guidelines.
5. **Pooled Analyses within IPSS:** Occasionally PI's may wish to pool their own collected data with data collected by one or several other IPSS sites (e.g. European or Asian centers). Because the data is ultimately owned by the individual sites (see Data Ownership section, below), the Publications Committee should be informed but these studies would not require 'permission' from the IPSS Publications or Executive Committee.

Violations of Publications Policies

Should a publications policy be violated, the Publications Committee will review the situation and decide upon the most appropriate and judicious course of action. Under the unlikely circumstance that a site PI is thought to have intentionally misused IPSS data, that course of action could include the exclusion of that co-investigator from author lists for future publications, and the refusal of any future research requests.

In addition, should a site PI submit IPSS data for publication without the final approval by the Publications Committee, that committee may choose to contact the Editorial Office of the journal in question to inform them of the unauthorized use of IPSS data. Appeals to decisions made by the Publications Committee may be made through the process described below (Appeals/Resolution of Conflict).

Appeals/Resolution of Conflict

Conflicts should be resolved within the Publications Policy Committee as soon as possible. However, the situation may arrive when the Publications Committee cannot resolve a conflict, or when a site PI wishes to appeal the decision made by the Publications Committee. The IPSS will have two levels of review for resolving a conflict or processing appeals.

1. **Internal Review:** The IPSS Executive Committee will adjudicate conflicts, including appeals. The Chair of the Executive Committee, with the advice of the publication committee membership, will address all appeals and conflict resolution.
2. **External Review:** The IPSS Executive Committee may elect a panel of external investigators to adjudicate conflicts, including appeals, which cannot be resolved within the IPSS.

Appendix I: IPSS Research Request Form (Version Date: March 2022)

Proposed Study Title:

Submitting IPSS Investigator:

Other contributing investigators:

Authorship Plan (please list names/roles/institution of proposed writing group members. If proposing a different working group setup/composition than IPSS, please detail):

1. Data requirement for proposal:
 - Use existing IPSS clinical data
 - Use existing IPSS imaging data
 - Request additional data on targeted sub-set of IPSS patients

If so, specify additional data required:

2. The intended data use:
 - Abstract
 - Manuscript
 - Local presentation
 - Grant preparation

3. Research question/objective:

4. Patient Population(s) of interest (select all that apply):

- Neonatal CSVT
- Neonatal AIS
- Childhood CSVT
- Childhood AIS
- Presumed Stroke
- Arteriopathy, no stroke
- Other, detail: _____

5. Corresponding Sub-Form:

- Arteriopathy Cardiac CSVT
- Perinatal Seizures tPA

6. Rationale / Background:

7. Statistical analysis plan (if involving an analyst/biostatistician, please include name in writing group above):

8. Post-approval timeline:

9. Relevant dates (abstract/grant submission deadlines):

Feasibility Check

10. **Variables for Data Feasibility Check** (please refer to the IPSS codebook to complete the tables below – if you do not have the latest codebook, please contact IPSS central)

a. Filter variables (max 5)

Please list variables that are required in your inclusion criteria:

Codebook Variable (e.g., gender)	Values Requested (e.g., Male (1))

b. Core Variables of Interest (max 10)

These variables will be used for IPSS Central to determine the data coverage for the eligible patients. Please list the core variables of interest:

Codebook Variable (e.g., art=arteriopathy)

11. What is your desired N for the study?

12. All IPSS variables requested (specify outcome measures and time-points):

13. **Variables for Imaging Data Feasibility Check (if applicable)**

a. Type of imaging data required MRI CT Both

b. Sequence(s) required:

c. Imaging time point(s) required:

Appendix II: Data Use Agreement

The recipient of the data set obtained from the International Pediatric Stroke Study (IPSS) Data Center agrees to use or disclose the data only as permitted in this data use agreement (DUA).

1. Name of IPSS Person releasing the Data Set:

2. Name and institution of the Recipient of the Data Set:

3. Purpose of Data Set Disclosure:
 - a. Abstract preparation
 - b. Manuscript preparation
 - c. Public presentation
 - d. Preliminary data for grant proposal
 - e. Other:

4. The recipient of the data set listed in #2 is permitted to use and disclose the Data Set in accordance with the IPSS Publications Policy for the following purpose: [e.g., specific analysis planned, organization to which data will be presented in abstract/grant/presentation format, anticipated dates, etc.]

5. The above named recipient also agrees that:
 - a. The recipient of the Data Set agrees to the IPSS Publications Policy, including time lines for the production of planned abstracts/manuscripts.
 - b. The data set will not be further used or disclosed other than as permitted by this DUA.
 - c. Appropriate safeguards will be used to prevent the use or disclosure of the data set other than as outlined by this DUA.
 - d. Any use or disclosure of the data set beyond that provided for in this DUA will be immediately reported to the IPSS Publications Committee.
 - e. Any agents, including subcontractors, to whom the recipient provides the data set, will agree to the same restrictions and conditions that apply to the data set recipient.
 - f. There will be no attempt to identify the persons from whom the data set originated or to contact such individuals.
 - g. The data set will be used for research purpose only and only for approved analysis plans.
 - h. Any use of the data set must abide by the IPSS Publications Policy, which includes gaining approval for all publications before submitting to journal/conference or any public presentation of the data.
 - i. The investigator must accept all responsibility for analysis of data, results from analysis, and any consequences resulting from breaching patient privacy in connection with the analysis.
 - j. The investigator will affirm that their local IRB does not require its own review and approval of the analysis, and if such a review and approval is required, it will be sought prior to initiation of the analysis.

6. The IPSS person identified in #1 above confirms that the Data Set does not contain any identifying information, including: patient/subjects names, postal address information, telephone/fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, etc.
7. By signing this form, the IPSS person releasing the Data Set is certifying that the information in the data set is being used only for the purpose identified in item #4 and does not contain any of the information indicated in item#6.

Signature of person in item #1 Date

8. By signing this form, the recipient is certifying that he/she will use the limited data set only as permitted in item #4 and #5.

Signature of person in item #2 Date

Please sign and fax or mail the form to the following address:

IPSS Data Management Center
Attention: Alexandra Linds
The Peter Gilgan Centre for Research and Learning
The Hospital for Sick Children
Child Health Evaluative Sciences
686 Bay Street, 12-9840
Toronto, Ontario, Canada
M5G-0A4

Secure Fax: (416) 813-5242

E-mail: Alexandra.Linds@sickkids.ca