The [Insert Study Name] Recruitment 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 |
| **TARGET RECRUITMENT PERIOD** | Recruitment months: X months to meet target enrollment  Recruitment start date: MM/YYYY  Recruitment end date: MM/YYYY |
| **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: |

#### Clinical sites

1. **SELECTION**

Clinical sites [will be/have been] selected based on the following criteria [list site selection criteria below]:

* [Access to target population]
* [Expected monthly enrollment rate]
* [Prior experience enrolling target population]
* [Number of participants recruited in similar or recent study]
* [Timeliness of IRB submission and contract execution]
* [Timeliness of query resolution]

1. **ACTIVATION**

Sites will be activated after completing all of the following [list activation tasks below]:

* [Obtain IRB approval on protocol, informed consent form (ICF) and recruitment & retention materials]
* [Submit a fully executed site contract]
* [Both site investigator and coordinator attend the Investigators Meeting on {Date} or remote training]
* [Complete a site start up call before recruiting]
* [Connect to Fox Trial Finder]

All sites will complete the *Recruitment Activities Questionnaire*  **(see Appendix)** to identify recruitment strengths and challenges.

1. **COMMUNICATION**
2. **Site Calls/Webinars**

All site investigators and coordinators will be asked to attend a mandatory teleconference or webinar on **[insert cadence e.g. each second Thursday and Friday of the month]**. If a low-enrolling site cannot participate at the scheduled time, they must arrange a separate call with the study project manager. The purpose of these calls is to:

* + - * [Review study recruitment progress holistically]
      * [Troubleshoot and brainstorm challenges among study sites]
      * [Highlight successes and opportunities to leverage]
      * [Foster positive morale through peer to peer interaction]
      * [Highlight/Showcase high-performing site staff]

1. **Recruitment Report**

Site investigators and coordinators will be emailed a report on the study’s recruitment progress and activities every **[insert cadence, e.g. week]**. This will keep sites informed on the study’s progress and the recruitment activities of other sites.

1. **Site Recognition**

Recognition of top enrolling sites will be included on [the recruitment report email, site calls/webinars, site newsletter and any in-person study meetings].

1. **SITE RECRUITMENT SUPPORT**

The following actions will be taken if a site is struggling to screen and enroll participants:

* [Reevaluate their recruitment activities by asking the site to complete the *Recruitment Reassessment Questionnaire* (**See Appendix**). This questionnaire asks underperforming sites to report reasons for recruitment challenges and outline recruitment activities that have been implemented.]
* [Determine new/additional recruitment efforts in and outside the clinic]
* [Create new or revised recruitment materials, as needed]
* [Review protocol eligibility criteria to determine if changes to inclusion/exclusion are needed]

If a site continues to underperform, the following actions will be taken:

|  |  |
| --- | --- |
| **Recruitment Activity** | **Action** |
| No screenings within X months of site activation | Complete the *Recruitment Reassessment Questionnaire* (**See Appendix**).  Principal investigator and study project manager schedule call with site investigator and coordinator to discuss challenges and determine remedial action plan. |
| No enrolled participants within X months of site activation | Consider closing site and replace with back-up/alternate site |

1. **SITE REPLACEMENT**

Sites that cannot meet the following criteria will be considered for replacement with a back-up site:

* [Unable to complete their contract and obtain their IRB/EC approval within X months of receipt of study documents]
* [Unable to enroll participants within X months of site activation]
* [Unresponsive to study team communications for X weeks]

#### Recruitment strategy and Materials

1. **RECRUITMENT AND RETENTION COMMITTEE**

The Recruitment and Retention Committee meets on a [**insert cadence, e.g. monthly]** basis to review recruitment strategies, identify challenges and develop solutions to recruitment issues. In addition to recruitment, the committee will plan ahead for retention activities and develop materials to facilitate participation, communicate and appreciate sites and participants and lay the groundwork to share study results. Note: See the [MJFF Retention Toolkit](https://www.michaeljfox.org/research/resourcepack.html#retention_tk) for a retention plan template.

