

## **BLAAC PD 2023 Site Selection Frequently Asked Questions**

Deadline: Thursday, July 27th

The information provided in this FAQ is meant to clarify the application process and the qualities the BLAAC PD team is looking for in a clinical site. We encourage interested applicants to utilize this information to understand what will be valued during this competitive process. If you have any additional questions, please contact Naomi Louie ([nlouie@michaeljfox.org](mailto:nlouie@michaeljfox.org)).

**Complete the pre-proposal form [HERE](#).**

**Q:** What is BLAAC PD?

**A:** BLAAC PD is an initiative of the Global Parkinson's Genetics Program (GP2) focused on increasing representation of Black and African Americans in Parkinson's disease (PD) genetics research. Through BLAAC PD, genetic information and cross-sectional clinical data are collected from participants with Parkinson's disease and control volunteers. These data join various cohorts of data in the GP2 database, where de-identified data are publicly available for analysis. Learn more: [blaacpd.org](http://blaacpd.org)

**Q:** What is GP2?

**A:** GP2 is a resource program of the Aligning Science Across Parkinson's (ASAP) initiative focused on improving our understanding of the genetic architecture of PD and making this knowledge globally relevant. GP2 is made up of member organizations around the world that are coming together to create a global research community dedicated to rapidly addressing emerging research needs in PD, and aims to use genetics knowledge to accelerate the path to the development and deployment of therapeutic strategies for PD.

**Q:** What does participation in the GP2 network mean for me?

**A:** GP2 sets out to create a first-of-its-kind research community, orienting scientists all over the globe to GP2's research mission. The GP2 network consists of multiple working groups and opportunities for collaboration that are available to GP2 members. GP2 also holds the Annual Investigators Meeting, which BLAAC PD Principal Investigators/Project Leads would be invited to attend.

**Q:** I am located outside the United States but work with communities of Black and/or African ancestries. Can I apply to be a BLAAC PD site?

**A:** Unfortunately, BLAAC PD is currently limiting site locations to the United States only. If you are located outside of the United States, there are still opportunities to join other cohorts in GP2. For more information about GP2 and how to get involved, browse the [GP2 website](#) or email [cohort@gp2.org](mailto:cohort@gp2.org).

**Q:** What are the participant eligibility criteria for BLAAC PD?

**A:** Individuals are eligible for participation if they are 18+ years, identify as Black or African American, and do or do not have a PD diagnosis. Healthy control volunteers also cannot have a

family (blood-related) history of neurodegenerative disorders. The BLAAC PD protocol is available upon request.

**Q:** What can I expect after submitting the pre-proposal?

**A:** Competitive applicants will be invited to submit a full proposal and to schedule a virtual video call. This will be accompanied by additional documentation requests, including the Project Lead/Principal Investigator's CV, letters of support, and/or a risk mitigation table. During the video call, BLAAC PD team members will ask questions to gain a more holistic understanding of your site and potential fit for BLAAC PD. You are welcome to ask any questions about BLAAC PD during this call, as well.

**Q:** What can I expect after the video call and full proposal?

**A:** Selected applicants will be contacted to schedule a site visit at a mutually agreeable time. One or two members of the BLAAC PD team will visit your site in person for a few hours. During this time, we want to gain a better understanding of the facility and resources available and get to know the site team. Applicants can expect site visits to occur in September 2023. Final site selection decisions will be shared with applicants following the conclusion of site visits.

**Q:** What is the difference between the "Applicant," "Project Lead/Principal Investigator," and "Point of Contact"?

**A:** The Project Lead/Principal Investigator leads the study team to accomplish established site goals in the study. The Applicant may be the Project Lead/Principal Investigator or may be another person on the team. The Point of Contact is any additional individual who should be included in all communications between the BLAAC PD team and the site. If there are no additional personnel to include in communications, the Point of Contact question can be left blank.

**Q:** What is expected of clinical sites?

**A:** Each site must be willing to serve as the sponsoring institution for implementing the BLAAC PD protocol at their site, have their own Institutional Review Board (IRB), already work with an independent IRB, or have an existing partnership with an institution with an IRB. Sites are expected to complete the IRB approval process with support from BLAAC PD's contract research organization. Additionally, sites must acquire a Genomic Data Sharing Certificate or equivalent, if available; execute a material transfer agreement with the NIH/NIA, and retain clinical trial insurance. All sites will also need to have study team members who can deliver clinical exams and confirm a Parkinson's disease diagnosis; which includes training to deliver the MDS-UPDRS and MOCA. The full protocol is available upon request. The study team should also have the ability to implement recruitment strategies within the site and in the community to promote enrollment of at least 5 participants per month over at least 24 months. Biospecimen samples collected from participants must be stored and shipped per the study protocol (additional storage and shipment requirements below). Compliance with all guidelines related to GP2, such as the [Code of Conduct](#) and [Publication Policy](#), is required. Lastly, sites must regularly communicate with the BLAAC PD study team and GP2 through participation in calls/meetings, emails, and regular expense and progress reports.

**Q:** What is the participant experience like?

**A:** Individuals who are eligible for BLAAC PD will be assessed in person with a study team member. Assessments differ if the participant has a Parkinson's disease diagnosis. A blood sample or saliva sample will be collected from all participants. After this enrollment visit, participants receive a \$25 incentive and may be contacted in the future about study findings. BLAAC PD currently does not return genetic results to participants. However, participants with Parkinson's disease are invited to co-enroll in [PD GENERation](#) to receive their genetic results. This is an optional addition for BLAAC PD sites to offer participants. Sites that are not part of the existing PD GENERation site network can receive technical support from the Parkinson's Foundation and BLAAC PD team to implement co-enrollment through the [online enrollment](#) website; however, no additional funding is available.

**Q:** What happens to the sample/data after they are collected?

**A:** Participant blood samples are stored in a -80.C freezer until a batch is ready for shipment. Frozen blood samples are packed on ice packs or dry ice in an insulated container within a cardboard box. Saliva samples are stored and shipped at ambient temperature. All samples are shipped to the National Institutes of Health for genotyping. Raw genetic results are shared back with the study team 2 weeks before the data are made available on the [GP2 data repository](#).

Sites are *not* required to have all the equipment or resources necessary for this process. The BLAAC PD team will take an inventory of resources in order to meet needs of selected sites to implement the protocol.

**Q:** What data are collected from participants?

**A:** Following consent, information will be collected about the participant's sex, age, race, ethnicity, diseases or syndromes, personal medical history, and family medical history. A clinical exam is conducted for participants with PD, including confirmation of PD diagnosis, onset of symptoms, treatment, MoCA, and MDS-UPDRS. Additionally, a blood or saliva sample is collected from all participants.

**Q:** What happens to the data and samples collected in BLAAC PD?

**A:** Samples are sent to the National Institutes of Health (NIH) and are genotyped using the NeuroBooster array. After genotyping, residual samples are then biobanked at the NIH. The Michael J. Fox Foundation, GP2, and their designees are entitled to use of biospecimen and data during and after the agreement period, including utilization of data in secondary research. Participants can choose to withdraw their data at any time. De-identified genetic data are also QC'd and released for public access through the [GP2 online database](#).

**Q:** What does analysis of the data and samples look like?

**A:** Raw genetic results are shared back with the study team 2 weeks before the data are made available on the GP2 data repository. Sites will have access to the clinical data collected and entered in their own BLAAC PD REDCap project. Sites have autonomy to ask any research questions on the data generated by their own biospecimens and/or data. GP2 database users

are required to sign a [data use agreement](#) and access is regulated by the AMP and GP2 Access and Compliance Teams. Democratization of data is a key principle in GP2.

**Q:** What if I want to collect additional data from BLAAC PD participants?

**A:** Additional data collection beyond BLAAC PD cannot be accommodated for individual sites in the existing BLAAC PD database and protocol. Additionally, BLAAC PD funds are to be utilized for BLAAC PD activities. Any additional data that sites would like to collect on BLAAC PD participants requires separate funding and IRB approval.

**Q:** Can I freely publish on analyzed data from BLAAC PD?

**A:** Yes, provided that publications on analyzed data from BLAAC PD comply with GP2's [Publication Policy](#). GP2 aims to have a “no surprises” policy and requests open and transparent communication about analyses, projects, and manuscripts. Preprint uploads, open access publication, and code sharing is required for GP2 led manuscripts.

**Q:** What does the BLAAC PD contract entail?

**A:** The BLAAC PD contract is an agreement between the site and The Michael J. Fox Foundation, GP2's implementation partner. The contract outlines the scope of work, site expectations required to be a part of BLAAC PD, and budget.

**Q:** What does the award amount cover?

**A:** BLAAC PD is offering up to \$90,000 to cover costs related to personnel time, participant incentives, supplies for blood sample collection (i.e., EDTA tubes, shipping materials), IRB costs, community engagement, and indirect costs. Personnel time covers up to 10% for the Project Lead/Principal Investigator, up to 5% for a sub-Project Lead/Principal Investigator, and up to \$36,000 support for a study coordinator not including benefits. A line item budget will be requested from sites with the full proposal. Additional reimbursements are paid to the study site per participant enrolled. Contract payments and reimbursements are totalled and paid quarterly. Travel reimbursement is available for participants facing transportation barriers and is provided separately from the award amount.

**Q:** I work at a non-academic institution, would my organization be a good fit for BLAAC PD?

**A:** We are excited to have non-academic institutions apply! To be a competitive applicant, we encourage you to partner with someone or an organization that has experience in clinical trials that can advise and support your team. For applicants with these types of partnerships, please be sure to provide this information in the “Additional Comments” section of your application. BLAAC PD also does not have a centralized IRB. This means that all applicants should have an institutional review board (IRB) or partner with an organization that has an IRB. Please be sure to include details about IRB and your plan for IRB approval in your application.

**Q:** What additional information would support my application?

**A:** If your study team will be representing more than one organization, please describe that in the “Additional Comments” section of your pre-proposal, along with how this partnership will

work in tandem to support the goals of BLAAC PD and your site's specified recruitment proposal.