POLICIES AND PROCEDURES FOR THE DEVELOPMENT OF PUBLICATIONS FROM THE ELGAN STUDY

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1. Principles For Writing ELGAN Papers

It is important to the ELGAN study that *all* investigators have an opportunity to publish, that the papers from this study be of the highest quality, and that the ELGAN Study database be effectively and efficiently exploited to advance understanding. Achieving these goals will require a lot of effort from those investigators for whom authorship of papers is a priority. The ELGAN Study database is defined as all research data collected on all ELGAN Study subjects and their family members (N = **1506**) as part of the conduct of NIH contract 5U01 NS040069-05 and 2R01NS040069 - 06A2.

It is likely that each of us has a slightly different idea of what constitutes authorship of a scientific paper. However, investigators are not completely free agents as we are bound by the standards of authorship established by medical journals. The most authoritative voice in this area is the International Committee of Medical Journal Editors state. Their criteria require that:

"…all authors must state that they have made substantial contributions to each of three activities:

1. *Conception and design or analysis and interpretation;*
2. *Drafting the article or revising it for critical intellectual content;*
3. *Approving the final version to be published."*

We would like our authorship standards to allow us to adhere as closely as possible to the above guidelines, while at the same time offering all our investigators ample opportunity to participate in the authorship of papers from the ELGAN Study database.

2. ELGAN Publications And Data Analysis Sub-Committee

The ELGAN Study Executive Committee will appoint and supervise a sub-committee, the ELGAN Study Publications and Data Analysis (PAD) sub-committee. All ELGAN Study specialty committees will be offered an opportunity to nominate individuals for membership in this sub-committee. The sub-committee will elect a chair. The purpose of this sub-committee is:

- Authorize presentations and publications
- Authorize use of ELGAN Study data in grant submissions
- Address prolonged delays in manuscript production and develop procedures to prevent delays in publication .
- Report back to the Executive Committee on any problems encountered in the area of authorship.

3. Authorship Requirements For ELGAN Study Papers

The most important criterion for authorship is willingness to put in the effort required to produce a scientific paper. Translating the requirements for authorship cited above into the ELGAN study, *each* ELGAN Study author must, at minimum:

- Participate in discussions of the hypotheses to be tested in the proposed paper.
- Review and discuss tabulated data analyses from the ELGAN Study data.
- Contribute to composing and editing the paper.
- Provide a final review of the paper to ensure that there are no errors in the section of the paper the author is most familiar with.

4. Study Research Interest Groups (RIGS) in the ELGAN Study

Papers in the ELGAN study will be prepared by *writing interest groups (in earlier versions of this manual, they were called "analysis groups")*. There will be two kinds of writing interest groups, and their composition will differ slightly. One group will develop *Primary* ELGAN Study papers, and a set of analysis groups will develop *Secondary* ELGAN papers.

- Primary ELGAN Papers

Primary ELGAN Study papers are a modest number (probably about 10) papers that focus on the *major* hypotheses of the ELGAN study as outlined in the grant. The

hypotheses for these papers will be specified in advance, and the Executive Committee will prepare a list of the hypotheses and the proposed papers to emerge from them for all ELGAN Study investigators. The writing interest group for these papers will include the ELGAN Executive Committee plus any ELGAN Study investigator who wishes to join in the analysis because of his or her interest in the hypothesis. We propose that each ELGAN Study investigator volunteer to join the writing interest group of at least one or two primary ELGAN Study papers. Analysis of data to support publication of primary ELGAN Study papers will have priority among data analyses, although preceding methodological and structural papers related to the cohort and outcomes may be given priority as well. Since some of the primary analyses and resulting manuscripts are likely to require more time than others, to the degree possible, other, secondary analyses, leading to manuscripts, also will be undertaken in parallel to the primary papers assuming that an appropriate PAD committee process and approval are granted (see below).

