CAROLINE TANNER M.D., PH.D.

PPMI FOUND (FOLLOW-UP OF PERSONS WITH NEUROLOGIC DISEASES)
WHAT IS FOUND?

- FOUND is a method for long term follow-up of research subjects using:
  - Emailed or mailed questionnaires
  - Telephone contact
  - Does not require in-person visits
- FOUND provides a “safety net” for in person follow-up to help researchers keep in touch with participants and ensure that their valuable information is not lost
- Through FOUND maintain contact information, vital status, diagnosis, and other valuable information
- There is a single IRB (UCSF): efficient communication, reduced number of participants lost to follow-up

**GOAL:** Life long follow-up with PPMI participants
ADVANTAGES OF FOUND IN PPMI

❖ Engage and enroll subjects from all PPMI cohorts
  • Including active, completed, or withdrawn subjects

❖ Contact information and diagnosis confirmed twice a year
  • Contact & diagnosis questions repeated bi-annually to track changes

❖ FOUND allows rapid and effective contact of all PPMI subjects
  • May be willing to participate in other assessments (i.e. FOX Insight)
  • Inform and provide info for on-going or potential therapeutic studies

❖ FOUND can coordinate support with PPMI Sites & PPMI Cores
  • PPMI Pathology Core follow-up post study completion
  • Subjects who are unable to complete site visits (i.e. advanced disease)
  ➔ Promote retention over the long term!
FOUND SITE PARTICIPATION

- FOUND approved and enrolling
  - all 21 US sites
  - 6 non US sites: Australia, England, Barcelona, San Sebastian, Italy, Greece
- FOUND IRB approval in progress
  - 4 non US sites: France, Germany, Norway
- FOUND IRB approval stalled
  - 2 non US site: Austria, Israel
FOUND ENROLLMENT (%)

- Enrolled
- Enrollment in progress
- Unable to enroll

Overall PD HC Prodromal Genetic Cohort
- PD
- Genetic Registry
- Una.

Enrolled: n=423, n=196, n=65, n=232, n=322, n=213, n=264
Unable to enroll: n=1719, n=423, n=196, n=65, n=232, n=322, n=213, n=264
FOUND UNABLE TO ENROLL (%)

- IRB not approved
- Subject not referred to FOUND
- Refused
- Deceased
- Ineligible

<table>
<thead>
<tr>
<th>Category</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>1719</td>
</tr>
<tr>
<td>PD</td>
<td>423</td>
</tr>
<tr>
<td>HC</td>
<td>196</td>
</tr>
<tr>
<td>Prodromal</td>
<td>65</td>
</tr>
<tr>
<td>Genetic Cohort PD</td>
<td>232</td>
</tr>
<tr>
<td>Genetic Cohort Una.</td>
<td>322</td>
</tr>
<tr>
<td>Genetic Registry PD</td>
<td>213</td>
</tr>
<tr>
<td>Genetic Registry Una.</td>
<td>264</td>
</tr>
</tbody>
</table>
Total enrolled and baseline survey completed, n=966
Withdrawal as of April 2018, n=2
Retention in FOUND: 99.8%
FOUND FOLLOW-UP COMPLETION BY GROUP (% OVER EXPECTED)

Retention: 99.8%

4/9/18
Participants enrolled in PPMI FOUND complete the RFQ once.

Questionnaires can be completed:
- at subject’s own pace
- remotely via REDCap for electronic completion

Available in all PPMI national languages. Areas assessed:

- Head Injury or Concussion
- Caffeine and Alcohol consumption
- Residential History (Entire Lifespan)
- Height & Weight (Entire Lifespan)
- Occupations (Entire Lifespan)
- Pesticides at Work and in Non-Work Settings (Entire Lifespan)
- Smoking & Tobacco use
- Ca Channel Blocker Medication History
- Physical Activity & Sleep
- Anti-inflammatory Medication History
- Toxicants
GOOD PDRFQ COMPLETION IN ALL COHORTS

% Completed any

% Not responding

Overall | PD | HC | Prodromal | Genetic Cohort PD | Genetic Cohort Una. | Genetic Registry PD | Genetic Registry Una.
PRELIMINARY RESULT: % EVER CIGARETTE SMOKING (AS OF 4/9/18)

- Ever regular smoked
- Never regular smoked

<table>
<thead>
<tr>
<th>Category</th>
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<td>De Novo PD</td>
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<tr>
<td>Genetic PD</td>
<td>87</td>
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<tr>
<td>Genetic Una.</td>
<td>221</td>
</tr>
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</table>
Next Steps for PPMI Found:

- Continue to engage all PPMI cohorts:
- Focus on retention of enrolled participants
- Continue to collect environmental exposure information
- Possible new activities:
  - Communicate study news
  - Collect other types of data
WE NEED YOUR HELP!

