WHAT IS THE PURPOSE OF THIS RESEARCH? Provide succinct, clear and digestible information about the study and the potential breakthroughs.

➢ The Systemic Synuclein Sampling Study (S4) is an observational clinical study to identify a biomarker to measure the progression of Parkinson’s disease (PD).
➢ A biomarker is a substance or characteristic in our bodies that is associated with the presence of disease or that changes over time in a way that can be linked to the progression of disease. For example, cholesterol level is a biomarker of heart disease.
➢ Currently there is no validated biomarker for PD, making this an important study to move forward the development of an objective measure of PD.
➢ One of the most promising biomarkers for PD is alpha-synuclein – a protein that clumps in the brains of people with Parkinson’s. We do not yet have a way to measure alpha-synuclein in the brain, but this protein can also be measured in elsewhere in the body, offering an alternative route to potentially monitor changes in the disease.
➢ The goal of the S4 study is to identify the best biofluid(s) and tissue(s) for measuring alpha-synuclein outside of the brain as a potential biomarker of Parkinson’s disease.

WHY ENROLL IN THE STUDY? Explain how this study increases our understanding of Parkinson’s disease and/or may lead to a new or improved treatment.

➢ Identifying a PD biomarker is important for several reasons:
  o It could increase the efficiency of clinical trials because researchers could more quickly determine if the treatment is having an effect on the disease process. For example, does a treatment reduce the levels of clumped alphasynuclein in the brain?
It would help researchers identify which individuals are best suited for certain clinical trials. An estimated 10 percent of PD trial enrollees unknowingly do not have PD, confounding study results.

It could help with early diagnosis and may allow doctors to give individuals new therapies earlier in the disease process.

- Individuals without PD (control volunteers) are needed to provide a standard for comparison to individuals with PD. When researchers match control volunteers and people with PD, they can evaluate whether differences are due to PD or another reason.
- Many people who participate in clinical research find it to be an empowering way to contribute to the Parkinson’s community, advance science, and learn more about PD and the latest research.

**WHO IS ELIGIBLE TO ENROLL?** Present eligibility criteria in a manner that prospective participants can understand, e.g. age and years since diagnosis.

- Individuals with any stage of PD and over the age of 40.
- Individuals without PD over the age of 50 who don’t have a first-degree relative with PD.

**WHAT IS INVOLVED FOR PARTICIPANTS?** Provide a clear understanding of what study participation entails.

- S4 is an observational study, which means participants will undergo tests and assessments and will provide biologic samples.
- Study volunteers will not receive an experimental drug or treatment and can continue their regular medication regimen.
- Volunteers who enroll in the study will undergo a screening process to confirm their participation eligibility.
- Up to four subsequent visits will be scheduled in the four months following screening.
- Participants will be asked to stay in the study for about six months.
- Participants will be asked to provide biofluids (blood, saliva, spinal fluid) and tissue (colon, skin, salivary gland) to measure the levels of alpha-synuclein protein found. This will help researchers understand if the amount of alpha-synuclein present in those fluids or tissue is a good biomarker of PD to measure disease progression.
Site staff will carefully walk all participants through each procedure and answer any questions. A frequently asked questions (FAQ) document is available for each procedure if a participant would like more information.

**WHAT RESOURCES ARE PROVIDED TO PARTICIPANTS?** Provide information about stipends, travel reimbursement, food, etc.

- All study procedures are provided at no cost.
- Participants will be reimbursed for travel to and from study visit.
- Participants will receive education and support throughout the study.

**WHO CAN I CONTACT WITH QUESTIONS ABOUT HOW TO DISCUSS THE STUDY WITH POTENTIAL PARTICIPANTS?** You can contact John Smith, the S4 Project Manager, or send an email to the study inbox, with questions about recruitment talking points and activities.

John Smith 1-800-555-5555
johnsmith@university.edu
Study Inbox: s4study@university.edu