Systemic Synuclein Sampling Study (S4) Publication Policy

Introduction

Publication of S4 data is a major goal of the S4 Steering Committee (SC) and the study sponsor, The Michael J. Fox Foundation for Parkinson’s Research (MJFF). The unique governance structure of the S4 study necessitates a robust publication policy that ensures both appropriate acknowledgment of MJFF as sponsor and funder, as well as study leadership for study design and implementation. The following document outlines both S4’s policies for publication, as well as authorship and acknowledgment guidelines by publication type for any publication utilizing S4 subject data or biospecimens.

The intent of this policy is to ensure that:

- S4 data is published fully, accurately and expeditiously
- S4 study members are recognized for their effort in study design, acquisition and analysis of data and collection of biospecimens
- S4 publications may be tracked to develop a complete record of the findings resulting from S4 efforts

Abstracts and Posters

Abstracts and posters must be sent to the S4 SC for administrative review prior to submission. S4 can only be listed as an author on an abstract and/or poster if authorship is approved by the S4 SC. Abstracts and posters which have not been approved by the SC should acknowledge S4 as the source of data within the body of the abstract or poster.

Publication Review Process

As per the S4 Data Use and Biospecimen Use Agreements, investigators are reminded that they should submit publications to the S4 SC for administrative review 2 weeks prior to the manuscript’s submission to a journal. Review of submitted publications to the SC is guaranteed within two weeks of submission. In the event that publications are developed after the formal S4 SC has dissolved, review of submitted manuscripts will be handled internally by staff scientists at MJFF. However, any manuscripts that include DaTscan data require submission 90 days prior, as review by GE is required.

The SC and MJFF will generally not review manuscripts for scientific quality, trusting that the peer-review process is the best way to judge the objective quality of a proposal or publication.

Unusual Situations

It is expected that the publication policies to follow will cover the majority of users of S4 data and specimens. We anticipate that investigators will follow these guidelines in good faith and that most analyses will be of reasonable quality. However, we do anticipate the possibility of some unusual circumstances.

V 25 Jan 2018
1. **Egregiously Poor Manuscripts.** If a review of a proposed manuscript reveals that it is egregiously poor in terms of language, writing or sensible substance, the SC can recommend to the authors that it not be submitted without significant revision. If the authors choose to submit the manuscript anyway, the SC will have three options: 1) request that the group authorship credit be withheld; 2) request that the authors publish a statement to the effect that while S4 data were used, the S4 SC did not find this manuscript of sufficient merit to warrant submission for publication, or; 3) revocation of privileges to use S4 data in the future.

2. **Failure to Follow S4 Data and Biospecimen Use Agreements.** If users inadvertently violate the Data or Biospecimen Use Agreements, it is likely that they will self-correct as infractions are discovered. If users willfully violate these Agreements, the sole sanction available to S4 will be to revoke access to future data and/or biospecimen requests managed by MJFF.

3. **Fraudulent Use of Data or Specimens.** Open access using only online registration raises the possibility that individuals could obtain access to data under false pretenses. It is possible that even the closely vetted samples could be used inappropriately. Should the SC discover an attempt to publish using S4 data or samples obtained fraudulently, the user will be sanctioned through SC communication with them or their academic supervisors. As soon as the SC becomes aware of any breach of either Use Agreements, immediate steps will be taken to cure the breach or end the violation. This may include discontinuing the user’s data access and/or reporting the violation.

4. **Journal Objections.** It is possible that journal editors may object to the group authorship format with the caveat that those S4 names credited have gathered data but not participated in the analysis and writing of the paper. In these situations the primary author of the paper should inform the SC of the issue. The SC will work with the author to resolve this problem in a way that is acceptable to the SC.

**Publications Policy**

Given the novel nature of S4, the S4 SC will conduct the primary analyses of the biofluids and tissues collected using the most current and effective methods available. All clinical data and remaining biospecimens will then be made available to the broader research community after primary analyses of biofluids and tissues are complete (categories IV & V below).