This strategic committee creates and distributes centralized plans and materials to assist sites with recruitment and retention and includes the following stakeholders:

* [Principal Investigator(s)]
* [Study Project Managers]
* [Clinical Site Representatives (Investigators and Coordinators)]
* [Representatives of patient-facing or advocacy organizations (e.g. The Michael J. Fox Foundation representative)]
* [Patient Advocate(s)]

1. **EDUCATING ON RESEARCH**

Before recruitment for the study begins, sites will be asked to have general research education/engagement materials in their waiting/exams rooms for patients to read. It takes more than one touchpoint about research to engage prospective participants. These materials will help prime the patient community for the upcoming study by explaining clinical trials and the value of research participation.

Sites will keep these materials on hand through the duration of recruitment.

The following resources/materials will be used to educate/prime the patient community at each site:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Insert name of Research Education material, e.g. “Six Facts about Clinical Trial Participation”]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for examples of these resources | To explain how clinical trials work and address frequently expressed misconceptions or concerns. | Patients |
| [Insert name of Research Engagement material, e.g. “Recently Diagnosed with Parkinson’s Disease? You can help speed a cure.”]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for examples of these resources | To communicate the importance of research participation for the target study population | Patients |

1. **PRE-SCREENING**

Sites are expected to start pre-screening patients as soon as possible, after IRB/REB approval, to identify potential study participants. Sites will identify any potential participants among their patient population as follows:

* [Review patient charts at the start of each clinic day and tag potentially eligible individuals to speak with about the study]
* [Review their EMR and any research registry (if one exists) for potential participants]

The following resources/materials will be used to collect pre-screening data:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Insert name of prescreening program/document] | Pre-screen data will be used to track the estimated number of potential participants at each site.  Data will also be reviewed to identify sites with low activity to contact these sites for follow up as needed and identify recurring eligibility/recruitment challenges.  Sites will be required to enter pre-screen information. Sites will be expected to update pre-screen data on a **[insert cadence]**. | Site staff |

1. **GENERATING STUDY AWARENESS**

**A. In Clinic**

All sites will complete the following to generate study awareness among its patient population:

* [Place patient materials about the study in waiting and exam rooms]
* [Remind all physicians at their site about the study’s eligibility criteria]

The following resources/materials will be used to generate study awareness at sites:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Study Flyer and Brochure]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for templates of these materials | To promote the study and encourage individuals to learn more about participation | Prospective participants |
| [Study Pocket Card]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To provide all on-site physicians with a tool to help remember the study’s eligibility criteria when seeing patients. | Physicians |

**B. Patient Community Engagement**

Local Patient Groups: Sites will be asked about their knowledge of local patient groups to utilize the opportunity to share study information. Site investigators and coordinators will present at local support groups.

Parkinson’s Events: Study team will have a presence at national Parkinson’s events such as the Parkinson’s Unity Walk and Moving Day. Site staff will also attend any Parkinson’s events in the vicinity of their site.

Local Press: Sites should attempt to include an article about the study in any local publications intended for the Parkinson’s community.

Parkinson’s Organizations: The study team will collaborate with Parkinson’s patient and research organizations to generate awareness about the study among their constituents. Potential PD organizations to partner with: Parkinson Disease Foundation, The Michael J. Fox Foundation, The Muhammad Ali Foundation, The Cure Parkinson’s Trust, etc. The study can collaborate with these groups as follows:

* [Identify areas for study promotion (blogs, newsletters, emails, events, webinars, etc.)]
* [Work with the organization’s patient advocates to generate study awareness in the community]
  + [Connect patient advocates to sites and determine process for liaising with coordinators]
  + [Ask patient advocates to provide feedback on how the study is perceived in the community]

The following resources/materials will be used to generate study awareness at sites:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Study Flyer and Brochure]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for templates of these materials | To provide individuals at support groups or events with study information to discuss with their family and/or doctor. | Prospective participants |
| [Study Slide Deck]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To present the study at support groups and patient event. | Prospective participants |
| [Webinar Slide Deck]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To present the study to patient groups/constituents of a PD organization via webinar. | Prospective participants |
| [Press Release]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To place in local PD publications | Prospective participants |

