UF Claude D. Pepper Older Americans Independence Center
UNIVERSITY of FLORIDA

RESOURCES AND SERVICES

Pre-grant Submission services
Post-Award/ Pre-IRB Approval
Clinical study operations management
Core Assessments
RC1 facilities, resources and equipment

RC1 - Clinical Research Core Services
Pre-grant Submission services 1. Assist with protocol development: • Provide guidance on feasibility of proposed study; • Provide guidance on the selection of measures best suited for the planned study. • Provide guidance and ensuring that safety measures, i.e. Data Safety Monitoring Plan (DSMP) are developed and included in the protocol 2. Development of study-specific Recruitment and Retention Plan: • Identification of potential recruitment sites that are better suited for a specific protocol; • Develop specific strategies for recruitment and retention of minority older adults, including sources and timeline 3. Provide budget estimates for Core services for grant proposals. 4. Develop and/or review data security procedures.
Post-Award/ Pre-IRB Approval 1. Regulatory assistance for Office of Clinical Research (OCR) and IRB submissions: • Provide assistance with ClinicalTrials.gov registration; • Provide advice on selection (type) of documents that need to be prepared for regulatory and compliance submissions • Providing assistance in obtaining forms needed for specific studies • Review documents that are being prepared for submission to RAC and IRB; • Review completed documents before submission to RAC; • Following RAC approval, review additional IRB related paperwork and submit to the IRB; • Provide Assistance in revising documents submitted to IRB if required 2. Provide budget estimates for Core services for currently funded projects. 3. Provide assistance with data capture • Provide assistance with creation of Case Report Forms (CRFs) specific for study's measures • Provide assistance with study-specific database creation 4. Review participant recruitment plan, and make revisions based on award revisions

5. Develop and/or review data security procedures.

Clinical study operations management

1. General Operations Management:
    - Provide regulatory oversight and assistance for all aspects of study;
    - Ensure study team members have appropriate Protection of Human Subjects in Research training, as well as GCP training
    - Ensure that all study team members have Health Clearance in order to have direct contact with participants and as well as current CPR training
    - Ensure study team members have their licenses and signed curriculum vitae current
    - Ensure study team members have completed all required trainings for their study specific role;
    - Ensure all study coordinators are properly trained on assessment procedures;
    - Ensure all intervention team members are properly trained in delivery of intervention;
    - Ensure all certifications related to specific study procedures are current;
    - Coordination of participant appointment schedules for study team members and room assignments through a web based tracking system;
    - Review and maintain data security procedures;
    - Review and maintain study drug receipt, storage, dispensing and accountability procedures.
2. Recruitment Services:
    - Provide assistance in developing study's logo and advertisements (e.g., postcards) and other recruitment related items (i.e., postcards, flyers, brochures)
    - Provide assistance in development of Phone Pre-Screening Interview script;
    - Program screening tools in data acquisition software
        - Engagement of specific community service/advocacy organizations; schedule recruitment talks, community presentations, etc.
        - Roll out marketing (e.g., direct mail, newspaper advertisements)
        - Pre-screening of potential participants during phone interviews;
        - Schedule potential participants for in person visits, process associated documents
        - Tracking of screening outcomes including study enrollment; adjust recruitment effort based on yields;
        - Progress Reports on study enrollment, typically provided on biweekly basis; provide investigators with real-time feedback regarding accrual, exclusion reasons, sources of leads
3. Retention Services:
    - Assist in development of overall retention plans for studies;
    - Track and provide updates on retention related outcomes for specific participants,
    - Flag "high risk" participants (e.g., those with missed visits, or who have expressed dissatisfaction) and implement a retention plan before loss
    - Coordinate multidisciplinary team (phone staff, assessors, interventionists) to implement remediation plans for specific participants
    - Monitor retention plan success (e.g., extra phone calls, letters, home visits, transportation provision) as necessary
    - Provide retention reports, typically on a biweekly basis

4. Safety and Regulatory Services:
    - Collection and assessment of adverse events
    - Reporting of adverse events to sponsors, IRB and required regulatory authorities
    - Reporting of deviations to sponsors and IRB
    - Preparation and submission of Continuing Reviews to IRB
    - Preparation and submission of protocol revisions to IRB
    - Assist investigators in working with IRB if issues with IRB approval arise
5. Core Operation Services:
    - Tracking of participants with web-based system;
    - Data collection for behavioral and functional outcomes;
    - Data management;
    - Phlebotomy;
    - Urine and other tissue samples collection
    - Blood and other tissue samples processing and shipping;
    - Transportation of participants to and from assessment facilities outside of IoA-CTRB
    - MD coverage (e.g., physical exam, review of blood tests' results, depending on study protocol – review of study eligibility criteria);

