APPENDIX I
P2P Platform Trial Publication Policy

The Path to Prevention (P2P) study is a platform clinical trial where multiple interventions will be examined. Timely publication of results from the P2P platform trial is central to the P2P mission. P2P is sponsored by The Michael J. Fox Foundation for Parkinson's Research (MJFF).

This policy applies to all publications authored by persons using P2P information, data and/or biospecimens ("P2P Resources"), including without limitation P2P Resources from any regimen specific sub protocol ("RSSP"), except for any publication: (a) by or on behalf of a company relating to its investigational product studied pursuant to an RSSP ("Industry Partner"); or (b) generated through P2P Resources obtained through PPMI ("Open Access") that does not include any author who worked on P2P or an RSSP. This policy should be included within or as an attachment to contracts with P2P sites, study cores and relevant vendors. Publications generated by or on behalf of an Industry Partner will be governed by written agreement between MJFF and the Industry Partner. Publications based only on P2P Resources obtained through PPMI that do not include any author who worked on P2P or an RSSP will be governed by PPMI policies, including without limitation the PPMI Publication Policy, available at https://www.ppmi-info.org/sites/default/files/docs/ppmi-publication-policy.pdf.[1]

P2P publications include manuscripts, abstracts and accompanying posters, presentations, and public website postings that report any results, including baseline characteristics, clinical and laboratory findings and conclusions of individual interventions, as well as those that address overall trial design and operations. Each regimen is expected to result in at least one peer-reviewed manuscript and presentations of RSSP results at national and international meetings.

All proposed P2P manuscript publications subject to this policy shall be submitted to the P2P Steering Committee ("SC") for review at least forty-five (45) days prior to submission for publication outside of P2P, and proposed P2P abstracts and other P2P materials subject to this policy shall be submitted to the P2P SC at least fourteen (14) days prior to their proposed publication. The foregoing time periods include an Industry Partner's thirty (30) or fourteen (14) day (as applicable to the type of publication) right of review for publications involving data generated pursuant to an RSSP involving an Industry Partner's investigational product, which shall be facilitated by the SC as set forth in the Submission Procedure section of this policy. An Industry Partner may delay publication for up to ninety (90) days in order to file for intellectual property protection, if applicable. Additional detail is provided below in the SUBMISSION PROCEDURE section of this policy.

Review & Approvals

The P2P SC will review all proposed publications subject to this policy to ensure scientific integrity and shall advise the authors if the P2P publication: (i) contains or discloses any intellectual property ("IP") of

[1] MJFF may determine that certain PPMI policies will include P2P specific riders as they relate to third party use of P2P Resources through Open Access.

a third party that might be compromised by publication, or (ii) contains any confidential information of a third party. The P2P SC has the option of requiring that the authors delete that portion of any proposed publication that may prejudice a third party's IP rights or that discloses confidential information of a third party. In addition, if applicable to a proposed publication, an Industry Partner may require or prohibit its identification in a proposed publication and, in such event, the P2P SC may require the authors to include or delete identification of the Industry Partner. MJFF will seek to include in its written agreements with Industry Partners that they will need to be identified as the source of the investigational product studied in the RSSP.

The P2P SC also will review any proposed publications related specifically to the P2P Master Protocol. If no RSSP data is included in the proposed publication, Industry Partner review will not be required.

The P2P SC also will coordinate review by the data and publications committee ("DPC"), any RSSP specific committee, and any Industry Partner that supplied an investigational product for which related data is included in the proposed publication. A P2P DPC may be formed by MJFF, or MJFF may determine to use the PPMI DPC, to review all proposed publications to ensure they comply with the below policy requirements for authorship, acknowledgements, and data sharing.

Authorship
For each RSSP-specific primary manuscript (defined below under SUBMISSION PROCEDURE), a list of authors will be generated based on intellectual contributions in accordance with International Committee of Medical Journal Editors (ICMJE) standards, *see* https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html. Authors should be listed in the following order: primary author (generally the RSSP lead investigator), followed by the RSSP co-lead investigator (when applicable), primary biostatistician(s), RSSP Steering Committee members, including industry representatives on the Steering Committee (if any) and P2P, and the P2P Principal Investigator as the senior author.

Each P2P publication subject to this policy must include the phrase "on behalf of the Path to Prevention Study *" at the end of the author line, as directed by the SC or DPC with an appendix to the manuscript to include full P2P authors list inclusive of , in order, the Master Protocol PI, coordinating centers and key staff, and site PIs or their designee (in descending order based on number of participants randomized per site) as appropriate. Any professional medical writing support should be disclosed. All other personnel who contributed to the study but do not qualify for the authorship will be included in the acknowledgement.

Acknowledgements
In addition to acknowledgement of MJFF and appropriate grant citations, the publication should include the ClinicalTrial.gov identifier, known as the NCT number. The respective Industry Partner may provide appropriate acknowledgements to be noted as well.

Arbitration
If conflicts exist regarding P2P publications, written summaries of the conflict submitted by those involved will be reviewed by the P2P SC, and, to the extent any non-P2P PPMI data also is applicable, the PPMI Executive Steering Committee (ESC). Any investigator who wishes to opt out of any automatic authorship listing may do so in writing to the P2P Steering Committee.

