The [Insert Study Name] Retention Plan



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#### study Overview

|  |  |
| --- | --- |
| **TARGET COHORT** | Recruitment goal: X Participants  Target population: e.g., 25 PD patient and 25 healthy controls  Racial/Ethnic minority recruitment: X% of target population or X racial/ethnic minority participants |
| **STUDY DURATION PER PARTICIPANT** | Duration: X weeks/months  Number of Visits: X visits |
| **CLINICAL SITES** | Number of sites: # sites  Locations:   * Country 1   + Site Name – City, State   + Site Name – City, State * Country 2   + Site Name – City |
| **STUDY INFRASTRUCTURE** | Sponsor:  Funder:  Steering Committee:  Patient advocate:  Central clinical coordinating center:  Biostatistics coordinating center:  Data management coordinating center:  CRO:  Recruitment and Retention Committee: |

#### retention monitoring

1. **Premature Withdrawals**

The study project manager will monitor the rate and reasons for premature withdrawals. The study team will review the root cause and establish an action plan for sites to prevent more early withdrawals.

The following actions will be taken if the study experiences multiple premature withdrawals:

* [Determine, through discussion with study sites, challenges of study participation]
* [Determine new/additional ways to facilitate participation (e.g. arrange car service to and from study visits; offer meals)]
* [Create new or revise materials to appreciate participants and explain value of research participation]

Sites must report the withdrawal of a study participant within **X days** to the study project manager. Sites should also notify the study project manager if a participant is at risk to drop out (i.e. expresses stress or dissatisfaction).

If a site experiences difficulties retaining study participants, the following actions will be taken:

|  |  |
| --- | --- |
| **Retention Challenge** | **Action** |
| 1 premature withdrawal | Study project manager schedules call with site coordinator to discuss reason for dropout and determine action plan |
| 1 or more premature withdrawals | Site must administer the *Participant Satisfaction Survey* to all its participants **(See Appendix)**  Study project manager and principal investigator schedule call with site coordinator and investigator to discuss reasons for dropouts and determine action plan |

#### Retention strategy and Materials

1. **RECRUITMENT AND RETENTION COMMITTEE**

In addition to outlining recruitment strategies, this committee meets on a [**insert cadence, e.g. monthly]** basis to develop retention strategies, discuss motivations and challenges of study participation and identify key touchpoints for communication with participants post-enrollment. Retention activities and materials will be finalized before the first participant hits **3 months** in the study.

1. **FACILITATING PARTICIPATION**

It is important to minimize burden and stress for study participants. The following are ways for sites to ease and simplify study participation:

* [Remind study participants of the next appointment date]
* [Remind study participants when to complete at-home activities such as diary entries by phone and/or email]
* [Explain and answer questions about study procedures/assessments]
* [Notify participant’s primary care physician of their involvement in the study]
* [Arrange and pay for transportation to and from study visits]
* [Offer participants a meal during long study visits]

The following resources/materials will be used to facilitate participation:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Appointment Card]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To remind participants of their next visit | Study participants |
| [Participant Introduction Letter]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To inform study participants about the resources available to them throughout the study | Study participants |
| [Calendar of Activities]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To explain what to expect at each visit and guide through participation | Study participants |
| [Trial Team Bios]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To familiarize participants with the study team | Study participants |
| [Insert name of Study Procedure materials, e.g. “MRI – Frequently Asked Questions”]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for examples of these materials | To explain study procedures to participants | Study participants |
| [Physician Notification Letter]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To inform a participant’s primary care provider of their involvement in the study | Physicians of study participants |

1. **Communicating Study Progress**

It is important share progress on major study milestones with both study participants and site staff. Sites should also send study updates to referring clinicians to maintain an engaged referral network. Remind participants, sites and referring clinicians that their participation advances Parkinson’s research. Study milestones to communicate include: [enrollment completed, X visits completed by all participants and final study results]. Study updates will be provided in the following ways:

* [Send a quarterly newsletter to participants with study updates and reminders]
* [Send a quarterly newsletter to sites on study progress and reminders]
* [Organize a webinar for participants and sites to hear directly from the principal investigator on study milestones]
* [Post updates on the study website]

In addition, study participants will be asked to share their experience in the study through an anonymous survey given [insert timing, e.g. three months after recruitment is complete]. The *Participant Satisfaction Survey* will help illustrate participants’ satisfaction with the study’s conduct or areas for improvement. The distribution of a survey to participants also demonstrates the study team values their opinion and seeks to enhance their study experience. **See Appendix for *The Participant Satisfaction Survey*.**

The following resources/materials will be used to communicate study progress:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Participant Newsletter]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To keep participants informed of study progress | Study participants |
| [Site Newsletter]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To keep site staff informed of study progress | Site staff |
| [Webinar Slide Deck]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To organize a webinar for participants and sites to hear directly from the principal investigator | Study participants  Site staff  Referring physicians |
| [Participant Satisfaction Survey]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To assess participants’ satisfaction with the study | Study participants |

1. **SHOWING APPECIATION**

The study team is committed to ensuring participants, caregivers and sites feel appreciated and understand the importance of their participation. It is also important to express gratitude to referring clinicians to maintain a long-term referral network. The study team will show its gratitude to participants, referring clinicians and site staff in the following ways:

* [Send thank you cards to participants/caregivers after completing X visits]
* [Send birthday cards to participants]
* [Send holiday cards to participants/caregivers in December]
* [Send thank you cards to sites after study completion]
* [Send thank you cards to referring clinicians]
* [Include messages of gratitude in participant and site newsletters and webinars]
* [Express gratitude to participants/caregivers at each visit]

