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|  | Washington University in St. Louis  Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU)  *Site Information Form* |

🡆 If you **ARE** interested in being considered for participation and/or receiving further information about the therapeutic trial, please complete **all pages** of this form

🡆 If you are **NOT** interested, please complete **only this page**

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| **Please RETURN via email to:** |

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| **ATTENTION: Kathleen Fanning** |
| **EMAIL ADDRESS: Kfanning@wustl.edu** |

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| **Investigator Name:** | |
| **Institution:** | |
| **DATE:** | **NUMBER OF PAGES:** |

**Please indicate your interest in participating in the studies, by completing the table below:**

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| **Washington University**  **DIAN Trials Unit**  **Protocol #: DIAN-TU-001** | **Definitely**  **Interested** | **Unsure**  *(Indicate reason using codes shown below)* | **Definitely NOT interested**  *(Indicate reason using codes shown below)* |
|  | **Please complete the entire form** | \*\* Reason No. \_\_\_\_\_\_ | \*\* Reason No. \_\_\_\_\_ |

**\*\* Reason(s) for being “Unsure” or “Definitely NOT interested”:**

1. Don’t follow DIAD patients 2. Protocol design issues
2. Competing protocols 4. Lack of available staff
3. Lack of required equipment. If yes, specify which equipment is required\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Lack of potential subjects
5. Other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **GENERAL SYNOPSIS OVERVIEW** |

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| **Protocol Title** | **A Phase II/III Randomized, Double-Blind, Placebo-Controlled, Cognitive Endpoint, Multi-Center Study and Open-Label Extension of Potential Disease Modifying Therapies in Individuals at Risk for and with Dominantly Inherited Alzheimer’s Disease** |
| **Clinical Phase** | Phase II/III |
| **Investigators** | Sites will be selected and qualified from the Dominantly Inherited Alzheimer’s Network (DIAN) Observational study sites as well as newly identified sites. |
| **Study Period** | Each subject will have a minimum of 4 years (208 weeks) on treatment. Double blind treatment will continue until the last patient completes their year 4 visit so if enrollment takes 36 months then the initially enrolled patients may be in the double blind treatment phase for up to 88 months. Mutation positive patients will be offered a 2 year Open-Label Extension Period if the treatment arms demonstrates efficacy. |
| **Study Objective\*** | To assess the safety, tolerability, biomarker and cognitive efficacy of investigational products in subjects who are known to have an Alzheimer’s disease-causing mutation by determining if treatment with the study drug slows the rate of progression of cognitive impairment and improves disease-related biomarkers.  ***\*****Recruitment goals will be increased as additional compounds are added to the trial(s).* |
| **Study Population** | Subjects who are either known to have a mutation causing Alzheimer’s disease OR who do not know their gene status but are “at-risk” for a dominantly inherited Alzheimer’s disease (DIAD) mutation AND who are either 1) cognitively normal and are between 15 years younger (-15) to 10 years older (+10) than their expected age of symptom onset or 2) have mild symptoms of dementia (CDR 0.5 or 1) and are within 10 years of the onset of symptoms of dementia. |
| **Number of Subjects** | It is currently planned that a total of 192 patients will be enrolled from sites that are globally distributed. The recruitment goal is 120 mutation positive subjects with the possibility to reduce the total number to as few as 112 subjects and to increase the total number to as many as 160 subjects depending on the outcome of the sample size re-estimation. An estimated 60 mutation negative subjects who are unaware of their genetic status (estimated to be 1/3 of total subjects) will also be recruited.  Non-carriers (**mutation negative**) subjects are included to maintain blinding as to genetic status for those who do not wish to know their genetic status. They will not be exposed to study drug and will be automatically assigned to placebo in a blinded fashion. |
| **Main Inclusion Criteria** | Subjects must meet ALL inclusion criteria. Below are the major inclusion criteria:   * Know they have an AD-causing mutation or be unaware of their genetic status and have a 50% chance of having an AD-causing mutation (e.g. parent or sibling clinically affected with known AD-causing mutation in family) * Are within -15 to + 10 years of the estimated age of symptom onset, or, if symptomatic within 10 years of their age of symptom onset * CDR 0-1 inclusive * Are able to undergo MRI, Lumbar Puncture, PET, and complete all study related testing and evaluations. |
| **Main Exclusion Criteria** | Subjects will be excluded if they have a major or unstable illness or are unable to complete all study related testing. Exclusions include implanted metal that cannot be removed for MR scanning, required anticoagulation and pregnancy. |