» REFER unenrolled to UCSF

» EDUCATE: purpose, importance, expectations

» THANK enrolled participants

» ENCOURAGE continuing participation
Thank You!
## FOUND Participation

### – By Cohort (as of April 6, 2018)

<table>
<thead>
<tr>
<th>PPMI Enrollment Cohort</th>
<th>Total Enrolled in PPMI</th>
<th>Total Eligible*</th>
<th>Total agreed to FOUND</th>
<th>% agreed over eligible</th>
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</thead>
<tbody>
<tr>
<td>Overall</td>
<td>1719</td>
<td>1472</td>
<td>1245</td>
<td>84.5</td>
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<tr>
<td>PD</td>
<td>423</td>
<td>369</td>
<td>315</td>
<td>85.4</td>
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<tr>
<td>HC</td>
<td>196</td>
<td>165</td>
<td>143</td>
<td>86.7</td>
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<td>56</td>
<td>54</td>
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<td>180</td>
<td>159</td>
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<tr>
<td>Genetic Cohort Unaff.</td>
<td>325</td>
<td>284</td>
<td>262</td>
<td>92.3</td>
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<tr>
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<td>213</td>
<td>174</td>
<td>108</td>
<td>62.1</td>
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<tr>
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<td>264</td>
<td>244</td>
<td>204</td>
<td>83.6</td>
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</table>

* Eligible – Sites have IRB approval
## FOUND Enrollment Progress – Overall by Cohort

<table>
<thead>
<tr>
<th>PPMI Cohort</th>
<th>Total Agreed to FOUND</th>
<th>Consent ed to FOUND</th>
<th>% agreed who Consented</th>
<th>Baseline Completed</th>
<th>% Consented who completed BL</th>
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<tbody>
<tr>
<td>Overall*</td>
<td>1245</td>
<td>1044</td>
<td>83.9</td>
<td>966</td>
<td>92.4</td>
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<tr>
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<td>315</td>
<td>258</td>
<td>81.9</td>
<td>244</td>
<td>94.6</td>
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<tr>
<td>HC</td>
<td>143</td>
<td>107</td>
<td>74.8</td>
<td>99</td>
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<tr>
<td>Prodromal</td>
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<td>75.9</td>
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<td>78.0</td>
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<tr>
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<td>182</td>
<td>89.2</td>
<td>168</td>
<td>92.3</td>
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</tbody>
</table>

* SWEDD not included
**FOUND ENROLLMENT PROGRESS BY CONTACT METHODS BY SPOKEN LANGUAGE**

<table>
<thead>
<tr>
<th>Language</th>
<th>Agreed</th>
<th>% of total</th>
<th>% consented</th>
<th>With email</th>
<th>% consented</th>
<th>Without email</th>
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<tr>
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<td>100%</td>
<td>83.7%</td>
<td>974</td>
<td>90.6%</td>
<td>271</td>
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<tr>
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<td>1092</td>
<td>87.7%</td>
<td>85.7%</td>
<td>876</td>
<td>92.1%</td>
<td>216</td>
<td>59.9%</td>
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<tr>
<td>Spanish</td>
<td>117</td>
<td>9.4%</td>
<td>76.9%</td>
<td>77</td>
<td>81.8%</td>
<td>40</td>
<td>67.5%</td>
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<tr>
<td>Greek</td>
<td>18</td>
<td>1.4%</td>
<td>22.2%</td>
<td>12</td>
<td>33.3%</td>
<td>6</td>
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<tr>
<td>Italian</td>
<td>18</td>
<td>1.4%</td>
<td>66.7%</td>
<td>9</td>
<td>88.9%</td>
<td>9</td>
<td>44.4%</td>
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</table>
## CHARACTERISTICS OF FOUND PARTICIPANTS BY SPOKEN LANGUAGE

<table>
<thead>
<tr>
<th>Language</th>
<th>Total N</th>
<th>Mean Age*</th>
<th>% Male</th>
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<td>Total</td>
<td>1044</td>
<td>60.1</td>
<td>54.3%</td>
</tr>
<tr>
<td>English</td>
<td>938</td>
<td>60.4</td>
<td>54.6%</td>
</tr>
<tr>
<td>Spanish</td>
<td>90</td>
<td>58.1</td>
<td>49.5%</td>
</tr>
<tr>
<td>Greek</td>
<td>4</td>
<td>52.9</td>
<td>33.3%</td>
</tr>
<tr>
<td>Italian</td>
<td>12</td>
<td>56.3</td>
<td>71.4%</td>
</tr>
</tbody>
</table>

