

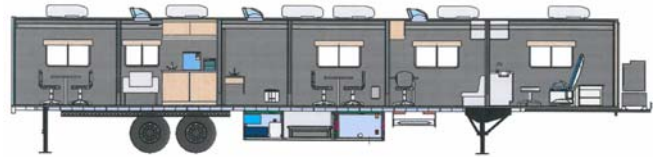
Clinical Trial Site Profile

USF Health Byrd Alzheimer's Institute presents the
MEMORY RESEARCH SUITE



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About the USF Health Byrd Alzheimer's Institute

The USF Health Byrd Alzheimer's Institute was founded in 2002 on the vision of former Florida Speaker of the House, Johnnie Byrd, Jr. whose father suffered from Alzheimer's disease and for a number of years was known as the Johnnie B. Byrd, Sr. Alzheimer's Center & Research Institute.

Today the Institute is a multi-disciplinary Center of Excellence at the University of South Florida that provides compassionate family-centered patient care, performs cutting edge research and delivers quality public and professional education. With a state-of-the-art building and a highly qualified team of researchers, doctors, clinicians and educators, the Institute is at the

forefront of Alzheimer's research and care.

We are pleased to announce the development of our mobile clinical trial unit, the *Memory Research Suite*, which is approximately 400 square feet of clinical research space specifically dedicated to the implementation of memory loss and Alzheimer's clinical trials.

Mission Statement

The USF Health Byrd Alzheimer's Institute is dedicated to the prevention, treatment and cure of Alzheimer's disease and related disorders.

Letter from the Medical Director - Amanda Smith, MD

My interest in neurodegenerative disease has been longstanding, with much of my passion devoted to the discovery of new treatments and therapies for Alzheimer's disease. My education and career at the University of South Florida has fostered several opportunities for such involvement.

The USF Health Byrd Alzheimer's Institute recognizes the need for community-based clinical research due to limited clinical trial sites in the state of Florida and the growing needs (and physical limitations) of the elderly population. Florida has a large number of senior residential communities spread over a large geographical area. The Byrd Alzheimer's Institute has also developed a Community-Based Memory Screening program which trains local retired and active health professions as volunteers to perform memory screenings in the community. Additionally, Florida also has an excellent network of state-supported Memory Disorder Clinics (MDCs) through the Alzheimer's Disease Initiative (ADI). Although these clinics care for 10,000 memory-impaired cases annually, many do not have the resources or expertise to offer their patients the opportunity to participate in clinical research. The mobile unit affords us the opportunity to bring a state-of-the-art research facility and dedicated, well-trained staff to areas all over Florida.

In December 2014, we conducted a 3-day workshop near Orlando, Florida and included experts on the conduct of Alzheimer's disease clinical trials, representatives from the Memory Disorder Clinics, personnel from agencies supervising the clinical trials (Clinical Research Organizations and university partners), the Alzheimer's Association and individuals with experience operating mobile clinical research units. With feedback from this collaborative meeting, we continued with our plans for designing this mobile unit and are pleased to announce the USF Health Byrd Memory Research Suite was delivered May 16, 2016.

We eagerly look for clinical research programs to run on this unit. We have several partners who have already indicated interest in participating with us by offering space to park our mobile unit to conduct local enrollment efforts in their areas, including Sun City Center, Sarasota, The Villages, Orlando, and St Petersburg. As a clinical trial sponsor, the mobile unit has the capability to offer multi-site enrollment numbers with a single team and contract, requiring far fewer of your resources than what would be required of multi-sites otherwise.

If you would like additional site information, please contact our Assistant Director for Clinical Research, Jill Smith, MA, CCRC at (813) 974-1294 or jsmith10@health.usf.edu.

Respectfully yours,

Amanda Smith, MD
Medical Director
USF Health Byrd Alzheimer's Institute

Memory Research Suite Team & Training

All clinical research staff members maintain current CITI and HIPAA certification. The study coordinator(s) is IATA trained for packing/shipping biological specimens. Research staff also have experience working with EDC systems such as Inform and MediData.

The mobile unit will include a minimum of 4 staff members:

- Sub-Investigator (MD or ARNP)
- Study Coordinator/Study Nurse
- Cognitive Rater
- Global Rater

We recognize that every location we station the Memory Research Suite unit at will be unique and different. When the unit is stationed at a medical clinic, we may utilize and delegate study activities to their physicians as study staff. This may include medical procedures such as physical/neurological exams, reviewing ECGs, verifying eligibility criteria, etc.

