

RC1 - Clinical Research Core Services

Pre-Submission

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 (**see attached list of Core measures**).
 - 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.

Post-IRB Approval - Operations Management and Services

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-CTRIB
 - MD coverage (e.g., physical exam, review of blood tests' results, depending on study protocol – review of study eligibility criteria);

6. Core Assessments (see attached list of Core measures):
 - Anthropometric measures (height, weight, etc.)
 - Vital signs (blood pressure, pulse, etc.)
 - Electrocardiogram (ECG)
 - Body Composition (DEXA)
 - 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:
 - Muscle Endurance (400MWT, 6MWT)
 - Extremity Function (Short Physical Performance Battery; SPPB)
 - Muscular Strength (Biodex, dynamometer)
 - Energy Expenditure (accelerometry, indirect calorimetry)
 - Compensatory Tasks (MoD tasks)
 - Gait Characteristics (GAITRite)
 - Balance (Tinetti Balance Scale)
 - Muscle Activity (surface electromyography)
 - Tissue Oxygenation and Blood Flow
 - Muscle Biopsy

CORE MEASURES RC1

MOBILITY AND PHYSICAL FUNCTION

- SHORT PHYSICAL PERFORMANCE BATTERY (SPPB)
- GRIP STRENGTH
- 6 MINUTE WALK TEST
- 400 METER WALK TEST
- BIODEX
- GAITRITE
- PEAK OXYGEN CONSUMPTION
- FRIED CRITERIA FOR FRAILTY

OBJECTIVE PHYSICAL ACTIVITY

- ACTIGRAPH

BODY COMPOSITION (SARCOPENIA)

- DEXA

COGNITION

- NIH TOOLBOX COGNITION MODULE

PAIN

- BRIEF PAIN INVENTORY

SLEEP

- SLEEP (PITTSBURGH SLEEP QUALITY INDEX)

DISABILITY

- SELF-REPORT DISABILITY (AM-PAC)

ADDITIONAL MEASURES

- BLOOD FLOW
- MUSCLE COMPOSITION
- MUSCLE BIOPSY

MOBILITY AND PHYSICAL FUNCTION

SHORT PHYSICAL PERFORMANCE BATTERY (SPPB)

The SPPB is designed to assess lower-extremity function by measuring three timed subtests: five timed repetitive chair stands, standing balance (i.e. hold tandem and semi-tandem foot position for 10 seconds), and gait speed during a 4 m walk at one's usual pace. Each subtest is scored from 0 to 4, with 0 indicating inability to complete test, and 4 indicating maximal performance. A summary score from 0 to 12 is calculated for the SPPB, where higher scores indicate better physical function.

GRIP STRENGTH

Hand grip strength is a commonly used measure of upper body skeletal muscle function and has been widely used as a general indicator of frailty with predictive validity for both mortality and functional limitation. Grip strength is measured in both hands using a Cybex 6000 Dynamometer (Biodex Medical System, New York, NY). The average of three readings is typically used to compute grip strength.

6 MIN WALK TEST

The 6 Minute Walk test measures the amount of distance the participant can complete on a standard walking course in six minutes without running or overexerting themselves. Participants are asked to walk as quickly and safely as possible at a pace that can be maintained for six minutes. The distance completed in six (6) minutes is then recorded. The Six Minute Walk Test has been found to be a valid and reliable measure of physical function in numerous studies.

400 M WALK TEST

The 400 m walk test is used to assess an individual's walking speed at their usual pace. Participants are instructed to stand with both feet touching the starting line and to start walking after a specific verbal command. Participants are allowed to use walking aids (cane, walker, or other walking aid) if necessary, but not the assistance of another person. Timing begins when the command is given, and the time in seconds needed to complete the entire distance is recorded.

BIODEX

Tests of isolated muscle function are conducted by performing unilateral knee extension and flexion maximal strength and endurance testing (Biodex machine). This test involves using an isokinetic dynamometer set at 90° per second. We have found and reported the reliability of strength testing to be very high (ICC=0.97; coefficient of variation=4.1%) when the testing sessions are separated by 4 weeks. Participants perform 50 maximal knee extension and flexion concentric repetitions, which are administered by trained research assistants. Maximal muscle strength is summarized as peak torque achieved in Newton-meters. A muscle endurance index is calculated as the decline in peak torque over the 50 repetitions. This is calculated as a slope and can be used to evaluate the effect of the test factor on muscle endurance.

