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.

Publication Policy
The intent of this policy is to ensure that:

- S4 data are 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; and
- Publications authored utilizing S4 data are accessible online, and free of cost or other access barriers.

Publication Categories
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 α-syn markers as potential surrogate markers for patient selection/enrichment that would be useful in future clinical trials, and (2) to compare α-syn load in the biofluids and tissues in PD subjects with healthy controls (HC).

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. Active steering committee members (see Appendix A)
2. Other researcher(s) analyzing samples, participating in statistical analyses, or preparing the manuscript; and
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. See appendix A.

B. **Acknowledgments (See appendix B)**

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

C. **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. 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) and active steering committee members;
3. Groups analyzing data, biofluid samples, and tissues (when applicable) and preparing the manuscript; and
4. “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. Appendix A.

B. **Acknowledgments: Appendix B.**

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

C. 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. 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 staining methods, comparison/recommendation of synuclein assays, studies that investigate PD pathophysiology using S4 samples 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; and
2. Active S4 steering committee members or other members of S4 team (Appendices A and B) who accept authorship and are involved in scientific aspects of the study and reporting of results.

B. Acknowledgments: Appendix A and B.

1. Active and prior s4 steering committee members
2. Site PI and collaborators
3. Michael J. Fox Foundation for Parkinson’s Research (MJFF) as sponsor/funder
4. Site coordinators (when applicable, e.g., recruitment, feasibility)
5. Study collaborators (when applicable, e.g., recruitment, feasibility, biopsy protocols)
6. Study participants

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 as well as all of the generous individuals who contributed their time and effort as a study participant.”

IV. INDEPENDENT INVESTIGATOR-DRIVEN ANALYSES USING SAMPLES AND DATA
A. **Authorship**
   1. Independent Investigators

B. **Acknowledgments:** Appendix A and B.
   1. Active and prior s4 steering committee members
   2. Site PI and collaborators
   3. Michael J. Fox Foundation for Parkinson’s Research (MJFF) as sponsor/funder
   4. Site coordinators (when applicable, e.g., recruitment, feasibility)
   5. Study collaborators (when applicable, e.g., recruitment, feasibility, biopsy protocols)
   6. Study participants

_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 appendix A]. S4 was made possible with the support of site Principal Investigators, site coordinators, and study collaborators, 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

*The S4 study, steering committee, and investigators are NOT to be listed as an author without approval of the S4 committee.

B. **Acknowledgments:** Appendix A and B.
   1. Active and prior s4 steering committee members
   2. Site PI and collaborators
   3. Michael J. Fox Foundation for Parkinson’s Research (MJFF) as sponsor/funder
   4. Site coordinators (when applicable, e.g., recruitment, feasibility)
   5. Study collaborators (when applicable, e.g., recruitment, feasibility, biopsy protocols)
   6. Study participants

_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, as well as all of the generous individuals who contributed their time and effort as a study participant.”

VI. All Other Publications Utilizing S4 Data
Since S4 data is free and publicly available, 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. External users of S4 data are strongly 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. All manuscripts by external authors must be submitted to the SC for administrative review prior to journal submission.

Publication Review Process

Investigators should submit publications to the S4 SC at openaccess@michaeljfox.org 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.

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.

Free Public Access to S4 Publications

The intent of the S4 Publications Policy is to provide for open, free, public access to analyses of S4 data. All publications that are produced by S4 funded investigators are required to publish in an open-access journal or in a hybrid open access journal as a fully open access article.

Open Access consists of the following principles:

- **Immediate free access**: Peer-reviewed, author accepted research must be made freely available immediately upon publication, without any embargo period (zero embargo).
- **Unrestricted reuse rights**: Articles must be published under the Creative Commons Attribution license CC BY 4.0, or equivalent. The license ensures that you receive attribution for the work (intellectual ownership) but allows your work to be freely shared (redistributed in any medium or format or adapted for future purposes). You can also select a more open license such as the CC0 license (applied to authors employed by the U.S. federal government) which does not require attribution for the work when being re-used.

MJFF provides coverage for open access articles when applicable and if certain requirements are met. Publications under the S4 Publication Policy may be eligible for payment of reasonable Article Processing Charges for open access. To apply for coverage, please complete MJFF’s online form. When the request is submitted, you will receive an email from the MJFF Open Access Publications team confirming receipt. They will review your request within 3-4 business days and notify you via email of the decision regarding the request.