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| **GENERAL STUDY PROCEDURE & VISIT OVERVIEW (DOUBLE BLIND)** |

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| PROCEDURE: | Baseline, Yr 1, 2, 3, 4, 5,6,7 | Every 3 mo. | Every 3 mo.  [1st 2 years only] | Every mo. |
| Informed consent | X (screen) |  |  |  |
| Med/Tx Hx | X (screen) |  |  |  |
| Clinical Assessment | X |  |  |  |
| PE & Neuro Exam | X |  |  |  |
| 12-lead ECG – Central Read | X (baseline) | X (year 1 = Every 6 months) |  |  |
| C-SSRS | X (years 3 & 4) |  | X (years 1 & 2) |  |
| Genetics/ApoE Testing | X (baseline) |  |  |  |
| Clinical Safety Labs |  | X |  |  |
| Vitals, Pregnancy testing |  |  |  | X |
| PK | X (baseline and every 3 months up to 6 months. Every 6 months in years 2- 4) |  |  |  |
| Cognitive Testing | X (full) | X (abbrev.) |  |  |
| 3T Safety MRI | X (incl vMRI) |  | X (years 1 & 2 only) |  |
| PET [Tau; PiB] | X (years 1, 2 & 4) |  |  |  |
| Lumbar Puncture (15-20 mL) | X (years 1, 2 & 4) |  |  |  |
| ConMeds & AE/SAE Assmt |  |  |  | X |
| Study Drug Dosing |  |  |  | Daily |
| Dermatologic Evaluation | Baseline and year 1 |  |  |  |

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| **ROLES & REQUIREMENTS FOR SITES** | |
| **Performance Sites** | **Partner Site** |
| * Participants: Know they have an AD-causing mutation or be unaware of their genetic status and have a 50% chance of having an AD-causing mutation (e.g. parent or sibling with known AD-causing mutation) * Approx. 10 eligible carriers (based on initial assessment of core inclusion/exclusion criteria) * Facilities:   + Cyclotron   + 3T MRI scanner   + PET Scanning ability * Availability of genetic testing and counseling * Experienced staff & resources:   + Staff with experience in FDA-regulated clinical trials (FDA & ICH/GCP proficient)   + Staff resources with availability to work on the trial (PI, study coordinator / nurse)   + Psychometricians for cognitive testing   + Staff experienced with Lumbar puncture | * Refer mutation carriers to performance sites to assist participants and families in gaining trial access * Obtain certification to serve as a remote safety MRI center (3T MRI required) * Possible location for local visits * Resource for unscheduled consults   ***Next Steps:***  Support can start now by sharing the expanded registry website [www.dianexr.org](http://www.dianexr.org) with your DIAD patients and their families   * Remain engaged during the conduct of the trial to serve as a resource/facility for interim needs if in closer proximity than the participant’s host DIAN-TU performance site, e.g. qualified safety MRI facility; unscheduled consults (expert neuro assessments), monthly visits * Register yourself as an interested researcher on the Expanded Registry website: * Spread the word to your patients about the registry * Discovery testing to identify potential participants for phase II &/or phase III trials |