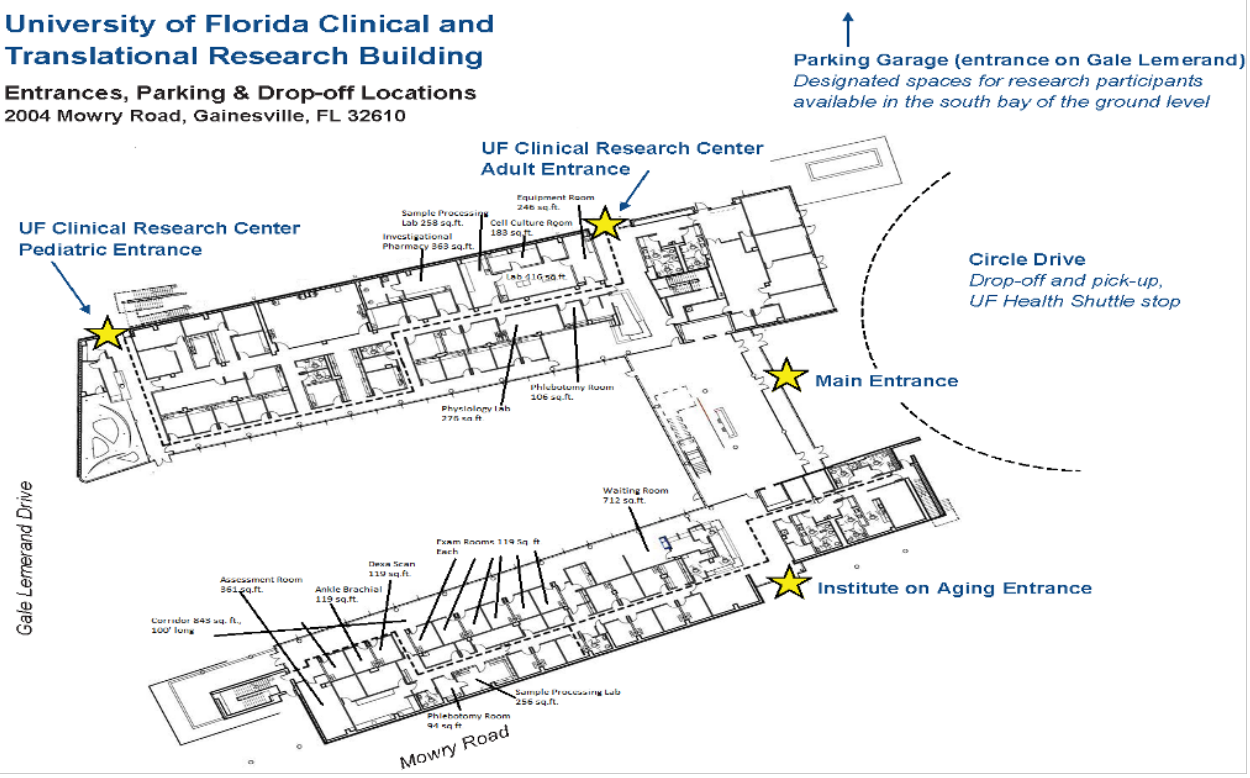
Core Assessments

- Anthropometric measures (height, weight, etc.)
- Vital signs (blood pressure, pulse, etc.)
- Electrocardiogram (ECG)
- Body Composition (DEXA)
- Comprehensive physical exam by a board certified Geriatrician
- Respiratory function (Spirometry and Maximum Inspiratory Pressure)
- Cognitive Function:
    - Processing Speed (Digit Symbol Substitution Test)
    - Language (Controlled Oral Word Association, Boston Naming Test)
    - Verbal Memory (Hopkins Verbal Learning Test - Revised)
    - Visual Memory (Brief Visual Spatial Memory Test-Revised)
    - Cognitive status (MMSE, Montreal Cognitive Assessment)
    - Response Inhibition (Eriksen Flanker Test)
    - Overall Cognitive Function (NIH Toolbox)
- Assessment of Pain perception (self-report and quantitative sensory testing)
- Quality of Life and Psychological Outcomes (self-report questionnaires)
- Physical Function and Performance:
    - Overall physical endurance (400MWT, 6MWT)
    - Disability (ADL and IADL) evaluation
    - Extremity Function (Short Physical Performance Battery; SPPB)
    - Muscular Strength (Biodex, dynamometer)
    - Energy Expenditure (accelerometry, indirect calorimetry)
    - Task Modification assessment via the MOD Scale)
    - Gait Characteristics (GAITRite)
    - Balance (Tinetti Balance Scale)
- Muscle Activity (surface electromyography)
- Tissue Oxygenation and Blood Flow
- Lower extremity muscle tissue biopsy