Any questions related to S4’s Open Access guidance should be directed to: openaccess@michaeljfox.org

Abstracts and Posters
Abstracts and posters must be sent to the S4 SC at openaccess@michaeljfox.org for administrative review 2 weeks prior to the abstract and/or poster 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.

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.

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 sanctions available to S4 will be to revoke access to future data and/or biospecimen requests managed by MJFF and/or reporting the violation to appropriate oversight organizations and publishers. Further, willful DUA violation will be taken into consideration in any future MJFF funding requests.

3. Fraudulent Use of Data or Specimens or other Research Misconduct. Open access using only online registration raises the possibility that individuals could obtain access to data or biospecimens under false pretenses. It is also possible that an individual could use S4 data or biospecimens in the misconduct of research, e.g., the manipulation of research materials, equipment, or processes or changing/omitting data or results such that the research is not accurately represented in the research record. Should the SC discover an attempt to publish using S4 data or samples obtained fraudulently or other research misconduct involving S4 resources, the user will be sanctioned through SC communication with them or their academic supervisors. Immediate steps will be taken to cure the breach or end the violation, or be subject to sanctions by S4 and MJFF. This may include discontinuing the user’s access to S4 and any other data and/or biospecimen requests managed by MJFF and/or reporting the violation to appropriate oversight organizations and publishers. Further, any fraudulent conduct involving the S4 data or biospecimens, will be taken into consideration in any future MJFF funding requests.

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.
Appendix A: Authors On Primary and Secondary Analyses; select authors on Field-Informing Analyses. Acknowledged on Independent Investigator and Data-Only Publications

Active Steering Committee Members:
Lana M. Chahine
Thomas G Beach
Charles H. Adler
Sherri Mosovsky
Jamie Eberling
Brit Mollenhauer

Inception/Former Steering Committee Members (in addition to active members above):
Danna Jennings
John Seibyl
Vanessa Arnedo
Lindsey Riley
Dave Kuldip
Carly Linder
Tatiana Foroud
Katherine Kopil

S4 study investigators and Study Core Authors:
David Russell       Site Investigator
Penelope Hogarth    Site Investigator
Rizwan Akhtar       Site Investigator
Amy Amara           Site Investigator
Connie Marras       Site Investigator
Naomi Visanji       Site Investigator
David P. Breen      Site Investigator
John Crary          Pathology Collaborator
Charles White       Pathology Collaborator
David Munoz         Pathology Collaborator
Chelsea Caspell-Garcia Statistics Core
Geidy E. Serrano    Pathology Core
Christopher Coffey  Statistics Core
Michael C. Brumm    Statistics Core
Luis Oliveira       Sponsor collaborator

Appendix B: Acknowledged on all publications

Study Core, Site coordinator, Industry acknowledgements:
Ergun Uc (Medical Monitor)
Jan Hamer (Biorepository)
Colleen Mitchell (Biorepository)
Scott Appel (Biostatistician)
Dixie Ecklund (Clinical and Statistics Core)
Holly Riss (Clinical and Statistics Core)
Lucia Sue (Pathology Core)
Anthony Intorcia (Pathology Core)
Michael Glass (Pathology Core)
Jessica Walker (Pathology Core)
Lindsey Guilmette (Imaging Core)
Vikash Oza (Dermatology Collaborator)
David Lott (ENT Collaborator)
Ali Keshavarzian (GI Collaborator)
Julie Schneider (Pathology Collaborator)
Thomas Kremer (Industry Collaborator)
Christian Schmauch (Industry Collaborator)
Peggy Taylor (Industry Collaborator)
Trevis Huff (Clinical and Statistics Core)
Danielle Smith (Biorepository)
Chaucer Noyes-Lloyd (Study Coordinator)
Rachael Purri (Study Coordinator)
Brandon Rothberg (Study Coordinator)
Courtney Blair (Study Coordinator)
K. Rose case (Study Coordinator)
Madeline Cresswell (Study Coordinator)
Amy Duffy (Study Coordinator)
Madeline Potter (Study Coordinator)
Study participants

General Electric for donation of DATscan™ doses in kind.