***PLEASE ANSWER THE QUESTIONS SPECIFIC TO THE LOCATION WHERE THE STUDY WILL TAKE PLACE***

***AND WITH REGARD TO THE ACTUAL STAFF THAT WILL BE WORKING ON THE STUDY***

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| **INVESTIGATOR INFORMATION** | | | | | | | |
| **Investigator Title\*:**  **Dr.** | | **Inv. First Name:** | | | **Inv Last/Family Name:** | | |
| **Institution/Practice Name:** | | | | | **Department:** | | |
| **Address (line 1):** | | | | | | | |
| **Address (line 2):** | | | | | | | |
| **Town/City:** | | | | **State:** | | | **ZIP code:** |
| **Phone:** | | | **Fax:** | | | **Mobile/Cell:** | |
| **Email:** | | | | | | | |
| **Setting:** | □ Hospital (public or private) □ Research Center □ University Hospital  □ Outpatient Care Clinic □ Solo/Group Practice □ Military/VA  □ SMO: please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ Other – please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **Medical specialty of the primary investigator at your site**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ Subspecialty, if any:  □ Other (please specify):  **Subspecialty, if any:** \_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **REGULATED,INVESTIGATIONAL DRUG CLINICAL TRIAL EXPERIENCE (FDA,EMA, ETC):**  **# Trials\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ # Years \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Phase I: \_\_\_\_\_\_\_\_\_\_\_**  **Phase II: \_\_\_\_\_\_\_\_\_\_**  **Phase III: \_\_\_\_\_\_\_\_\_**  **Have you had a formal GCP training?**  □ Yes □ No | | | | | | | |

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| |  | | --- | | **PRIMARY STUDY COORDINATOR INFORMATION** | | **Study Nurse / Coordinator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Facility / Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**□ Same as above  **Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**□ Same as above  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Phone# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Email Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | **REGULATED,INVESTIGATIONAL DRUG CLINICAL TRIAL EXPERIENCE (FDA,EMA, ETC):**  **# Trials as Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ # Years as Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Phase I: \_\_\_\_\_\_\_\_\_\_\_**  **Phase II: \_\_\_\_\_\_\_\_\_\_**  **Phase III: \_\_\_\_\_\_\_\_\_**  **Formal GCP training?** □ Yes □ No  **Intralinks Training?** □ Yes □ No  **Electronic Data Capture (Inform) Experience** □ Yes □ No  **Attach primary study coordinator’s CV:**  **Please provide a copy of the study coordinator’s percent efforts from your institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
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| **SITE INFORMATION** | |
| **Please indicate if you are, or have ever been, one or more of the following:** | |
| □ DIAN Observational site □ ADCS performance site  □ ADNI performance site □ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Please indicate what languages are spoken by your patients (P) and site staff (S):** | Participants: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Site Staff: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **SITE’S PATIENT POPULATION\***  *\*specify below or attach a separate document with the requested information* | | | | |
| **Please answer the below questions based on the number of patients at your site that you have seen and which meet the following criteria. This section must be completed for your site to be considered for participation:**   1. Have an AD-causing mutation (confirmed via genetic testing); or 2. Are unaware of their genetic status and have a 50% chance of having an AD-causing mutation (e.g. parent or sibling with known and documented AD-causing mutation). 3. Are within -15 to +10 years of estimated age of symptom onset (or unknown) 4. CDR = 0, 0.5 or 1 | | | | |
| **Mutation Type** | **Mutation Location** | **# Patients seen at your site (by CDR)** | **# Additional family members in pedigree (not including those noted in left column)** | **How many patients are within driving distance of your site?** |
| **Example:** PSEN1 | **Example:** ASN141TYR | **Example:**  CDR 0: CDR 0.5: CDR 1:  1 0 1 | **Example:**  CDR 0: CDR 0.5: CDR 1:  2  \_\_0\_\_ \_\_1\_\_ | **Example:** Current patients are in driving distance; others in pedigree are 4 hour drive from site |
|  |  | CDR 0: CDR 0.5: CDR 1:  *\_\_\_\_\_ \_\_\_\_\_\_ \_\_\_* | CDR 0: CDR 0.5: CDR 1:  *\_\_\_\_\_ \_\_\_\_\_\_ \_\_\_* |  |
|  |  | CDR 0: CDR 0.5: CDR 1:  *\_\_\_\_\_ \_\_\_\_\_\_ \_\_\_* | CDR 0: CDR 0.5: CDR 1:  *\_\_\_\_\_ \_\_\_\_\_\_ \_\_\_* |  |
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| 1a | Please describe your strategy/plan for enrolling subjects: | | | |
| 1b | This study will require annual assessments which will require several days to complete and include MRIs, two PET scans, Lumbar Punctures, cognitive testing, and other safety assessments. Considering the study procedures, or any other contributing factors, do you anticipate any limitations to enroll subjects in this study?  **\*If Yes**, please provide comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | □ Yes □ No |
| 1c | After reviewing the **inclusion/exclusion criteria**, do you anticipate any limitations to enroll subjects in this study?  **\*If Yes**, please provide a comment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | □ Yes □ No |
| 1d | Taking into account the inclusion and exclusion criteria listed in the Study Synopsis:  -How many subjects do you estimate your site would be able to **screen per month**?  -How many subjects do you estimate your site would be able to **randomize per month (keep in mind the screening is 2- 8 weeks, and baseline/randomization visit is approximately 3 full days)**?  -How many subjects do you estimate your site would be able to **randomize total (keep in mind recruitment period is expected to be a total of 36 months from April 2017-April 2020)**? | | | Screened subj/month:  Randomized subj/month:  Total # randomized subjects: |