GAITRITE

Participants walk across a carpet that contains sensors arranged in a grid pattern (48 X 288) (GAITRite Inc.). The system collects footfall patterns that yield temporal (step time, gait cycle, single support time, double support time, stance time and swing time) and spatial (step length and stride length) parameters. Accurate quantification of these gait parameters has been validated against three-dimensional motion analysis. Participants are typically asked to walk over the GAITRite carpet at a usual pace and then at a fast pace, performing two trials of each walking speed.

PEAK OXYGEN CONSUMPTION

A graded exercise test is conducted to assess peak metabolic rate (e.g. cardiopulmonary capacity). Oxygen consumption is measured using a portable metabolic unit while exercising on the treadmill. We utilize a modified Bruce Protocol that slowly ramps the intensity of the test. The treadmill protocol might be modified to accommodate highly fit individuals or those with a slow walking speed.

Each test is graded on the following criteria: Plateau in VO_2 , heart rate (HR) within 10 beats/min of age-predicted maximal HR, respiratory exchange ratio > 1.10 , exhaustion defined as RPE of 9-10 on the Borg CR-10 scale, or achievement of predicted maximal work rate. Participants are given strong encouragement to achieve exhaustion during the test. Electrocardiography is monitored for abnormal rhythms throughout the test in UF Health's Cardiovascular Unit.

FRIED CRITERIA FOR FRAILITY

Frailty is a state of increased vulnerability to endogenous and exogenous stressors. Frailty involves fatigue, weight loss, infections, balance, strength and gait impairment leading to an increased risk of falls, delirium, and disability. In addition frailty is associated with inflammation and thus it may be averted by anti-inflammatory interventions. We characterize frailty with Fried criteria developed by Fried et al. that consist of self-reported exhaustion, unintentional weight loss, low energy expenditure, slow gait speed, and weak grip strength. Those with ≥ 3 of the 5 factors are judged to be frail, those with 1 or 2 factors as pre-frail, and those with no factors as non-frail.

OBJECTIVE PHYSICAL ACTIVITY

ACTIGRAPH

The ActiGraph GT3X (ActiGraph™ LLC, Pensacola, FL) is used to assess the relative impact of interventions on physical activity over time. The ActiGraph is a small (3.8 cm x 3.7 cm x 1.8 cm, 27g) triaxial accelerometer that is designed to detect accelerations in three axes. Output from the ActiGraph is in the form of step counts, body positions (standing and sitting/lying) and activity counts for a specific time period (i.e., epoch). Activity count cut-points (e.g., counts·min⁻¹) can be identified to determine the amount of time a participant spends in sedentary, light, moderate, hard, or vigorous activity.

BODY COMPOSITION

SARCOPENIA (DEXA) BODY COMPOSITION WITH DUAL ENERGY X-RAY ABSORPTIOMETRY

Dual-energy X-ray absorptiometry (Hologic, Discovery QDR Series, Bedford MA) whole body scan, is used to assess both fat-free and fat mass. Participants lie still on a table while the scan is acquired. Scans are acquired by certified technicians.

COGNITION

NIH TOOLBOX

Global domains of cognition are assessed using the NIH toolbox. These measures are used as descriptive characteristics and modifier variables in statistical analyses. The NIH Toolbox provides a standard set of royalty-free, brief and comprehensive assessment tools that can be used in a variety of studies. The use of the NIH Toolbox provides a common measurement across studies to promote the economy of scale. The battery takes 30-40 minutes to complete and contains six domains: executive function, attention, episodic memory, language, processing speed, and working memory.

EXECUTIVE FUNCTION. Executive Function is the capacity to plan, organize, and monitor the execution of behaviors that are strategically directed in a goal-oriented manner. The NIH toolbox uses the “dimensional change card sort test” (DCCS) and the “flanker inhibitory control and attention test”. DCCS is a measure of cognitive flexibility. Two target pictures are presented that vary along two dimensions (e.g., shape and color). Participants are asked to match a series of bivalent test pictures (e.g., yellow balls and blue trucks) to the target pictures, first according to one dimension (e.g., color) and then, after a number of trials, according to the other dimension (e.g., shape). “Switch” trials are also employed, in which the participant must change the dimension being matched. For example, after 4 straight trials matching on shape, the participant may be asked to match on color on the next trial and then go back to shape, thus requiring the cognitive flexibility to quickly choose the correct stimulus. Scoring is based on a combination of accuracy and reaction time, and the test takes approximately 4 minutes to administer. The Flanker task measures both a participant’s attention and inhibitory control. The test requires the participant to focus on a given stimulus while inhibiting attention to stimuli (fish for ages 3-7 or arrows for ages 8-85) flanking it. Sometimes the middle stimulus is pointing in the same direction as the “flankers” (congruent) and sometimes in the opposite direction (incongruent). Scoring is based on a combination of accuracy and reaction time, and the test takes approximately 3 minutes to administer.