SUBMISSION PROCEDURE

Primary Manuscripts: The primary RSSP manuscript is written by the RSSP Steering Committee, led by the primary author(s) (generally the RSSP lead investigator, and describes results and analysis of the study (i.e., analyses addressed in the formal study Statistical Analysis Plan {SAP}). After the RSSP database lock, Top Line Results (TLR) will be presented to the RSSP Steering Committee, as outlined in the P2P Data Sharing Plan. After that presentation, the primary author(s), and RSSP Steering Committee will begin manuscript development in accordance with the analyses plan specified in the SAP. The RSSP PI and protocol statistician(s) will be the primary contacts for any writing group, unless another statistician is assigned to support a specific writing group. Requests for additional analysis beyond TLR believed to be necessary for the primary manuscript will be reviewed by the P2P SC.

a) Authorship must be agreed upon by the SC of each regimen and approved by the P2P SC as outlined in the Authorship section.
b) A manuscript reporting the primary RSSP results should be submitted by the primary author(s) to the P2P SC in a timely manner but no more than 6 months from the date the primary author(s) are provided TLR. The manuscript should be submitted along with the P2P Platform Trial Publication Submission Form (**P2P Platform Trial Publication Submission Form** Exhibit A).
c) The P2P SC will provide manuscripts to: Industry Partners for their review of identifying company or company confidential information, which may be removed from the publication upon the company's request (subject to MJFF's written agreement with the Industry Partner), any suggested input or additional relevant information, and delay up to ninety (90) days to file for intellectual property protection, and the Data Safety Monitoring Board (DSMB) to review publication of the primary analysis for each intervention, prior to their distribution to any journal.

Additional Manuscripts: Additional manuscripts are those arising from other secondary or exploratory analyses of data by members of the RSSP writing group, analysis of released study data by other investigators, and methodological papers. These may include but not limited to baseline data, exploratory analysis, trial methods and operations.

a) Manuscripts based on the Master Protocol, including P2P methods and operations, must be submitted to the P2P SC. Manuscripts based on these topics also will be written and led by the Master Protocol PI/designee with input from Berry Consultants and PPMI Biostatisticians and the P2P SC.
b) Additional manuscripts that utilize final RSSP data may be proposed by the RSSP lead and co-lead investigators (where applicable), site investigators or other investigators involved with the RSSP design and execution. These additional manuscripts may be considered after the primary manuscript has been accepted for publication in a peer-reviewed journal.
c) Each manuscript proposal that seeks to include RSSP data must be submitted to the P2P SC for review and approval, and coordination of approvals, as set forth above, and must be accompanied by a written statement of manuscript and authorship approval from the RSSP lead investigator. Manuscripts reporting on the data collected from an individual study site by site investigators must be submitted to the P2P SC for review and approval,

and coordination of approvals as set forth above, at least 45 days prior to submission.

d) The P2P SC should be notified of any invited reviews and book chapters that include discussion of P2P.

Abstracts for Oral/Poster Presentation: Abstracts, posters, and oral presentations are those prepared for presentations at professional meetings that will utilize P2P information and data, including without limitation from any RSSP, and/or information relating to P2P or any RSSP methods and operations.

a) Draft abstracts shall be submitted to the P2P SC by the lead author at least fourteen (14) days prior to submission. Authors of abstracts are to ensure that the appropriate acknowledgments are included, and all co-authors have had an opportunity to review the abstract prior to submission.

b) Draft abstracts are review and approved by the entities, and according to the standards and procedures, as set forth above in this policy. For clarity, if the abstract contains data related to an RSSP, the Industry Partner will be provided a copy of the abstract for review (via the RSSP Steering Committee) for its review and suggested input.

Other P2P Material/Press Releases: Other materials discussing P2P, including press releases and materials to be posted on-line, should be submitted directly to the P2P Master Protocol PI and MJFF for review at: PPMI.Publications@indd.org.

a) Draft online material and press releases shall be submitted at least fourteen (14) days prior to submission.

b) If the online materials and press releases contain information related to an RSSP, the Industry Partner will be provided a copy of the materials for review (via the RSSP Steering Committee).

P2P Platform Trial Publication Contract Terms

The principles set forth in P2P Platform Trial Publication Policy addendum shall align with the contractual terms of the written agreements between MJFF and the sites, other vendors, and with Industry Partners. This policy may be reviewed and amended on an as needed basis, including without limitation for the purpose of aligning it with any written agreements governing the operation of P2P.

Exhibit A: P2P Platform Trial Publication Submission Form

Submission Procedure:
Please submit the Publication Submission Form along with your publication to PPMI.Publications@indd.org for distribution to P2P Steering Committee for review to ensure they comply with PPMI and P2P Platform Trial requirements for authorship, acknowledgements and data sharing in accordance with the PPMI Publication Policy and P2P Platform Trial Publication Addendum. Please email PPMI.Publications@indd.org with any questions.

Study ID:
Submitted by (Name):
Contact email:
Date of Notification to P2P Steering Committee:
Working Title:

Authorship
Lead Author:
Contributing Authors *(please list all)*:

Rationale for Authorship *(please describe)*:

Does the writing group agree with authorship? □Yes □ No
(if No, please describe and note timeline for escalation to Executive Steering Committee):

Publication
Type of Publication *(select one)*:
□ Abstract for oral or poster presentation □ Oral or poster
□ Manuscript

Subject matter:
□ Primary results □ Baseline results
□ Other *(please specify)*:

Publication/abstract to be submitted to:

Submission Deadline:

Additional Comments:

FOR COMMITTEE USE ONLY
Authorship – is it sufficiently justified and consistent with the PPMI Publication Policy and P2P Platform Trial Publication Addendum?
□ Yes
□ No *(if no, please describe)*:

Acknowledgements – are they consistent with the PPMI Publication Policy and P2P Platform Trial Publication Addendum?
□ Yes
□ No *(if no, please describe)*:

Reviewed by applicable Industry Partner(s)?
□ Yes
□ No *(if no, please describe)*:

Data Use– are they consistent with the P2P Platform Trial Data Sharing Policy?
□ Yes
□ No *(if no, please describe)*:

Approved By:
Signature: Date:

Role: