NAPS CONSORTIUM
For REM Sleep Behavior Disorder

INVESTIGATOR/SITE FEASIBILITY QUESTIONNAIRE

The North American Prodromal Synucleinopathy Consortium is conducting a site feasibility assessment and would like to obtain information about your interest in conducting a REM Sleep Behavior Disorder (RBD) study. The purpose of this research study is to create a registry of individuals with RBD and collect information to help plan a treatment study for people with RBD. Many, but not all, individuals with RBD develop neurodegenerative diseases such as Parkinson's Disease, Lewy body dementia, or multiple system atrophy, and our goal is to test treatments that can stop or slow the development of these diseases.

The following questionnaire is designed to obtain information for the recruitment of interested and qualified investigational sites. Thank you for your interest in becoming a NAPS site.

Please return your completed questionnaire within 7 days to: naps@wustl.edu

If you have questions, please contact: naps@wustl.edu

I am ☐ **Interested** ☐ **Not Interested** in participating as a site in the NAPS Consortium

If not interested, please explain why _____

PLEASE PRINT ALL INFORMATION CLEARLY OR TYPE

Investigator Name : _____ _____
Last **First**

Name of Institution: _____

Specialty: _____

Investigator credentials & title _____

Mailing Address: _____

_____

City **State** **Zip Code**

Investigator email address: _____

Phone number: _____
(please include area code and any extension number)

Fax number:

INVESTIGATOR/SITE FEASIBILITY QUESTIONNAIRE

Study Coordinator or Research Contact:	
Study Coordinator or Research Contact email address:	
Phone number:	
(please include area code and extension number)	
Fax number:	
Sub-Investigator Name(s):	

Research Facility	
1. Which best describes your research practice?	☐ Academic ☐ Private Practice ☐ Hospital Based ☐ Other, please describe:
2. Site features (check all available at your site)	☐ Sleep Center or research facilities with polysomnogram capabilities ☐ -80˚C freezer ☐ 4˚C Centrifuge ☐ Exam room for clinical research capable of accommodating orthostatic vital signs (see below) ☐ Procedure room (phlebotomy) ☐ Procedure room (lumbar puncture) ☐ Research-dedicated MRI scanners Brand/Model: _____ ☐ Research-dedicated PET and SPECT scanners
3. What type of IRB do you use?	☐ Central, *skip to question # 8* ☐ Local
4. How frequently does your local IRB meet?	☐ Every other week ☐ Every other month ☐ Monthly ☐ Other: _____
5. What is the submission deadline for a scheduled IRB meeting?	

6. Is local IRB approval tied to contract finalization?	Yes ☐ No ☐
7. How long does it typically take from initial IRB submission of the protocol to IRB approval?	

8. Can your site accommodate 3 to 3.5hr study visits in a quiet, well lit room with a table/chairs for test administration?	Yes ☐ No ☐
9. Does your site have a 10ft hallway or room where you could mark the floor and conduct a timed walk test?	Yes ☐ No ☐
10. Does your site have currently certified staff/investigator to administer the Clinical Dementia Rating Scale (CDR)?	Yes ☐ No ☐
11. Does your site have currently certified staff/investigator to administer the Movement Disorder Society sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS)	Yes ☐ No ☐
12. Is the primary investigator certified to administer the MDS-UPDRS?	Yes ☐ No ☐
13. Type of PSG equipment your sleep center (or research center PSG platform)	_____

Budgets/Contracts/Insurance	
14. Who handles budget and contract negotiations?	Name: _____ Title: _____ Phone: _____ Fax: _____ Email: _____