ATTENTION. Attention refers to the allocation of one’s limited capacities to deal with an abundance of environmental stimulation. It is the foundation for all other types of mental processes. Attention is measured using the Flanker test described above.

EPISODIC MEMORY. Episodic Memory refers to cognitive processes involved in the acquisition, storage and retrieval of new information. It involves conscious recollection of information learned within a context. The term “learning” refers to the acquisition of skills and knowledge, while the term “memory” refers to the persistence of this learning over time and/or the facility with which one is able to spontaneously recall the information following a delay. The Picture Sequence Memory Test is used to test episodic memory. It involves recalling increasingly lengthy series of illustrated objects and activities that are presented in a particular order on the computer screen. The participants are asked to recall the sequence of pictures that is demonstrated over two learning trials; sequence length varies from 6-18 pictures, depending on age. Participants are given credit for each adjacent pair of pictures (i.e., if pictures in locations 7 and 8 and placed in that order and adjacent to each other anywhere – such as slots 1 and 2 – one point is awarded) they correctly place, up to the maximum value for the sequence, which is one less than the sequence length (if there are 18 pictures in the sequence, the maximum score is 17, because that is the number of adjacent pairs of pictures that exist). The test takes approximately 7 minutes to administer.

LANGUAGE. Language refers to a set of mental processes that translate thought into symbols (words, gestures) that can be shared among individuals for purposes of

communication. Language is measured using the “Picture Vocabulary Test” and the ‘Oral Reading Recognition Test.” The Picture Vocabulary Test measures receptive vocabulary is administered in a computerized adaptive format. The respondent is presented with an audio recording of a word and four photographic images on the computer screen and is asked to select the picture that most closely matches the meaning of the word. This test takes approximately 4 minutes to administer. For the Oral Reading Recognition test, the participant is asked to read and pronounce letters and words as accurately as possible. The test administrator scores them as right or wrong. The test is given in a computerized adaptive format and requires approximately 3 minutes.

PROCESSING SPEED. Processing Speed is either the amount of time it takes to process a set amount of information, or, the amount of information that can be processed within a certain unit of time. It is a measure that reflects mental efficiency. The Pattern Comparison Processing Speed Test will be used to test speed of processing by asking participants to discern whether two side-by-side pictures are the same or not. Participants’ raw score is the number of items correct in a 90-second period. The items are designed to be simple to most purely measure processing speed. The test overall takes approximately 3 minutes to administer.

WORKING MEMORY. Working Memory refers to a limited-capacity storage buffer that becomes overloaded when the amount of information exceeds capacity. This updates the traditional construct of “short-term memory,” which refers to a passive storage buffer, to include the notion of an active computational workspace. The List Sorting Working Memory Test requires immediate recall and sequencing of different visually and orally presented stimuli. Pictures of different foods and animals are displayed with accompanying audio recording and written text (e.g., “elephant”), and the participant is asked to say the items back in size order from smallest to largest, first within a single dimension (either animals or foods, called 1-List) and then on 2 dimensions (foods, then animals, called 2-List). The score is equal to the number of items recalled and sequenced correctly, and the test takes approximately 7 minutes to administer.

PAIN

BRIEF PAIN INVENTORY (BPI)

The Brief Pain Inventory (BPI) is used to assess the presence and location of daily pains, as well as pain severity and pain-related interference. The BPI measures pain severity using a series of 0 (no pain) to 10 (worst possible pain) scales, which assess average pain, worst pain, and least pain in the past week, as well as current pain at the time of testing. There are seven BPI interference questions, each ranging from 0 (does not interfere) to 10 (completely interferes), assessing the extent to which pain has interfered over the past 24 hours with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. This instrument has been validated for assessing outcomes in participants with non-cancer pain and has been used to quantify treatment outcomes.

SLEEP

PITTSBURGH SLEEP QUALITY INDEX (PSQI)

Sleep is evaluated via the Pittsburgh Sleep Quality Index (PSQI). This tool assesses perceived sleep quality and disturbances.