Participants will also receive the following tokens according to the below schedule:

|  |  |  |
| --- | --- | --- |
| **Timing** | **Gift Item** | **Audience** |
| 12-month Visit | Phone case | Study participants |
| 24-month Visit | Travel bag | Study participants |
| 36-month Visit | Blanket | Study participants |

The following resources/materials will also be used to thank participants, referring clinicians and site staff:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Thank You Card]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To thank participants/site staff/referring clinicians for their time and effort | Study participants  Site Staff  Referring physicians |
| [Birthday Card]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To show appreciation to participants on their birthday | Study participants |
| [Participant/Site Newsletter]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for templates of these resources. | To share study progress and include thank you messages. | Study participants  Site staff |

1. **SHARING STUDY RESULTS**

Once the study has closed and analyses have been completed, it is important to communicate study results to site staff, study participants and referring clinicians. Sharing study results builds long-term research engagement and helps individuals understand the ways in which their contributions advance research.

To receive study results, participants must consent to future communications. For participants who consent to future communications about study results, sites will collect up-to-date email/mailing addresses on a secure document.

Sites will consult with their ethical review board to ensure appropriate steps are taken to share results with participants once available.

The study team will convey study results to both participants and sites when publication occurs as follows:

* Individualized communication:
  + [Send letter/email to sites explaining study results]
  + [Give sites a study results letter/email to send participants]
  + [Give sites a study results letter/email to send referring clinicians]
* Scaled communication:
  + [Post study results summary on the study website]
  + [Send letter/email to sites explaining study results and/or date of a study results webinar or website posting]
  + [Give sites a letter/email to send participants notifying them about a study results webinar or website posting]
  + [Give sites a letter/email to send referring clinicians notifying them about a study results webinar or website posting]

The following resources/materials will be used to share study results:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Study Results Letter/Email to Sites]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To share study results with site staff and instructions on how to share results with participants and referring physicians | Site staff |
| [Study Results Letter/Email to Participants]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To share study results with participants or notify of a study results webinar/website posting | Study participants |
| [Study Results Letter/Email to Referring Clinicians]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To share study results with referring clinicians or notify of a study results webinar/website posting | Referring physicians |
| [Webinar Slide Deck]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a template of this resource. | To share study results with participants, sites and referring physicians via webinar | Study participants |
| [Study Website]  Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a sample of this resource. | To post a summary of study results for the PD patient and researcher community | Study participants |

#### appendix

**WHY GIVE THE STUDY SATISFACTION SURVEY?**

Data gathered from the Study Satisfaction Survey helps assess participants’ experience in the study (i.e. Do they feel their participation is appreciated? Are they comfortable bringing questions and concerns to site staff?). This information can be used to minimize the risk of early withdrawals by better addressing participant needs. This survey is especially valuable for long-duration studies (over 12 months) looking to keep study participants engaged. The distribution of a survey to participants also shows the study team values their opinion and seeks to enhance their experience.

**WHEN/HOW SHOULD THIS SURVEY BE ADMINISTERED?**

Administer this survey once you have completed enrollment of all participants. The survey can be distributed to all participants at once or only participants who have completed a certain number of visits (e.g. all participants who completed their 12-month visit). The study team can also choose to administer the survey after a retention event such as a participant webinar or lunch/dinner.

Indicate to participants how the survey should be submitted so that anonymity is maintained. Consider setting up a drop box or mailbox where participants can submit surveys. Explain to participants that their feedback is very valuable to the study team but that completion of the questionnaire is not mandatory.

**AFTER THE SURVEY IS COMPLETED, HOW DO I MAKE USE OF THE DATA?**

Create a spreadsheet to track the individual answers that study participants give for each question.

Based on summary data, you may observe trends or patterns in participant responses that will help identify challenges in study participation. Action steps based on data:

* If the majority of participants agree with most or all the statements in the survey, they feel well-informed about the study, valued and comfortable with study staff. Be sure to mirror participant enthusiasm by continuing to appreciate them and addressing any questions and/or concerns.
* If the majority of participants disagree or feel neutral about most or all statements in the survey, they may not be well-informed about the study objectives or feel appreciated. Site staff should maximize approachability to participants and show appreciation for their time and effort in the study. The study team should consider developing talking points for site staff and organizing a webinar/teleconference to review the study objective and express gratitude to participants and their care partners for their participation. Failure to enhance participants’ experience may lead to premature withdrawals.

**The Study Satisfaction Survey can be found on the next page.**

Study Satisfaction Survey

The [Study/Trial Name] team would like to learn more about your experience in study so that we can better address any needs or concerns. This survey takes about 5-10 minutes to complete. All responses will be kept anonymous. We appreciate your time to complete this survey.

**For the statements listed below, please circle the number that best indicates how strongly you agree.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Strongly Disagree** | **Disagree** | **Neutral** | **Agree** | **Strongly Agree** |
| I have a clear understanding of the overall goals of the study. | 1 | 2 | 3 | 4 | 5 |
| I feel that my participation in the study is valued. | 1 | 2 | 3 | 4 | 5 |
| I feel confident addressing site staff with questions and/or concerns I may have about the study procedures. | 1 | 2 | 3 | 4 | 5 |
| The facilities of the study site are comfortable and clean. | 1 | 2 | 3 | 4 | 5 |
| Overall, my participation in this study has been a positive experience. | 1 | 2 | 3 | 4 | 5 |
| I feel confident that I can continue to comply with the study regimen through the duration of the study. | 1 | 2 | 3 | 4 | 5 |

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| --- |
| **If you have any additional comments, please list them below:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ­­­­­­­­ |

### **Thank you for completing this survey!**