- Authorship Format For Primary ELGAN Study Papers

The writing interest group for primary ELGAN Study papers will select a writing leader for each paper and the group will determine order of authorship. Authorship place should be based on contributions to both the conduct of the study and the writing and editing efforts. Primary ELGAN Study papers will differ from secondary ELGAN Study papers in including, at the end of the list of authors, if permitted by the publishing journal, one or more of the following grouped listings:

- The ELGAN study site investigators (all site PI's)
- The ELGAN study psychologists/examiners
- ELGAN study autism/behavioral investigators
- ELGAN study neuroradiologists
- ELGAN study neurologists/epileptologists
- ELGAN study psychiatrists
- As appropriate, ELGAN-1 Study groups, including ophthalmologists, pathologists, sonologists

The grouping list used in any paper will depend upon the nature of the data used in the study. All primary ELGAN Study papers will include the phrase "…for the ELGAN

study site investigators" at the end of the author list, and those investigators will be named in the acknowledgements section separately from the acknowledgement of their institution when feasible. All primary ELGAN Study papers that use specific study/research groups will include the phrase…for the ELGAN ……study group", and the membership of the group will be listed in the acknowledgements section if feasible. This listing does not preclude site investigators or members of discipline groups from also being co-authors of primary ELGAN Study papers. Appendix C lists writing interest groups as of May 2013.

- Secondary ELGAN Study Papers

Most papers emerging from the ELGAN Study data will be secondary papers. Writing interest groups for secondary ELGAN Study papers take on the task of developing specific hypotheses within a circumscribed scientific area that is included in the ELGAN Study database. Any topic may be studied, but a procedure will be developed for initial approval of formation of a writing interest group to ensure that there is no conflict with any primary ELGAN Study paper or with other secondary ELGAN Study writing interest groups. Any investigator can form or join any secondary writing interest group, but membership will have to be flexible enough to permit the group to address several hypotheses within the circumscribed area. It is likely that research/writing interest groups will require both a concentration of specific subject area skills by ELGAN Study experts (e.g. most psychologists will participate in papers dealing centrally with cognitive outcomes), and diversity of skills (e.g. all writing interest groups will need someone with epidemiological/statistical skills). This implies that there will probably be core and ad-hoc writing interest group membership. Writing interest groups will meet by conference call to propose and discuss analyses, and to draft and edit papers. Members will have to become reasonably familiar with the structure of the ELGAN Study database, and the nature of the variables to be used in a writing interest, including their strengths and limitations. They must be willing to work closely with the data analysis center of the ELGAN study. Conversely, the data center will work collaboratively with investigators in analyses that require database support.

- Authorship Format For Secondary ELGAN Study Papers

Each writing interest group will select a writing leader who will take the lead in developing the analyses and writing the first draft. That individual will be first author of the paper. Each secondary writing interest group will include a member of the ELGAN Executive Committee, or an individual designated by the Executive Committee, who will serve as a liaison to the Executive Committee, and who, with the consent of the writing interest group, may elect to be a co-author. Order of authors after the first author will be by consensus of the writing interest group with recognition given to the degree of contribution to both the conduct of the study and the writing and editing efforts. It is strongly recommended that writing interest groups rotate writing leaders so that every opportunity is provided for all investigators to first-author papers if they so desire. The writing leader will be the convener of the /writing interest group, and will be expected to adhere to a reasonable schedule that will ensure prompt production of papers. Should production of papers be greatly delayed, the PAD sub-committee may recommend to the writing interest group that it change its designated writing leader. If the problem continues to remain unresolved after discussions between the PAD sub-committee and the writing interest group, the issue will be referred to the Executive Committee. To encourage authorship of secondary papers, the executive committee will periodically solicit proposals for secondary analyses from the ELGAN Study investigators.

- Initiation Of Secondary ELGAN Study Papers

The process by which authorship of secondary papers will be initiated is as follows. Development of a secondary writing interest team will begin with submission of the ELGAN Study analysis request form (Appendix A), which will be distributed to all ELGAN Study investigators, which will request the following information:

  - Name of principal investigator for the analysis
  - Name of proposed membership of secondary writing interest team
  - Request, if any, for additional member(s) of the writing interest team to be suggested by the executive committee to supplement skills of secondary writing interest team
  - Brief statement of hypothesis to be studied
  - Brief review of literature and background justifying the hypothesis

- Abbreviated list of variables collected in ELGAN Study which are likely to be central to the analysis (see appended ELGAN Study Matrix of Variables)
- A draft timeline for completion of the manuscript.

Upon approval of an analysis request, but before requesting information from the data center, the writing interest team must write a LIT-UP which briefly reviews the relevant scientific literature that supports the concept to be studied. This LIT-UP, which should be of about the average size and depth of current ELGAN Study LIT-UPS, will be circulated by the ELGAN Study PI to all ELGAN Study investigators.

Once approved, requests for analysis to the data center must be further developed so that they have a clearly laid out set of hypotheses, define the population of interest, and specify the forms that contain the data elements to be used, the variables of interest, and the value categories required for analysis. If new variables need to be created, the algorithm to do so must be provided. Preparing tables, showing column headers and row labels, will help the data center understand what is required.

If more than one investigator lays claim to the same hypothesis or variable set, the executive committee will adjudicate between claims and may suggest merger of groups and/or may designate the PI for a secondary analysis. If several analyses are proposed at the same time, the PAD sub-committee will prioritize the order in which the analyses will be conducted. If the leader of a secondary writing interest group feels that special circumstances make it important for that particular analysis to be prioritized, the leader should arrange to participate in the PAD sub-committee conference call that will be taking up that paper, to make his or her case directly to the sub-committee. In case of disagreement between the leader and the PAD sub-committee's decision, appeal can be made to the Executive Committee (*see section 7*).

- Affirming Authorship Responsibility For Elgan Study Papers

  To confirm that each author (of either a primary or secondary ELGAN Study paper) has participated in activities a-d listed in section 3 above, an ELGAN Study Authorship Credit form (Appendix B) must be completed by each author.

5. Centralized Data Analysis

All data analyses for ELGAN Study papers will be performed centrally at the ELGAN Study data center at Boston Children's Hospital, except for individual center analyses (*see below, section 9*). Requests for analyses will be forwarded from groups that have constituted themselves as authors of primary or secondary ELGAN Study papers. Analyses supporting primary ELGAN Study papers will have priority over those supporting secondary ELGAN Study papers. The PAD sub-committee will determine priorities among requests for analyses for primary and secondary papers.

- Abstract Deadlines

It is the view of the PAD subcommittee that the data analyses that underlie presentations at meetings will be at, or nearly at, the level of sophistication and completeness required for publishable papers. Moreover, the complexity of the ELGAN Study database and the large number of investigators who depend upon the ELGAN Study data center make it impossible for the data center to rapidly undertake analyses to meet an impending deadline. Considering also the requirement (*see section #6 below*), that all publications and abstracts from the ELGAN Study database be approved by the PAD sub-committee, authors should submit requests for analyses intended to support presentations at meetings at least three months prior to the deadline for abstract submission.

6. Approval Process For Presentation And Publication

The ELGAN Study PAD sub-committee must approve all presentations of ELGAN Study data to ensure both scientific quality and adherence to authorship guidelines It is the responsibility of the person who wants to present ELGAN Study data at regional, national, or international meetings to seek approval for submission of an abstract in timely fashion that will not prevent or delay presentations. For this to occur, we require that all requests for approval with a deadline (e.g. for submission of an abstract to a meeting) must be submitted to the PAD sub-committee for approval two weeks prior to the deadline. The PAD sub-committee will provide a response to the requester within one week of receipt of the request. Approval of an abstract does not constitute approval of a paper evolving from that abstract for publication. All procedures described above are subject to the approval of the ELGAN Study Executive Committee.

Although not a requirement, every presenter (whether platform or poster) is expected to have a fairly complete manuscript shortly before presentation. This allows the presenter to be equipped to handle questions, and reflect well on the co-authors and other ELGAN Study investigators.

Once an abstract has been accepted for poster or oral presentation, the first author should distribute the poster/written paper and powerpoint to co-authors for review and editing at least ten days prior to the presentation. The presentation does not have to be reviewed by the PAD sub-committee.

7. Appeals Process

We recognize that in any large multicenter, multidisciplinary effort, conflicts are bound to arise, particularly in issues surrounding publication. If a participant in the ELGAN Study project feels that his or her concerns in the area of publications or data analysis (e.g. insufficient support for data analysis; hypothesis receiving lower priority; replacement of first author for lack of productivity) have not been dealt with satisfactorily by the PAD sub-committee, the investigator can formally appeal to the ELGAN Study Executive Committee. The Executive Committee will review all relevant materials and provide the opportunity for the complaining investigator to make a written or oral presentation to the Executive Committee, if so requested.

8. Universal Acknowledgements Policy

All papers emerging from any ELGAN Study data must acknowledge the NIH grant number for support (NS 40069 and 2R01NS040069 - 06A2). All papers from the ELGAN study will provide a full list of all participating investigators from all institutions contributing data to the analysis.

9. NIH Public Access Policy

The Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) states: *SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their*

final peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

The first author (or the corresponding author) of an accepted-for-publication ELGAN Study paper is asked to address copyright issues when signing the publication agreement (see How to Comply at http://publicaccess.nih.gov/ and http://publicaccess.nih.gov/address_copyright.htm) and to submit the final peer-reviewed version of the manuscript to Pub Med Central if necessary (See http://publicaccess.nih.gov/submit_process.htm).