DISABILITY

SELF-REPORT DISABILITY (AM-PAC)

The Activity Measure for Post-Acute Care (AM-PAC) is used to assess participants' level of perceived functioning. The total score on the AM-PAC is an excellent composite measure of disability or difficulty in performing basic and instrumental activities of daily living (ADLs), especially those related to lower extremity function, and of inability to move around (mobility limitations), which contribute the most to dependency, need for assistance from another person or a device, placement in an assisted care facility, or a nursing home.

ADDITIONAL BIOLOGICAL MEASURES

Blood Flow

The NIRO-200 uses near infrared spectroscopy to measure Tissue Oxygenation Index via blood flow. Measures of Hb, HbO₂ and tissue O₂ are assessed continuously throughout the following testing paradigms.

- a) Muscle tissue oxygenation. Participants are asked to perform a leg extension endurance exercise while two light diodes are placed on their vastus lateralis. The endurance task entails performing maximal continuous unilateral leg extensions until the participant reaches volitional failure. Participants then rest until oxygenation is recovered in the leg. Outcomes are the nadir and the time to half recovery of oxygenation.
- b) Brain tissue oxygenation. Two light diodes from the NIRO-200 unit are placed on the forehead during a long-duration cognitive test. The N-Back Test, which measures working memory, is conducted for 10 minutes. Participants see individual letters at a two-second rate on a computer screen and are asked to indicate whether the presented letter is the same as the second back letter. Outcomes are the maximal nadir, slope change during testing as a function resting values, and the time to half recovery of oxygenation.

Ultrasound

Our facility contains a MyLab 30CV ultrasound (Biosound Esaote, Indianapolis, IN) with 10 and 3 MHz probes for visualization of musculoskeletal anatomy and estimation of blood flow. This equipment offers portability and applicability over a wide range of research projects including echocardiograms, lower-extremity blood velocity, and assessment of muscle cross-sectional area. MyLab30 CV implements phased array technology with color flow Doppler technology for cardiac imaging, linear array for vascular and small parts imaging, as well as curved array and microconvex for general imaging. The system allows for the evaluation of the heart, vasculature and organs of the body with the appropriate transducer technology and the appropriate measurement and analysis packages. The MyLab® 30 CV ultrasound system weighs less than 19 pounds and provides portable capability that can adapt to many research and clinical environments. The equipment contains:

- XStrain - 2D Strain and Strain Rate imaging
- Multiple digital management choices - DICOM, multimedia, native format
- Integrated CD/DVD writer, RJ 45 port and USB port for transferring clinical data
- Windows® platform
- Ergonomic design and workflow

The Core also contains a Rheo Dopplex II Photoplethysmography and bi-directional Doppler Unit with 5Mhz Vascular Probe for portability and field use.

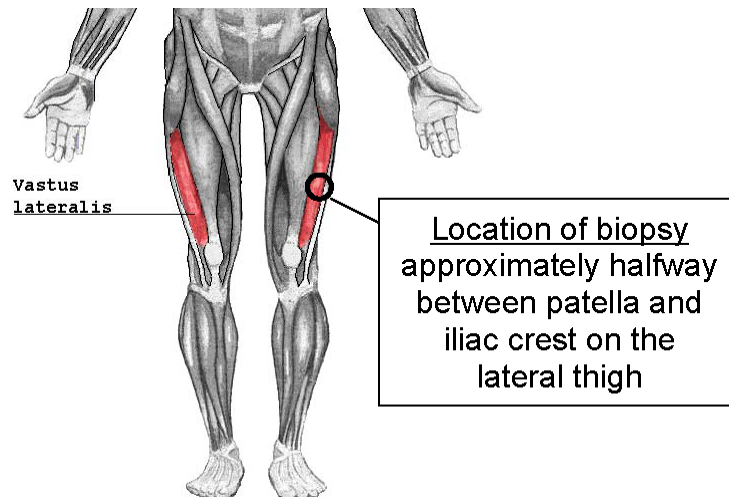
Lower extremity muscle composition. We utilize the same methodology that we successfully implemented in previous studies where 3D-MRI was used to quantify the amount of intermuscular fat and true contractile area. The images are acquired on a clinical 3.0 Tesla magnet (Phillips Acheiva) using a knee quadrature coil for the calf and the body coil for the thigh. Participants are placed in supine position with their thighs in the horizontal plane. Images will be collected from the most proximal to the most distal segment using the following parameters: *3D spoiled gradient-echo* images (30 degree flip angle) with a TR of 31 msec and TE of 10 msec. The images are acquired with an encoding matrix of 256x256x28 and a field of view of 20-24 cm. The volume of the thigh/calf muscles and fat regions (subcutaneous and inter-muscular) will be determined for each 5mm slice using the interactive computer program, Medical Image Processing, Analysis and Visualization (MIPAV) software. We calculate volumes based on 10 slices at the mid-distance of each limb region. We have extensive experience in quantifying tissue composition using MRI and report a low technical error of CV = 0.26%.