* Age at PPMI enrollment
FOUND PARTICIPATION BY AGE

Mean age agreed
Mean age not agreed

Overall PD HC Prodromal Genetic Cohort PD Genetic Cohort Una. Genetic Registry PD Genetic Registry Una.
DATA QUALITY IS GOOD

- Data checks performed on 476 who completed all survey
- Data clean, no queries - 45% (214/476)
- At least one query - 55%
- More than 3 queries – 16.2%
PPMI FOUND TALKING POINTS FOR INVESTIGATORS & COORDINATORS
THE FOUND SYSTEM PROVIDES AN ACCESSIBLE, EFFICIENT AND COST-EFFECTIVE WAY FOR PPMI VOLUNTEERS TO CONTRIBUTE TO THE STUDY AIMS AND STAY INFORMED ON PPMI NEWS AND UPDATES.

» If PPMI participants are no longer able to complete in-person visits, they can continue contributing to the study through FOUND.

» The FOUND infrastructure also allows for PPMI leadership to share study news and updates with participants electronically, making sure volunteers know the latest from their contributions.
PPMI AND UCSF ARE WORKING TO MAKE PARTICIPATION IN FOUND AS EASY AS POSSIBLE.

» If you choose, consent to have your name, email and phone number shared with the UCSF FOUND team. Email correspondence is preferred for efficiency.

» FOUND team members will contact you to explain the project further and obtain consent if you choose to participate.

» FOUND will send you surveys and PPMI study updates periodically, no more than twice a year.
FOX INSIGHT PROVIDES ANOTHER OPPORTUNITY TO ELECTRONICALLY CONTRIBUTE PATIENT-REPORTED DATA THEN LINKED WITH ONE’S PPMI PROFILE TO BUILD A MORE ROBUST PICTURE OF PARKINSON’S DISEASE.

» The Michael J. Fox Foundation has built Fox Insight, a digital platform and dynamic online clinical study, to build a large, diverse cohort of patients and control volunteers providing drug makers, regulators and payers critical insight into the lived experience of Parkinson’s disease.

» Fox Insight’s flexible design enables integration of diverse data collection modalities (including surveys, mobile technologies such as smartphones and wearable devices, and genetic sequencing).

» Data entered through Fox Insight is de-identified and can be linked to one’s PPMI profile to expand the value of molecular and genetic data by correlating it with patients’ own characterization of the disease.
SITE REPORTS, ELECTRONIC CONTACT INFORMATION
SITE REPORT OF FOUND IN PPMI

Follow up with PPMI subjects with a Status Code of 3-4 at their next visit

Monthly FOUND in PPMI Pending Subject Report
PPMI Site: 073 UCSF
Date: 1April 2017

Thank you for taking the time to review the FOUND in PPMI study with your PPMI participants and to collect contact information for follow-up by University of California at San Francisco (UCSF). Please thank all your subjects for considering participation.

<table>
<thead>
<tr>
<th>PPMI Subject #</th>
<th>Visit date</th>
<th>Subject Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>56558</td>
<td>3</td>
<td>ICF sent 02/14/2017</td>
</tr>
<tr>
<td>2</td>
<td>55842</td>
<td>3</td>
<td>ICF sent 08/29/2016</td>
</tr>
<tr>
<td>3</td>
<td>52646</td>
<td>4</td>
<td>Questionnaire sent 01/10/2017</td>
</tr>
<tr>
<td>4</td>
<td>54384</td>
<td>4</td>
<td>Questionnaire sent 08/26/2016</td>
</tr>
<tr>
<td>5</td>
<td>52276</td>
<td>4</td>
<td>Questionnaire sent 08/29/2016</td>
</tr>
<tr>
<td>6</td>
<td>56491</td>
<td>4</td>
<td>Questionnaire sent 12/02/2016</td>
</tr>
<tr>
<td>7</td>
<td>3150</td>
<td>7</td>
<td></td>
</tr>
<tr>
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<tr>
<td>9</td>
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</tr>
<tr>
<td>10</td>
<td>3168</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Subject Status Code
(1) CRF: "Contact information – FOUND" indicates the participant agreed to share contact information with UCSF. Contact information has not been received at UCSF. Please send UCSF the FOUND contact form for these participants.
(2) Contact information received at UCSF is not valid. Please update contact information and provide updates to UCSF.
(3) Participants have not responded to multiple contact attempts by the UCSF FOUND in PPMI team. Please let these participants who Consented to the FOUND in PPMI study know that the UCSF PPMI team will be contacting them by email via FOUNDinPPMI@ucsf.edu (and possibly by telephone [415-571-4035] or mail [C.Tanner MD Box #1838, FOUND in PPMI, 1635 Divisadero St. Suite 520, San Francisco CA 94115]).

At this time review the participant’s contact information. Provide any updates to the FOUND team. Please remind the participant that the purpose of FOUND is to provide a mechanism for the PPMI study team to keep in touch with both active and completed PPMI subjects.

(4) Participant signed the FOUND in PPMI consent form provided by UCSF, but did not complete the "Getting Started: First Survey". Please remind participant(s) that UCSF will be contacting subjects by email, unless another contact method was noted, to complete the Enrollment Questionnaire.

(5) Participant in progress: Please thank these participants for signing up and let them know that the UCSF team will be contacting them by email (or possibly by phone or mail).
(6) Declined: Participants provided contact information, but declined to participate in FOUND in PPMI. (Participants sometimes refuse because at this particular time it is not possible for them to participate. If participants refused initially, but later wish to participate please update the Contact Information CRF and send an updated contact form to UCSF. As one goal for the FOUND in PPMI ancillary study is to collect optional data on the PPMI subjects, any subject, active or completed can enroll in FOUND at any time.)
(7) Participants enrolled and the initial FOUND questionnaire was completed. These participants have successfully enrolled. Please thank these participants for signing up and let them know that they can expect to receive a FOUND questionnaire every 6 months.
EXAMPLES FOUND IN PPMI FOR REVIEW WITH PARTICIPANTS

» Screen shots of email initial contact
» Screen shots of electronic consent
» Screen shots of electronic survey

» All these screen shots will be included in the PPMI Operational Manual
Dear PPMI participant,

Thank you very much for your willingness to learn more about FOUND in PPMI. We received your information from Boston University, your PPMI study site. FOUND in PPMI is a method for helping researchers keep in touch with PPMI participants. In PPMI, you are helping researchers learn new ways to identify Parkinson’s disease and track disease progression. FOUND in PPMI is one more way that the goals of PPMI can be achieved. FOUND in PPMI will allow us to keep in touch with you and collect information about your health using questionnaires. Approximately twice a year, we will ask you to answer some simple questions using surveys that we will send to you in the mail. We truly appreciate your help. Without people like you, this research would not be possible.

You will find an informational brochure at the bottom of this email. The consent forms will be sent to you in a separate email soon. The email will come from a member of our research staff.

If you have any questions regarding the email or consent forms, you can reply to this email or call (415) 571-4035 or toll free at 844.421.6834 to get in touch with us. We will get back to you as soon as we can, most likely within 2 business days.

We greatly appreciate your willingness to volunteer your time to further our understanding of Parkinson’s disease.

Thank you for your interest in FOUND in PPMI.

Sincerely,

Caroline Tanner, MD, PhD
Principal Investigator

Cheryl Meng  Samantha Betheil  Samantha Konz
FOUND Project Manager  Research Assistant  Research Assistant
STUDY BROCHURE

FOUND In PPMI
(Follow-up of Persons with Neurologic Diseases in the Parkinson’s Progression Markers Initiative)

What is the FOUND in PPMI Project?
The FOUND in PPMI Project (Follow-up of Persons with Neurologic Diseases in the Parkinson’s Progression Markers Initiative) helps researchers keep in touch with participants in PPMI. We will mostly contact you electronically through email and other secure methods, but we will occasionally use mail and telephone. In PPMI, you are helping researchers to learn about new ways to identify Parkinson’s disease and track how it progresses. FOUND in PPMI is one more way that the goals of PPMI can be achieved.

Who is eligible?
Everyone who participated in PPMI is eligible for FOUND in PPMI.

Why participate?
Your participation in this study could help society as a whole. By taking part, you will be supporting researchers who are dedicated to learning more about Parkinson’s disease and finding better treatments for it. As in PPMI, the information you provide will help to guide future research on Parkinson’s disease.

What is required of the study participants?
You will be asked at enrollment and then every 6-12 months to complete surveys. These surveys will include questions about your health.
You will be sent a link to the survey by email, or if you prefer we will contact you by mail or by telephone.

What will you do with the results?
The results will add to the findings of PPMI. Together, PPMI and FOUND in PPMI will help researchers better understand the onset and progression of Parkinson’s disease and develop better treatments.