10. Amendment To Publication Agreement For Dissemination Of Publications On ELGAN Study Website

After receiving notice of acceptance of a paper for publication, we request that authors ask the publisher to sign an "Amendment to publication agreement". This document can be found on the elganpub website. A signed "Amendment to publication agreement" grants the author the right to post the published article along with other study publications on the ELGAN Study website.

11. Single Institution Papers

All ELGAN Study site investigators will receive, upon request, a file of all data on all subjects enrolled at their institution in the ELGAN study. The ELGAN Study data analysis center will not be available to provide data analysis for single institution papers, though it will be happy to provide advice and guidance, time permitting. Publication and presentation, including rules of authorship and acknowledgement, for such papers will be determined by the site investigator and their institution, except that the universal acknowledgements policy described above must be adhered to, and that prior approval for analysis must be sought from the Publications and Data Analysis Sub-committee to ensure no conflict with ongoing or planned analyses of the same topic in the entire database. The Data Analysis and Publications Sub-committee must approve presentations and publications emerging from single institutions. In general, the Sub-committee will not approve single institution papers on topics which could be addressed

in the entire database. The focus of single institution papers should be on testing hypotheses via the examination of data uniquely available at that institution which can be linked to ELGAN Study data collected at that institution.

12. Forms To Be Developed

In addition to the two forms appended, the PAD sub-committee will develop forms and documents to monitor and implement the processes described above. Such forms will include:

- Membership list of each /writing interest group, including writing leaders.
- Time forms, indicating dates of formation of writing interest groups, dates of conference calls/meetings, dates of submitting requests for data, dates of receipts of data analyses, dates of submission of abstracts and manuscript drafts.

13. Data Sharing Policy

- Non-Published Research Products

In the course of developing the ELGAN study, a variety of questionnaires, policy and procedure manuals, instructional booklets and videotapes, and similar non-publishable research products have been developed, and will continue to be developed. In general, the policy of the ELGAN study is to make these materials available to other investigators with the following provisos:

  - That the ELGAN study be acknowledged in writing as the source of the material
  - That the person requesting the material cover administrative costs required for example for copying, mailing, handling and other activities related to provision of the materials
  - That the materials will not be used to enhance corporate or individual financial gain or profit.

- ELGAN Study Data

NIH now requires that all of its funded research projects develop a plan to place their datasets in the public domain for use by researchers for the purpose of scientific

research. The ELGAN Study database, which includes all prenatal, neonatal, age six month, 12-month and 24-month and 9-year assessments, stripped of all identifiers (identifiers defined by HIPAA regulations), will be placed in a password-protected website five years after the completion of the last 9-year assessment. Access to the website will be provided to investigators not affiliated with the ELGAN study who have received permission from the ELGAN PAD sub-committee to analyze ELGAN Study data. In order to receive such permission, the investigator must provide:

- The personal identification, institutional affiliation and current resume of all individuals who will have access to the ELGAN Study database.
- A description of the proposed analysis of the database
- Written and signed attestation that:
    a. The purpose of the analysis is to support publication of the results in a peer-reviewed journal.
    b. The intention of the analysis is not to further a lawsuit or legal claim against any individual or corporate entity
    c. The primary purpose of the analysis is not to enhance corporate or individual financial gain or profit.
    d. The analysis is not being used for any illegal purpose.
    e. The analysis will not attempt to identify any individuals who are subjects of the research, unless there are compelling medical or scientific reasons for doing so.
    f. Should a research subject be inadvertently identified, the investigator will immediately notify the ELGAN PAD sub-committee, and destroy all files or copies of the data set in which any subject is identifiable.
    g. All publications which make use of ELGAN Study data will adhere to the Universal Acknowledgements Policy (*see section 8*).
    h. The coding handbook provided by the ELGAN study will not be copied, and will be available only to investigators working on the project for which permission has been obtained.

The investigator must also undertake to pay a one-time fee for obtaining access to the data. An additional charge will be levied to obtain up to five copies of the coding

handbook. If the investigator finds it necessary to obtain consultation from the ELGAN Study Data Analysis Center, such consultation can be obtained for a charge per hour or fraction of an hour. The purpose of these fees and charges is to support the continued activity of the ELGAN PAD sub-committee and other staff beyond the duration of funded research to monitor use of the data. Fees will be determined based on having sufficient resources to cover the expenses of this work.