We recognize study training requirements and the importance of continuity for clinical trial raters for optimal data collection. The study coordinator/nurse and both raters will remain permanent members of the mobile unit study team. These team members will be experienced in clinical trials and will meet all study sponsor training requirements.

Study Drug Maintenance Capacity

At this time, we plan to implement trials with ambient investigational medications on the mobile unit, with plans to possibly add infusion-based treatments later, particularly if the sponsor is willing to allow for home infusions.

Our clinical trial staff is trained in drug inventory, maintenance, dispensing, and accountability. Our SOP is to utilize a double check method so that two study staff members sign off on all drug dispensed to ensure accountability.

The current SOP for study drug is for the drug to be permanently stored at the USF Health Byrd Alzheimer's Institute. Each morning, when the mobile unit team meets to collect required materials for the day, the study medication will be dispensed via IWRS or IVRS systems. It will be stored separately for each patient during transportation and while ambient medications are on the Memory Research Suite, they will remain locked with secure access in a temperature regulated container. The staff will monitor drug temperatures utilizing temperature tracking devices.

MRI Brain Imaging and Lumbar Puncture Capacities

We understand the growing need for both MRI brain imaging and lumbar puncture capacities in clinical trials for memory loss and Alzheimer's disease. Our university-based practice utilizes two partners on campus for conducting brain MRI scans and lumbar punctures, both with experience working with our site on clinical trials. Lumbar punctures are conducted under CT guided fluoroscopy by a trained radiologist.

USF Radiology
13330 USF Laurel Drive
Tampa, FL 33612

Machine: 3T – HDX

Contact: Keven Clifford

kcliffor@health.usf.edu

University Diagnostic Institute
3301 Alumni Drive
Tampa, FL 33612

Machine: 1.5T – GE Excite, 11.1_0919a

Machine: 3T - Philips Achieva, 2.6.3.7

Contact: Pam Edwards (813) 972-3351

pedwards@udimri.com

In addition to these established partnerships, it may be more optimal to utilize local imaging sites for each location the mobile unit will be visiting if a particular clinical trial has frequent imaging requirements. This will be done on a case-by-case scenario after thorough discussion of its feasibility with a study sponsor, number of required scans, and distance of each location to USF. Any MRI machines used/qualified for a clinical trial will remain consistent for study subjects.

PET Brain Imaging

We are able to conduct and have experience with FDG, β -amyloid, and Tau PET brain scans in clinical trials on-site at the Byrd Institute. Our facility has a hot lab and three injection suites, monitored by video cameras. We have standards in place for overnighting MRI discs or uploading them to central systems.

PET Scanner Location:

USF Byrd Alzheimer's Institute
4001 E Fletcher Ave
Tampa, FL 33613

Machine: GE Discovery 600 CT/PET

Operating System: PET_Velocity.53HP_P_G16

Serial #: 269769HM6

Ram License #: 806-6, Expires 7/31/2016

Contact: Jennifer Bogush, CNMT (813) 396-0683

jbogush@health.usf.edu



As PET scans grow as a vital efficacy marker in clinical trials, we plan to utilize our institute's PET scanner and well-experienced research PET technologists for all clinical trials completed on the Memory Research Suite mobile unit. Subjects will be offered transportation for the procedures, as needed.

Central and Local Laboratories

We have experience with Covance, ICON, PPD, and Quest Diagnostics central laboratories. Our study staff is IATA trained to pack and ship study specimens. We will have dry ice on hand in the mobile unit for same day shipping.

If local laboratory services (such as CSF testing) are needed, we utilize Quest Diagnostics Services. Certificates and licenses for our local laboratory available upon request.

Our base institute lab certificates (CLIA) will be used on mobile unit.

Exam Rooms

We currently have one exam room on the mobile unit designated for clinical trial physical and neurological exams. This room is equipped with the proper medical equipment, including weight scale and vitals machine. All medical equipment is calibrated annually. Certificates for calibration are available upon request.

Blood Draw Capacities

We have a designated lab space on the mobile unit for blood draws and locked storage of clinical trial lab kits. This suite has a refrigerated centrifuge and deep freezer (-20°C). Lab equipment is calibrated annually. Site maintains a manual log of temperatures to ensure reliability of the freezer if samples are stored.

CRO and Sponsor Monitoring

When clinical monitoring is needed, we can utilize one of the two testing rooms to allow a monitor to review records on the unit or can arrange for space the Byrd Institute where we also have two designated work spaces that can accommodate up to two monitors which has wireless internet access, copier, and work tables.