It is anticipated that there will be several categories of S4 publications, as listed below. Additional details on each publication type are found in the relevant section:

I. Publications on the primary objectives of the study
II. Publications on the secondary objectives of the study
III. Field-Informing Analyses
IV. Independent investigator-driven analyses using samples and data
V. Independent investigator-driven analyses using only data
I. **PUBLICATIONS ON THE PRIMARY STUDY OBJECTIVES:**

*Primary Publications* are defined as those reports, analyses, and publications identified by the S4 Steering Committee as fulfilling the primary objectives of the study: (1) to evaluate the $\alpha$-syn markers as potential surrogate markers for patient selection/enrichment that would be useful in future clinical trials, and (2) to compare $\alpha$-syn load in the biofluids and tissues in PD subjects with healthy controls (HC). A list of planned Primary Publications is listed in the S4 Publications Plan.

The SC will be primarily responsible for completion of all key Primary Publications. Key Primary publications will be authored by the Steering Committee, Investigators, Study Cores and Working Groups reflecting the contribution of those authors.

A. **Authorship**

1. SC (named directly from most recent version of S4 author list)
2. Other researcher(s) analyzing samples, participating in statistical analyses, or preparing the manuscript
3. “and the Systemic Synuclein Sampling Study (S4)*” will be written on the author line of the manuscript with an asterisk referring to the list of names of individuals identified on the S4 author list. The author list must be included as an appendix to ensure that all authors may be cited. The complete list of S4 Study Investigators can be found at [https://www.michaeljfox.org/page.html?s4](https://www.michaeljfox.org/page.html?s4).

B. **Acknowledgments**

1. MJFF as sponsor/funder
2. Site PIs
3. Site coordinators
4. Study collaborators
5. Study participants

   a. **Sample Language:**

   “The Systemic Synuclein Sampling Study (S4) is funded by The Michael J. Fox Foundation for Parkinson’s Research, who is responsible for overseeing the design & conduct of the study. S4 was made possible with the support of site Principal Investigators, site coordinators, and study collaborators [https://www.michaeljfox.org/page.html?s4](https://www.michaeljfox.org/page.html?s4). Finally, we would like to thank all of the study participants and generous MJFF donors that made this study possible.”
II. PUBLICATIONS ON SECONDARY STUDY OBJECTIVE(S):

Publications on the secondary objectives of the S4 study are defined as reports, analyses and publications that are initiated by S4 study members that utilize S4 data, but which do not address the primary objectives of the study. Examples of these studies include a focus on study feasibility or recruitment, or methods of biofluid & tissue collection and analysis. It is anticipated that these publications will be developed by study investigators and cores, and authorship will reflect the contribution of those authors.

A. Authorship

1. Study Investigator and/or Core Member(s) leading publication effort
2. S4 Principal Investigator(s)
3. "the Systemic Synuclein Sampling Study (S4) Steering Committee:" (named directly from most recent version of S4 author list, when not included above)
4. Groups analyzing data, biofluid samples, and tissues (when applicable) and preparing the manuscript
5. "and the Systemic Synuclein Sampling Study (S4)*" will be written on the author line of the manuscript with an asterisk referring to the list of names of individuals identified on the S4 author list. The author list must be included as an appendix to ensure that all authors may be cited. The complete list of S4 Study Investigators can be found at https://www.michaeljfox.org/page.html?s4.

The following people should also be listed on the author line when applicable:

a. Recruitment – Jennings, Linder
b. Biologics – Jennings, Kopil
c. Feasibility/safety – Jennings, Kopil, Linder
d. Tissue staining – Jennings, Kopil, Kremer [or Roche collaborator(s)]
e. Biopsy protocols – Jennings, Kopil, GI/ENT Collaborators
f. Imaging – Jennings, Seibyl

B. Acknowledgments

1. Michael J. Fox Foundation for Parkinson’s Research (MJFF) as sponsor/funder
2. Site PIs
3. Site coordinators (when applicable, e.g. recruitment, feasibility)¹
4. Study collaborators (when applicable, e.g. recruitment, feasibility, biopsy protocols)
5. Study participants

a. Sample Language:

“The Systemic Synuclein Sampling Study (S4) is funded by The Michael J. Fox Foundation for Parkinson’s Research, who is responsible for overseeing the design & conduct of the study. S4 was made possible with the support of site Principal Investigators, site coordinators, and study collaborators [https://www.michaeljfox.org/page.html?s4]. Finally, we would like to thank all of the study participants and generous MJFF donors that made this study possible.”
III. FIELD-INFORMING ANALYSES

Field-informing analyses are defined as reports, analyses and publications that may be initiated by S4 study members and utilize S4 data, but which do not address the primary or secondary objectives of the study. Examples of these studies include a comparison/recommendation of tissue fixation/staining methods, comparison/recommendation of skin biopsy regions, comparison/recommendation of synuclein assays, etc. It is anticipated that these publications will be developed by study investigators and cores, and authorship will reflect the contribution of those authors.

A. Authorship

1. Groups analyzing data, biofluid samples, and tissues (when applicable) and preparing the manuscript

2. “and the Systemic Synuclein Sampling Study (S4)*” will be written on the author line of the manuscript with an asterisk referring to the list of names of individuals identified on the S4 author list. The author list must be include as an appendix to ensure that all authors may be cited. The complete list of S4 Study Investigators can be found at https://www.michaeljfox.org/page.html?s4.

B. Acknowledgments

1. MJFF as sponsor/funder of S4
2. Study Investigators
3. Study participants
   a. Sample Language:

   “The Systemic Synuclein Sampling Study (S4) is funded by The Michael J. Fox Foundation for Parkinson’s Research, who is responsible for overseeing the design & conduct of the study. Tissue and sample processing and analysis protocols for S4 were critically informed by the work of [PI names]. S4 was made possible with the support of site Principal Investigators, site coordinators, and study collaborators [https://www.michaeljfox.org/page.html?s4], as well as all of the generous individuals who contributed their time and effort as a study participant.”

All Other Publications Utilizing S4 Data

It is expected that outside investigators will conduct research and seek to publish analyses using S4 data and specimens once primary analyses of biofluids and tissues have been completed by S4 SC. These individuals are encouraged to publish novel scientific findings that result from their research using S4 data. Authorship of such a publication will not include S4 in the author line, but will acknowledge S4 in other ways.
IV. INDEPENDENT INVESTIGATOR-DRIVEN ANALYSES USING SAMPLES AND DATA

A. Authorship
   1. Independent Investigators

B. Acknowledgments
   1. MJFF as sponsor/funder of S4
   2. SC
   3. Study Investigators
   4. Study participants
      a. Sample Language:

      “The Systemic Synuclein Sampling Study (S4) is funded by The Michael J. Fox Foundation for Parkinson’s Research, who is responsible for overseeing the design & conduct of the study. S4 was designed and directed by the S4 Steering Committee. Members of the S4 Steering Committee include: [named directly from most recent version of S4 author list]. S4 was made possible with the support of site Principal Investigators, site coordinators, and study collaborators [https://www.michaeljfox.org/page.html?s4], as well as all of the generous individuals who contributed their time and effort as a study participant.”

V. INDEPENDENT INVESTIGATOR-DRIVEN ANALYSES USING ONLY DATA

A. Authorship
   1. Independent Investigators

B. Acknowledgments
   1. MJFF as sponsor/funder of S4
   2. SC
   3. Study Investigators
   4. Study participants
      a. Sample Language:

      “The Systemic Synuclein Sampling Study (S4) is funded by The Michael J. Fox Foundation for Parkinson’s Research, who is responsible for overseeing the design & conduct of the study. S4 was designed and directed by the S4 Steering Committee. Members of the S4 Steering Committee include: [named directly from most recent version of S4 author list]. S4 was made possible with the support of site Principal Investigators, site coordinators, and study collaborators [https://www.michaeljfox.org/page.html?s4], as well as all of the generous individuals who contributed their time and effort as a study participant.”