RC1 facilities, resources and equipment

Clinical research space

RC1 has access to Approximately 10,000 sq. ft. in the IOA-CTRB are dedicated to clinical research space. That space includes 1,000 sq. ft. of physical performance laboratory and 15 dedicated interview, assessment and examination rooms and a 25 meter corridor specially dedicated to perform walking testing. The facility has a street address, dedicated parking lot in front of the building and a direct entrance to facilitate access of research participants, a reception and waiting area, exam and interview rooms, meeting rooms, procedures rooms, a biological specimens processing laboratory, data entry stations, study coordinators offices, a study drugs storage room, and several secured storage areas for study documents and areas for freezers for biological specimens. RC1 is also equipped with space to recruit and retain participants in clinical trials. Space on the second floor are used as interview rooms for in-person screening, a telephone screening area composed of 9 enclosed cubicles, a mass-mailing area, and an owner provided transportation van. The latter is of critical importance to maximize participation, retention and adherence to study protocols of older persons who have mobility and transportation difficulties.



Pepper Center Participant Registry.

RC1 has developed and continues to mainted a large participant registry since July 2007. There are nearly 3,500 participants current in the Pepper registry. This is an IRB approved database containing contact information and minimal demographics (age, race, sex, ethnicity) for persons

who consent to be contacted with recruitment opportunities. The registry contains no information regarding health or functional status (since these are labile phenomena, and need to be rescreened by each individual study at time of recruitment). Registrants are recruited at the time they consent to participate in individual studies; they are also recruited if they fail to qualify for an OAIC-supported study. Registrants have also been identified through a direct-mail campaign (10,000 pieces sent to elders in the catchment area), community presentations as well as persons screened for various studies. Unsolicited inquiries from elders seeking to participate in research are also directed to the registry. Each registrant receives a consent form (which is reviewed with a member of the RC1 staff prior to signing), and then a contact record (name, address, phone, email) and a demographic questionnaire. The contact information is entered and stored separated from the demographic information. The registry contains 2700 older persons. Regular communication with registrants is an essential element of retention. When specific studies are recruiting, registrants are contacted in one of three ways: (1) the quarterly newsletter, THRIVE, highlights specific studies and also includes summary "blurbs" for individual studies; (2) direct mail of flyers to eligible registrants; and (3) follow-up phone calls to eligible registrants.

Major Equipment

Biodex System pro4: RC1 operates an isokinetic dynamometer which provides constant velocity with accommodating resistance throughout a joint's range of motion. This resistance is provided using an electric or hydraulic servo-controlled mechanism at a user-defined constant velocity. This type of muscle contraction has become a popular method by which to assess dynamic muscle function in both clinical and research settings. With the interfacing of Biodex isokinetic dynamometers, objective measures of human muscle function on variables related to torque, power, and endurance can be obtained.

Biopac System (MP 150 system): The MP System provides high resolution (16 bit), variable sample rates for analog and calculation channels, 16 analog inputs and two analog outputs, digital I/O lines (automatically control other TTL level equipment), and 16 online calculation channels. The MP150 System has high-speed acquisition (400 kHz aggregate), Ethernet connectivity, and the ability to view and control systems across a network. The systems use the AcqKnowledge software included with each MP System. The software is based on a user-friendly graphical interface that allows the user to instantly view, measure, analyze, and transform data. Perform complex data acquisition, triggering and analyses using simple pull-down menus and dialogs. The BioPac MP150 data acquisition unit is interfaced with 2-channels of electrocardiogram amplifiers and four electromyographic amplifiers that collects recordings up to 100,000 Hz.

Automated Electrocardiograms: RC1 possess two Burdick Atria 3000 automatic STAT operation ECG with 3-, 4-, 6-channel 12-lead tracings with high resolution thermal prints and interpretation software based on the Glasgow Royal Infirmary algorithm.

GAITRite Walkway System: The system automates the measuring of spatial and temporal parameters of gait using an electronic walkway connected to a PC. It contains six sensor pads encapsulated in a roll up carpet to produce an active area 24 inches wide and 20 feet long. The

system captures the relative geometry and the applied pressure of each footfall as a function of time, and can test patients using ambulatory aids, such as crutches, canes, or walkers**.**

Dual-energy X-ray Absorptiometry (DXA): A Hologic Discovery QDR Series (2011 Discovery Model, Hologic Inc. Bedfor MA), is dedicated to research studies at the IOA-CTRB. All DXA operations are performed by a technician holding a Basic X-ray Operator License from the State of Florida. The technician has also received DXA specific training from the manufacturer and follow-on training through the International Society for Clinical Densitometry, the latter leading to designation as a Certified Densitometry Technologist.

2008 Honda Odyssey Touring Elite Mini-van: The IOA and OAIC owns and operates a van to service participants with transportation needs. Transportation will be available for all participants enrolled in the proposed study.