Other Clinical Trial Equipment on Mobile Unit

Fax / Copier
Telephone
Wireless Internet Connection
Deep Freezer (-20°C)

Dry Ice
Study Drug and Lab Kit Storage
12-Lead ECG

Institutional Review Boards

Local University IRB

University of South Florida, Research Integrity and Compliance
3702 Spectrum Blvd., Suite 175
Tampa, FL 33612-9444
(813) 974-5570
4 Research Boards, each meets weekly

Central IRBs Approved for Use at USF (can be used as local IRB)

Western Institutional Review Board

3535 7th Avenue SW
Olympia, WA 98502
(800) 562-4789
Multiple boards, ongoing meetings

Quorum Institutional Review Board

1601 Fifth Avenue, Suite 1000
Seattle, WA 98101
(877) 472-9883
Multiple boards, ongoing meetings

Schulman Associates IRB

4445 Lake Forest Drive
Suite 300
Cincinnati, Ohio 45242
(513) 761-4100
Multiple boards, ongoing meetings

Average study approval time is approximately 6 weeks but is often faster if the sponsor has done a pre-review process with their selected central IRB.

Each site that the Memory Research Suite visits will have a physical address, such as a memory disorder clinic, health clinic, hospital, church, etc, and will be listed on FDA form 1572, informed consent, etc.

Study Start-Up Timelines

Contract negotiations and IRB submission can occur simultaneously.

Average time for completed contract: 4 weeks

Average time for IRB approval: Central IRBs, 4 weeks
USF IRB, 4-6 weeks

Contracts and Budget

All contracts/budgets should initially be sent directly to site who will review and send in for processing. Contracts and budgets are handled at the university level by the Office of Clinical Research.

Site Contact: Jill Smith
jsmith10@health.usf.edu

University Contact: Office of Clinical Research
OCR@health.usf.edu

Standard university overhead on industry sponsored clinical trials is currently 30%.

Potential Recruitment Sources

Community based recruitment efforts will take place within a 90 minute radius of the USF Health Byrd Alzheimer's Institute. In addition to our own institute recruitment efforts, noted below, we will also utilize memory disorder clinics and community partners where we have established memory screening programs.

USF Health Byrd Alzheimer's Institute, Outpatient Geriatric Psychiatry Practice

A large part of our recruitment efforts occur through our clinic and patient care. Established in 1980 within the University of South Florida, Morsani College of Medicine, the Eric Pfeiffer Suncoast Alzheimer's Center is the flagship clinic of the USF Health Byrd Alzheimer's Institute. The Suncoast Alzheimer's Center offers patients and their families a variety of clinical services. Our clinical experts are uniquely qualified to perform:

- Comprehensive clinical assessments that will diagnose memory problems
- Medication review and follow-up care after diagnosis
- Family counseling

Support Groups

The institute has three different support groups:

- Alzheimer's patient support group (for the diagnosed patient themselves)
- Caregivers of Mild Cognitively Impaired (MCI) individuals
- Caregivers of individuals with Alzheimer's disease and other dementias.

Caregiver Seminars

Sponsored directly by our institute, six to eight caregiver seminars are conducted in North and South Tampa, Lakeland, Lakewood Ranch, Sun City and the Villages, reaching over 500 family caregivers annually. The caregiver seminar, "*Alzheimer's Disease: What Caregivers Need To Know*," presents practical information for family caregivers including information on current clinical trials.

Florida Memory Disorder Clinics

Florida has a number of memory disorder clinics that are within the designated travel radius of the Byrd Institute. These clinics have a large population of subjects already diagnosed with Alzheimer's disease, but generally lack the resources and staff to implement clinical trials. These clinics have indicated enthusiasm over collaborating with our mobile unit to offer their patient populations more treatment options and research programs.

Community Based Memory Screening Programs

The USF Health Byrd Alzheimer's Institute has developed a number of community based memory screening partnerships. We have trained local residents to conduct free memory screenings on older individuals with memory concerns. We receive and store these results at the Byrd Institute in a secure database that can be queried with eligibility criteria.

Other Recruitment Avenues

We have used advertising techniques in the past with success including newspaper ad runs and special interest stories. Additionally, our local news channels have done PI and study participant interviews in the past, which have bolstered recruitment for a number of projects and clinical trial interest in the community.

Photos of Mobile Unit Interior

Reception Area



Exam Room



Consultation Rooms (2)



ADA Compliant Bathroom



Phlebotomy Area