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| **SITE RESOURCES** | |
| **Genetic counseling:** | □ Available at our site  □ Other: (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Can the genetic counselor be “on call” during the subject’s visit? □ Yes □ No |
| **Genetic Testing:** | □ Available at our site  □ Other: (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Do you perform**  **lumbar punctures**  **(LPs)?** | □ No  □ Yes → Please describe your current experience with LPs, fluoroscopy-guided LPs, ability to  complete blood patches, any issues with collection, processing or shipment of 15-20  mL volume, etc.:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Pharmacy:** | □ Yes, we have a pharmacy on site  □ If No to either → please describe where the investigational product will be stored (other/satellite locations):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **IMAGING AT YOUR FACILITY** | |
| **3T MRI:** | □ Yes, we perform them at our institution □ No  □ No, not at this location but if necessary we refer patients to the following:  **Facility:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Contact name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Phone #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**   * Is the MRI facility experienced in conduction 3T scans for clinical trials: □ Yes □ No * Approximate distance from your site (**specify miles or kilometers**): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Can the facility upload images to a central location electronically? □ Yes □ No |
| **TAU PET:** | □ Yes; Please list the source/manufacturer of every tau tracer utilized at your institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ No  □ No, not at this location but if necessary we refer patients to the following location:  **Facility:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Same as above  **Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Contact name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Phone #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Cyclotron:** | **This section must be completed for your site to be considered for participation:**  □  Yes, we have access to a cyclotron to produce PET tracers at our institution, Please complete all information below  □  No, not at this location but if necessary we refer patients to the following:  **Facility:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Same as above  **Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Contact name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Phone #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**   * Approximate distance from your site (**specify miles or kilometers**): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Does your cyclotron facility manufacture tracers in a GMP compliant manner? (i.e. follow USP 823 or its international regulatory equivalent) □  Yes □  No * Is the Cyclotron facility experienced in manufacture of PET tracers for clinical trials:  □ Yes   □ No * Additional Details:  1. Radioisotope Production Capability 2. Cyclotron Manufacturer & Model Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. Isotopes Routinely Produced \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. Target Material and Composition \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 5. Facility and Equipment Capability 6. Production Hot Cell Controls □  Classifed ISO Class Target \_\_\_\_\_\_\_\_\_\_   □  No   1. Aseptic Processing Hood Controls □  Classifed ISO Class Target \_\_\_\_\_\_\_\_\_\_   □  No   1. Sterility Test Hood Controls □  Classifed ISO Class Target \_\_\_\_\_\_\_\_\_\_   □  No   1. Production and Process Controls 2. Automated Synthesis Modules □ Yes   □ No 3. Automated Synthesis Modules Manufacturer & Model \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. Stability Determination 5. Typical stability or expiration times for radioligands \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 6. Tests used to establish stability \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **ADDITIONAL SERVICES / RESOURCES** | |
| **Urgent / Emergency Care:** | Please describe what emergency / critical care resources are present at your site (e.g. crash cart, treatment for anaphylaxis, etc.):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Sample Storage:** | Please mark which of the following you have on site and/or access to:  □ Centrifuge □ Refrigerated Centrifuge □ Dry ice □ -20 freezer □ -70 freezer |
| **Analog Phone Line Access:** | Does your site have access to an analog phone line to use for ECG transmission during this study.  □ Yes, we currently have an analog line □ No, we currently do not have an analog line |
| **Internet Access** | Please mark which of the following you have on site and that will be accessible to a Site Monitor and Site Staff for use:  □ Wired Internet Access □ Wireless Internet Access □ No internet Access |
| **Cognitive Testing:** | Do you have psychometricians at your institution and/or affiliated with your institution?  □ Yes → please specify how many psychometricians are on site: \_\_\_\_\_\_\_\_\_\_\_  □ No → please specify what resources are available for cognitive testing (referral centers):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Dermatology:** | Do you have a dermatologist at your site?  □ Yes □ No  If no, do you have a dermatologist you could partner with?  □ Yes □ No |