**C. Physician Referral Network**

Sites will be encouraged to reach out to the healthcare providers in affiliated institutions and local clinics to inform them about the study. Healthcare providers include general neurologists, primary care physicians, nurses, technicians, surgeons, and physical rehab professionals. Sites can engage these groups as follows:

* [Present the study at clinician events such as ground rounds]
* [Hold meetings or lunches/dinners for community providers who see PD patients]
* [Maintain regular e-mail communication with community healthcare providers about the study]

The following resources/materials will be used to generate study awareness at sites:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Physician Referral Letter]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for template of this resource | To make local healthcare providers aware of the study and request referrals. | Referring physician |
| [Study Pocket Card]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To provide all physicians with a tool to help remember the study’s eligibility criteria when seeing patients. | Referring physicians |
| [Study Flyer and Brochure]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for templates of these materials | To provide to their patients and place in waiting and exam rooms. | Referring physicians |
| [Study Slide Deck]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To present the study to community healthcare providers at events/conferences such as grand rounds. | Referring physicians |
| [Webinar Slide Deck]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To present the study to community healthcare providers via webinar. | Referring physicians |

1. **Digital Channels**

Study Website: A website will be created as an online resources for patients to learn more about the study. The website URL will be placed on all print study materials and linked to any social media posts about the study.

Digital Publications: Sites will be encouraged to include a blurb about the study on their own institution website (if possible). A blurb about the study may also be included on Parkinson’s patient and research organizations (i.e. NINDS clinical trial page).

Social Media: Sites will be asked to post about the study on their social media (Facebook/Twitter) if approved by their ethical review board and marketing department. May also ask patient support groups, patient organizations or patient wellness programs to post about the study on their social media. All posts will directed to the study website.

Paid Digital Ads: The study team will pay for ads about the study to appear on search engines (i.e. Google) and/or social media (i.e. Facebook) targeting individuals who like or follow Parkinson’s-related pages and live close to clinical sites. All ads will direct to the study website or Fox Trial Finder.

The following resources/materials will be used to generate study awareness through digital channels:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Study Website]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a sample of this resource | To serve as an online resource for patients, include on printed materials and link to digital ads/publications | Prospective participants |
| [Facebook posts or Tweets]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To provide sites and/or patient groups with Facebook posts and/or Tweets about the study to place on their social media channels | Prospective participants |
| [Press Release]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this material | To place in digital publications/blogs about PD | Prospective participants |

1. **Fox Trial Finder**

The study will be posted on Fox Trial Finder. Site coordinators will monitor and respond to volunteer messages directed to their site.

The following resources/materials will be used to generate study awareness through Fox Trial Finder:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Fox Trial Finder Message Template]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for templates of these materials | To provide sites with a lay-friendly message template to send volunteers on Fox Trial Finder | Prospective participants |

1. **Racial/Ethnic Minority Recruitment**

The study has a goal of X% minority enrollment, or approximately X minority participants. Minorities include Hispanics, Asians, Black or African Americans or individuals who identify as more than one race. Minority individuals are underrepresented in clinical research due to language and transportation barriers and limited knowledge of research. To increase the racial/ethnic diversity of study participants, along with the above recruitment activities, the following additional efforts will be implemented.

Priority Sites: The study team will identify and prioritize sites with higher percentages (<20%) of minority populations based on local demographics. The study project manager will contact these sites on a **[insert cadence, e.g. monthly]** basis to discuss minority recruitment. Priority sites may submit a proposal for additional funding outlining how they will engage minority groups (community center dinner, Spanish support group, church gathering, etc.) and the funding requested.

The following are priority sites for racial/ethnic minority recruitment:

* [Site Name] – [Location]
* [Site Name] – [Location]
* [Site Name] – [Location]

Recruitment Strategies: All sites will be regularly reminded of the minority recruitment goal and discussion of minority recruitment strategies will occur on monthly site calls/webinars. Sites, particularly priority sites, will be encouraged to engage minority populations as follows:

* [Identify and contact local healthcare providers who see a large number of minority patients to discuss the study]
* [Encourage collaborations between sites and minority community leaders such as religious leaders]
* [Contact local lay and/or professional organizations and community centers that see minority populations to schedule lunch or dinner events to present the study]

The following resources/materials will be used to generate study awareness among racial/ethnic minorities:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Translated Study Materials] | To provide non-native English speakers with information about the study | Prospective participants |
| [Translator] | To provide sites without multilingual staff a trained translators on-site or via remote connection to aid in communication during study visits | Prospective participants |
| [Supplemental funding] | To sites who propose a minority recruitment strategy | Site staff |

1. **Point of Contact**

Site Contact: Sites will designate someone as the recruitment point of contact whose phone and email will appear on [the central study website, Fox Trial Finder, and ClinicalTrials.gov]. This individual will also be in regular communications with the study project manager about recruitment.

Central Contract: The study website will have [a toll-free number and general email] that interested individuals may use to learn more about the study. This number and email address will be managed by the study project manager. The study project manager will connect potential participants to their closest site. The study project manager will follow up with sites to confirm site staff contacted the interested individual.

1. **GUIDING THROUGH CONSENT**

Sites will be provided with tools and resources to walk prospective participants through study details and procedures during the consent process. It is important to answer all questions about the study before consent to have well-formed participants and reduce risk of premature withdrawals.

The following resources/materials will be used to guide participants through consent:

|  |  |  |
| --- | --- | --- |
| **Resources/Materials** | **Purpose/Use** | **Audience** |
| [Site Staff Talking Points]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this resource | To help site staff convey the study purpose in a lay-friendly manner and address any potential concerns. | Site staff |
| [Calendar of Activities]  Note: See the [MJFF Recruitment Toolkit](https://www.michaeljfox.org/research/resourcepack.html#recruitment_tk) for a template of this resource | To provide prospective participants with a simplified schedule of activities to understand what to expect | Prospective 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 prospective participants | Prospective participants |

#### Recruitment Material Prep

This section contains centralized messaging for all recruitment materials. It is important to standardize messaging across all recruitment materials to prevent confusion among potential study participants and ensure all content is lay-friendly.

Study messaging should be written in an 8th grade or below reading level, avoid scientific jargon and define unfamiliar terms. The following are resources to help write lay-friendly content: [Program for Readability in Science & Medicine (PRISM)](https://www.kpwashingtonresearch.org/about-us/capabilities/research-communications/prism/) and [Readable.io](https://readable.io/text/).

Once the study team has agreed to the messaging outlined below, simply copy and paste the content into all recruitment materials.

|  |  |
| --- | --- |
| **Recruitment Messaging** | |
| **Shortened Study Name or Acronym** | Shortened study name or acronym helps potential participants recall your study and distinguish from other Parkinson’s studies. |
| **Study Rationale** | In two or three sentences, describe the background and scientific rationale for this clinical study. |
| **Study Objective** | In one sentence, describe the question this study seeks to answer or theory you hope to prove. |
| **Potential Impact** | In one or two sentences, explain how the study holds potential to affect Parkinson’s diagnosis, care/treatment or research. If you have more than one target population be sure to customize this section for each audience (i.e. PD patient vs healthy control). |
| **Eligibility Criteria** | List one to three high-level eligibility criteria that are interpretable by a lay audience, such as age and years since diagnosis. Do not include criteria that may be misinterpreted or unfamiliar, e.g. “Off” periods or clinical scales. Provide examples of any exclusionary medications, e.g. MAO-B inhibitors such as Selegiline (l-deprenyl, Eldepryl®) and Rasagiline (Azilect®).  1.  2.  3. |
| **Study Duration** | Note study duration for participants from screening to final study visit, e.g. 10 study visits over 12 months. Include any virtual or phone visits. |
| **Study Procedures** | In one sentence, provide a high-level overview of study assessments and procedures. Fox example, “Participants will complete motor, cognitive and biological (i.e., blood and spinal fluid) tests.” |
| **Participant Resources** | In one to two sentences, note the resources that will be made available to participants. For example, “All study assessments/procedures are provided at no cost and travel reimbursement is available. You will also receive education and support from the study team throughout your participation.” |
| **Study Logo/Image** | Insert study logo or image to place on recruitment materials. A study logo/image helps individuals remember the study and also break up text-heavy documents.  L:\Research\Research Partnerships\Recruitment & Retention Team\BPM & Toolkit\Toolkit\R&R Toolkit\Design\Final Template Icons\insert_study_image-logo-text.jpg  To replace the image above, right click and select “Change Picture.” |
| **Study Color Scheme** | Choose one to two colors to standardize the style of study materials. Do not use these colors as font colors if particularly hard to read colors like yellow and green.  To change the color in the above ovals, right click and select a color under the “Fill” field. |

#### appendix

Ask all study sites to complete the *Recruitment Activities Questionnaire* before screenings begin to understand the recruitment activities that will implemented.

|  |  |
| --- | --- |
| **Recruitment Activities Questionnaire** | |
| **Date:** | |
| **Site Name:**  **Site Investigator Name:**  **Site Coordinator Name:** | |
| **Enrollment Goal:** | |
| Expected enrollment per month: |  |
| What is your goal for the number of patients you will screen per week/month? |  |
| What are your racial/ethnic minority recruitment goals (based on your patient population demographics)?   * How was this determined? * How do you plan to engage minority groups about the study? |  |
| Do the coordinator and investigator have time set aside each week to discuss recruitment? |  |
| What challenges or barriers, if any, do you anticipate in pre-screening and screening of subjects? |  |
| What are your plans for addressing these barriers or challenges? |  |
| If you have pre-screened or screened patients already, what were the challenges?  How did you overcome them? |  |
| How will you use provided recruitment materials e.g. flyers, brochures, press release, slide deck, etc.? |  |
| Do you have a local healthcare provider referral network? If so, what are your recruitment plans with this network? |  |
| Do you have PD support groups in the area or patient groups where the target population is referred to?   * If so, will/have you reached out to them and provided study materials? * Provide dates for meetings and let us know which ones you will attend. |  |
| Do you have plans to promote the study in any local print media aimed at PD patients?  If so, what publications and when? |  |
| Do you have plans to promote the study through digital channels such as your site webpage or social media channels? |  |
| Have you used Fox Trial Finder to recruit for other studies?  Do you need training? |  |
| What are your back-up plans if recruitment does not go as expected? |  |
| How will you track patients contacted and how soon will you follow up? |  |
| Do you have a calendar or schedule to know when site staff are available to schedule visits (due to meetings, vacations, etc.)? |  |
| Is there anything that we can do to help your site? |  |
| Please provide any other applicable comments/ideas: |  |

Ask underperforming sites to complete the *Recruitment Reassessment Questionnaire* to understand their recruitment challenges and alternative activities to identify participants.

|  |  |
| --- | --- |
| **Recruitment Reassessment Questionnaire** | |
| **Date:** | |
| **Site Name:**  **Site Investigator Name:**  **Site Coordinator Name:** | |
| **Current # Screened:**  **Current # Screen Fails:**  **Current # Enrolled:** | |
| If applicable, provide reasons for screen failures and declines |  |
| Are you considering if any screen fails might be eligible at a later time (i.e. will their ineligibility factors change)?  If so, how are you tracking these individuals? |  |
| If no screenings are scheduled, what is preventing you from screening? |  |
| Do the coordinator and investigator meet each week to discuss recruitment? |  |
| How are you using the provided recruitment materials e.g. flyers, brochures, press release, slide deck, etc.? |  |
| Have you engaged local healthcare providers?   * If so, how? * If not, why? |  |
| Are you working with a PD support group in the area or patient groups where the target population is referred to?   * If so, have you reached out to them and sent study materials? * If so, have you presented the study to the group or have a meeting scheduled? | ` |
| Have you promoted the study in any local print media aimed at PD patients?  If so, what publications and when? |  |
| Have you promoted the study through digital channels such as your site webpage or social media channels? |  |
| Are you regularly using/checking Fox Trial Finder?  If so, how often do you send messages to volunteers? |  |
| How soon do you follow up with individuals who express interest in the study? |  |
| Have you experienced any unexpected changes at your site such as staff changes? |  |
| Is there anything that we can do to help your site? |  |
| Please provide any other applicable comments/ideas: |  |