Will my information be kept confidential?
The information will be used only for scientific purposes. You will be identified by a code number.

For more information about the FOUND in PPMI Project:
Phone: 415-353-4031       Email: foundinppmi@ucsf.edu
ELECTRONIC CONSENTING
DOCUSIGN EMAIL

From: DocuSign System <dse@docsign.net> on behalf of Samantha Bethel <Samantha.Bethel@ucsf.edu>
To: Bethel, Samantha
Cc:
Subject: PPMI Michael J Fox Foundation FOUND Project: Please review and sign the attached consent forms

Caroline Tanner, MD, PhD
Principal Investigator

Cheryl Meng, MPH
FOUND Project Manager

Samantha Bethel
Research Assistant

Samantha Konz
Research Assistant

View Documents

Alternatively, you can access these documents by visiting docsign.com, clicking the “Access Documents” link, and using this security code:

829578E8C9D74EE1AE23CED4AE43D0A91

PLEASE READ: As the intended recipient of this email, you acknowledge responsibility for any signature on the document should you grant someone else access to this email either by forwarding or by delegation. For
CLICK THE CHECKBOX “I AGREE TO USE ELECTRONIC RECORDS AND SIGNATURES”, THEN HIT “CONTINUE”.

Dear PPMI participants,

Please read the Electronic Records and Signature Disclosure.

I agree to use electronic records and signatures.

CONTINUE
CLICK “START” AND CONTINUE TO CLICK “NEXT” AS YOU READ THROUGH THE CONSENT FORM.

FOUND In PPMI
(Follow-up of Persons with Neurologic Diseases in the Parkinson’s Progressive Markers Initiative)

What is the FOUND in PPMI Project?
The FOUND in PPMI Project (Follow-up of Persons with Neurologic Diseases in the Parkinson’s Progression Markers Initiative) helps researchers keep in touch with participants in PPMI. We will mostly contact you electronically through email and other secure methods, but we will occasionally use mail and telephone. In PPMI, you are helping researchers to learn about new ways to identify Parkinson’s disease and track how it progresses. FOUND in PPMI is one more way that the goals of PPMI can be achieved.

Who is eligible?
Everyone who participated in PPMI is eligible for FOUND in PPMI.
CHOOSE “YES” OR “NO” FOR THE OPTIONS PROVIDED AND THEN CLICK ON “INITIAL” TO PROVIDE YOUR ELECTRONIC INITIALS FOR THIS SECTION OF THE INFORMED CONSENT FORM.

I agree to be contacted to learn about participation in the Fox Insight study.  
Yes [ ] No [ ] DATE and INITIAL 4/26/2016

Permission to Record Phone Interview

I agree the phone interview may be recorded for quality control purposes.  
Yes [ ] No [ ] DATE and INITIAL 4/26/2016

CONSENT
CLICK “SIGN” TO PROVIDE YOUR ELECTRONIC SIGNATURE FOR FOUND IN PPMI.

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

4/26/2016
Date

Participant's Signature for Consent

Print Name

Samantha Betheil

Date

Person Obtaining Consent

Print Name

Samantha Betheil
CLICK “FINISH” FOR THE FORMS TO BE COMPLETED AND SENT BACK TO UCSF.
STUDY SURVEY
CLICK “GETTING STARTED: FIRST SURVEY” IN THE EMAIL IN ORDER TO ACCESS YOUR PERSONAL SURVEY

Dear PPMI Participant,

Thank you very much for agreeing to participate in FOUND in PPMI and sending back the consent forms. Your participation will help us learn more about Parkinson’s disease over the course of time.

Please click the link below to complete the survey and submit it back to us within a week if possible.

Please do not hesitate to contact us with any questions or concerns at (415) 571-4035. We can also be contacted by email at foundinPPMI@ucsf.edu.

We cannot thank you enough for your time, energy and your invaluable contributions to our research.

Best Wishes,

Samantha Bethell
Research Assistant

You may open the survey in your web browser by clicking the link below:

getting started: First Survey

If the link above does not work, try copying the link below into your web browser:

https://redcap.ucsf.edu/surveys/?s=LEDUc3tuEF

This link is unique to you and should not be forwarded to others.
THIS IS WHAT THE WINDOW OF THE SURVEY WILL LOOK LIKE. CLICK + OR – IN THE RED CIRCLE ON THE TOP RIGHT OF THE PAGE TO ADJUST THE FONT SIZE OF YOUR SURVEY.
AFTER COMPLETING THE SURVEY PLEASE HIT “SUBMIT” AND THE SURVEY WILL BE SENT BACK TO UCSF