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| **INVESTIGATIVE SITE STAFF** | | | | | | | | | | |
| **2a** | How many investigators at you site would be working on the trial? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*\*Please complete table under section **2g** with investigator details.\*\* | | | | | | | | | |
| **2b** | Do you have back up staff available if your primary study personnel are unavailable? | | | | | | | □ Yes □ No | | |
| **2c** | **Back Up** **Study Coordinator**:  **Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Facility / Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** □ Same as Site  **Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** □ Same as Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Phone# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Email Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Formal GCP training?** □ Yes □ No **Intralinks Training?** □ Yes □ No  **Electronic Data Capture (Inform) Experience** □ Yes □ No  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \*\*Please complete table under section **2g** with Study Coordinator (Primary/ Back-up) details.\*\* | | | | | | | | | |
| **2d** | Please provide name of the **Regulatory Coordinator** (if your site has one):  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Intralinks Training?** □ Yes □ No  Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Same as Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |
| **2e** | Has your institution/practice ever been audited by the FDA?  ***Please provide the date of your most recent audit****.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Were you issued an FDA 483 as a result of an audit?\*  **\*IF YOU WERE ISSUED A FORM 483 AS A RESULT OF AN AUDIT, PLEASE PROVIDE A COPY OF FORM 483** | | | | | | | | □ Yes □ No  □ Yes □ No | |
| **2f** | If you have been audited, have all audit findings been resolved? **PLEASE PROVIDE YOUR RESPONSES TO FORM 483** | | | | | | | | □ Yes □ No | |
| **2g** | Site Staff Table (Please complete table below in full for all applicable staff members that will be working on this study | | | | | | | | | |
| **Site Staff**  **Member Name** | | **Site Staff Role**  (PI, SI,  Psychometrician, Cog/Clinical Raters, SC, Back-up SC, Imaging Personnel, other) | **Credentials/ Background** | **Years of Clinical Research (CR) Experience** | **Years of CR Experience with AD Trials** | **Have you completed formal GCP training?** | **How many regulated**  **(FDA, EMA, etc.) studies are you currently working on in your role** | | | **What percentage of your time will you be able to dedicate to this study?** |
| *Example:* | | PI | MD, PhD | 10 | 10 | yes | 3 Phase 2 (2-enrolling, 1 in maintenance);  4 Phase 3 (3 enrolling, 1 in maintenance) | | | 15% |
| John Smith | |
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| **IRB/EC & CONTRACT/BUDGET** | |
| **3a** | From the time you receive the protocol, what is the usual timeline to initiate patient screening? (Inclusive of IRB/Ethics approval, approval from other required committees and execution of the final contract at your site)? *Please consider that radiation / radioactivity will be a part of this study should any Radiation Safety Boards be required to review / approval. Please also consider the review/approval turnaround for the IRB governing the imaging center if you will be using an off-site imaging center)*  □<2 months □ 2-3 months □ 3-4 months □ 4-5 months □ 5-9 months □ 9 -12 months □ 12-18 months |