15. How long does it typically take to finalize a contract at your site?	
16. What is your institution's grant overhead (F&A) rate?	☐ Federal ____% ☐ Other _____%
17. What other fees are required in the contract; excluding per patient costs? (*i.e. local IRB fees*)	
18. Can someone on your study team perform phlebotomy?	Yes ☐ No ☐ If no, what is the fee for a laboratory to draw 4 x 10ml of blood? _____
19. Is there a lab fee for processing samples?	Yes ☐ No ☐ If yes, what is the fee for the lab to process 4 tubes of blood? _____
20. Is there a fee for storing samples in a -80 freezer at your site?	Yes ☐ No ☐ If yes, what is the fee for storing up to 8 boxes 3"x3"x2" cryoboxes? _____
21. Do you typically reimburse your participants for their travel expenses?	Yes ☐ No ☐ If yes, what is the typical per visit reimbursement? _____ per visit
22. Is there a fee for exam room usage?	If yes, what is the fee for a ~3.5hr visit? _____ per visit

Site personnel experience and qualifications	
23. Has the Investigator previously conducted clinical research studies?	Yes ☐ No ☐ If yes, please enter the number of studies _____
24. Has the Investigator previously conducted RBD research?	Yes ☐ No ☐

	If yes, please list below:
For each trial, list year(s) of trial, phase (I-IV), sponsor, # enrolled at your site, # randomized at your site	
25. Are you currently working on a study that would compete for enrollment in NAPS?	Yes ☐ No ☐ If yes, please specify and include date that enrollment is expected to be completed: _____
26. Are you planning to conduct any competing studies within the next 18 months?	Yes ☐ No ☐ If yes, please specify: _____
27. How many research studies (investigator initiated and industry sponsored) are you currently conducting?	
28. What percentage of the Investigator's time is typically spent conducting clinical research?	_____%
29. How many study coordinators work at the site?	____ Full-time _____ Part-time
30. What is the average number of years of experience of the study coordinators?	_____ Years
31. Have your potential study coordinators previously worked on RBD trials?	Yes ☐ No ☐ If yes, how many coordinators have experience working on these trials? _____
32. How many physician co-investigators, study coordinators, and psychometricians are anticipated to work on this trial?	SI: _____ SC:_____ PSY:_____
33. Does your study team have experience performing neurocognitive testing (MoCA, Trails A & B, verbal/semantic fluency, Craft Story, etc.)?	Yes ☐ No ☐

34. Do you have experience using REDCap for electronic data entry?	Yes ▭ No ▭
35. Has the Investigator and site staff had ICH-GCP training within the last 2 years?	Yes ▭ No ▭ If yes, what year? _____
36. Is someone on your study team IATA certified and able to ship samples on dry ice?	Yes ▭ No ▭ If no, what is the fee for preparing a shipment? _____
37. Has the investigator, sub-investigator(s) or site ever been audited by the FDA?	Yes ▭ No ▭ If yes, please explain and/or attach copy of FDA form 483 and follow-up correspondence. _____

Participant population	
38. How many RBD patients (age 18+) with PSG confirmed RBD are seen in your clinic each month?	_____ patients
39. Do you have experience reading polysomnograms and diagnosing REM sleep without atonia (RSWA)?	Yes ▭ No ▭
40. Do you have experience exporting polysomnograms to EDF, creating epoch reports, and uploading PSGs to a central reader?	Yes ▭ No ▭
41. Are you able to install new software onto a computer for research?	Yes ▭ No ▭
42. How many adults with idiopathic RBD do you estimate you could enroll in a 12-month period?	_____
43. For this trial, what would be the source of your research participant population? Please indicate the estimated percentage for each source type.	▭ Practice _____% ▭ Research Database _____% ▭ Advertising _____% ▭ Referrals _____% ▭ Other _____ _____ % Please describe other referral source(s):

44. What challenges do you anticipate enrolling 20 number of participants over 12 months?	_____ _____ _____ _____

General	
45. Is there an ADC (Alzheimer Disease Center) at or affiliated with your institution?	Yes ☐ No ☐ If yes, name: _____ _____
46. Would you like to recommend any other Investigator(s) who may be interested in participating in NAPS?	Yes ☐ No ☐ If yes, please provide contact information: Name:_____ Facility/State/Country:_____ Phone or email:_____
47. Does your site have a Material Transfer Agreement (MTA) in place with the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)?	Yes ☐ No ☐
_____ **Investigator Printed Name**	_____ Investigator Signature and Date

Thank you for completing this questionnaire!