EXPOSURES & CONFOUNDERS
Blood biomarkers
Prenatal characteristics
Maternal
SES
Pregnancy
Natal/placenta characteristics
Labor and delivery
Placenta histopathology
Placenta microbiology
Placenta CRH mRNA
Newborn characteristics
Gestational age
SGA
Congenital microcephaly
Cranial US (WMD, Vmeg, Crbllm)
Inflammation (NEC, sepsis, vent)
Postnatal medications (steroids…)
ROP
CLD
24-month follow-up characteristics
Cerebral palsy
GMFCS
BSID-II MDI
BSID-II PDI
M-CHAT (ASD screen)
Microcephaly

OUTCOMES
Neuropsych
IQ
KBIT-2 Matrices
DAS-II Verbal Cluster Score
DAS-II Nonverbal Cluster Score
Executive Function
NEPSY-II (sort, attn., inhib, wrk mem)
NEPSY-II (arrows, geo puzzles)
NEPSY-II (tapping, V-M precision)
Language
OWLS Oral Composite Score
WIAT-III (word read, decode, spell)
CFCS
Computation/math
WIAT-III numerical operations
ADHD
CSI-4 symptom count
CSI-4 symptom severity
Autism/ASD status
SCQ +
SCQ +, Autism + (ADI-R & ADOS)
SCQ +, Autism - (ADI-R & ADOS)
SRS
CCC-2 (lang pragmatics scales)
Epilepsy
Psychiatric symptoms
OCD
Anxiety
Mood
PQoL
MRI
Volumetrics
Lesional abnormalities
Motor
GMFCS
MACS
CHQ

APPENDIX A

ELGAN STUDY FORM FOR PROPOSING ANALYSES OF ELGAN STUDY DATA FOR PURPOSE OF PUBLICATION

Date:_____

Provisional title of paper: _____

Lead Author: _____

Co-authors: _____ _____

_____ _____

_____ _____

Brief statement of the goal, hypothesis, or research question to be addressed:

Main variables to be used in the analysis:

Section of ELGAN Study data to be used: Entire data base ____ Other ____ (explain below)

Expected date of LITUP submission: _____ _____ _____
Mo Day Year

Expected date of first presentation: _____ _____ _____
Mo Day Year

Expected date of manuscript submission: _____ _____ _____
Mo Day Year

Note to investigators: To obtain analyses from the ELGAN Study data center

1. Frame your request as clearly as possible;
    a. Have a clearly laid out set of **hypotheses**
    b. **Define the population** of babies you are interested in, if the analyses apply to a subset of infants. Be clear as to which **variables** must be identified to describe the subset of babies you are interested in.
2. Identify the **forms (see below)** which contain the data elements that you are interested in analyzing.
3. Within the forms, define which **variables, identified both by number and name**, interest you.
4. Within a variable, define which **values** of the variable you would like analyses to break down for you.
5. Should you want **new variables** created based on existing variables please provide the algorithm that defines the new variable.
6. Prepare the tables you want to have completed, showing **column headers and row labels**.

To find ELGAN Study data forms and manuals, go to http://www.fstrf.org/ELGAN
The login is: elgan.followup
The password is: preemie

1. Click on “Forms and Instruction Manuals” under the heading, "Documentation."
2. View and/or print the PDFs of the forms and manuals.
3. If you have difficulty accessing the site or the documents, please contact Liz Allred (lizard@hsph.harvard.edu).

APPENDIX B

ELGAN STUDY AUTHORSHIP CREDIT FORM

Date:

_____

Title of Paper:_____

_____

Short Name of Paper: _____

_____

Please check each task to which you have made a contribution, and sign at end of form. This form will be checked by the lead author to confirm your role as author of this paper.

A. CONCEPT AND DESIGN

Development of the study design of this paper ☐

B. RESEARCH RESOURCES AND DATA

1. Recruitment of subjects ☐
2. Monitoring subjects while in study ☐
3. Laboratory testing ☐
4. Assessment of study subjects(e.g. imaging, examination) ☐
5. Medical record review, form completion ☐

C. ANALYSIS AND INTERPRETATION

1. Statistical consultation ☐
2. Statistical analysis ☐
3. Production of graphs and tables ☐
4. Participation in discussions of analyses ☐

D. WRITING

1. Authorship of first draft ☐
2. Authorship of segments of paper ☐
3. Reviewing and critiquing drafts ☐
4. Review of literature, provision of citations ☐

Signature _____

Print Name _____

Form adapted from Paneth N, Separating authorship responsibility and authorship credit: a proposal for biomedical journals. *Am J Public Health*, 1998; 88(5):824-6.