| **3b** | Please list the name and address of your IRB:  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3c** | Based on past experience with you IRB and their process, how long do you anticipate it will require compile the initial application to the IRB once all documents are provided to you?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  What is the turnaround time for initial review and approval of a study with your IRB? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  What is the turnaround time for approvals/ reviews after the study is initially approved? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  What is the frequency that your IRB meets? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please include any additional details regarding your IRB, such as additional review boards, etc. If possible, please attach a copy of the IRB submission date and review schedule.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3d** | Please specify who will handle **contracts/budget negotiation** for this project on behalf of your site  **Contracts**  Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Same as Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Budget Negotiation (Check here if same as contract contact above** □)  Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Same as Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3e** | Insurance: Are there any site-specific indemnification requirements? □  Yes □  No  **If Yes**, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3f** | Are there any site-specific requirements concerning the Consent Form language, contract language or institutional-required start-up fees? □  Yes □  No  **If Yes**, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3g** | Does the contract-budget need to be executed before you can submit to the IRB? □  Yes □  No  **If Yes,** please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3h** | What is the typical **turnaround time** with regards to the review and execution of contractual documents?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3i** | Are there any **special provisions** (information/documentation) needed from monitors who come to work at your site? □  Yes □  No  **If Yes**, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **HOME HEALTH NURSING** | |
| **Home Health Nursing (HHN):** | Have you ever used home health nurses (HHNs) for any purpose, i.e. clinical setting, clinical trial setting, drug administration, etc.? □ No □ Yes → Please describe your experience(s):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Distribution of IP to HHN** | Do you anticipate any issues/concerns with shipment of IP directly to HHN? □ No □ Yes → Please provide details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **HHN Use:** | Do you anticipate any issues/concerns with obtaining approval for the use of HHNs from your national regulatory agency or local ethics committees? □ No □ Yes → Please provide details:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Participant View:** | Do you expect the use of HHNs for the home visits to be needed for your participant and/or used by them?  □ Yes → our participants don’t live close to our center, it is essential to use HHNs  □ Yes → they will prefer the convenience of visits to occur at home before/after working hours, or  weekends  □ No → they prefer to come to be seen at our site/center each visit, or seen by a physician  □ Other → please explain if you think your participants will/won’t utilize home health nursing for the trial, or other expected needs:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **ALZHEIMER’S DISEASE CLINICAL RESEARCH EXPERIENCE** | | |
|  | | How many industry-sponsored clinical studies have you conducted for AD in the past 5 years?  How many studies contained a cognitive measure in the patient assessments (mild cognitive impairment [MCI], dementia, Alzheimer’s, etc.]? | # of Trials:    # of Trials: | |
|  | | Do you or your staff have experience in administering and scoring the following instruments:  MMSE □ Yes □ No  CDR □ Yes □ No  CSSRS □ Yes □ No  Electronic Cog state testing □ Yes □ No  Paper and Pencil psychometric testing (i.e. Trials A&B) □ Yes □ No | | |

**Additional Information / Considerations:**

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| Please specify any additional constraints at you site (local or national laws/regulations), i.e. radiation limits, inclusion of non-carriers, population limitations and/or special considerations: |
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***Thank you!***

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| **Please RETURN via email to:**  **kfanning@wustl.edu** |