MUSCLE BIOPSY

Muscle biopsies are performed by a trained physician. Skeletal muscle samples are obtained under local anesthesia, typically from the *vastus lateralis* muscle using a percutaneous needle biopsy technique. The skin is closed with steri-strips. Participants are contacted by phone three days following this procedure, and return for a wound check 10 days after the procedure date. Approximately 150-250 mg of muscle tissue is removed. Portions of the muscle are immediately processed for permeabilized fiber high-resolution respiration measurements and a very small piece of tissue is mounted in embedding medium and frozen in isopentane for future histochemical analysis. The remaining tissue is immediately frozen in liquid nitrogen and stored at -80°C until analysis. See page 8 for a detailed description of the muscle biopsy procedure.

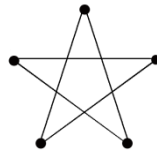
Muscle Biopsy Procedure – Vastus Lateralis

- Have the participant lie comfortably in a reclined position with both legs outstretched. Support calves/feet with pillows to maintain relaxed position
- Check the patient binder to see which leg was tested during the strength measurement or MRI. Perform the biopsy on this leg. Otherwise it is PI or participant preference
- Ask participant if they are allergic to latex, and if so, use alternative material gloves.
- The muscle biopsy will be obtained approximately midway between the patella and iliac crest on the lateral thigh. See figure below. This distance was chosen so each participant will receive the biopsy at the same relative length of their lower extremity.



- The site can be marked with pen ink or pressing into the skin to leave an indentation
- Do not allow the participant to watch the procedure.
- If necessary, an area of skin can be shaved to prevent hair from entering the incision and improving adhesion of the sterile bandage.
- The skin is cleaned with Chloraprep solution. Swab starting from the anticipated biopsy site in a circular motion extending to a diameter of approximately 4-5 inches
- Record procedure start time.

- Inject 1 to 2 ml of 2% lidocaine intradermally and subcutaneously. Allow a brief period (30-60 seconds) for the skin to numb before injecting the remaining volume more deeply. Insert the needle to just below the fascia, aspirate to assure that needle is not in a vessel, inject a small amount of lidocaine starting below the fascia and continue while drawing the needle straight up through the subcutaneous tissue. Repeat in a star pattern. See figure below:



- Wait 8 to 10 minutes after injection of the lidocaine before proceeding to ensure maximal participant comfort.
- **Scalpel skin test:** Using a no. 11 blade scalpel, gently touch the scalpel to the anticipated site and ask the patient if they can feel anything where touched. It may help to have the patient close their eyes. If they can feel the scalpel, allow more time and retest in 5 minutes. If the participant can still feel the blade touch, consider switching to carbocaine
- When the participant is properly numbed, make a small (5 mm) incision in the skin down through the muscle fascia. It may make only a small nick
- Insert the closed trocar through the incision, and through the fascia, advancing the trocar into the muscle belly. The trocar window extends 2cm from the tip. To obtain proper suction it is necessary to have the whole opening below the fascia.
- Once in position the surgeon places their thumb over the hole atop the inner cannula. The sterile assistant will state “up” when ready to apply suction. The surgeon will raise the inner cannula 1 inch, opening the trocar window. The assistant will immediately apply suction through a 60 cc syringe, drawing tissue into the cutting chamber as the surgeon advances the inner cannula in a rapid guittione-like action. Be sure the trocar does not advance deeper in the leg with this action.
- To maximize tissue yield, rotate the trocar 90 degrees without removing from the leg, and repeat the suction procedure two more times for a total of four separate muscle samples.

- The needle is passed to the sterile assistant who removes the accumulated tissue on a sterile gauze with use of the forceps and needle plunger. The tissue is quickly placed on an iced receptacle such as a weight boat or saline soak gauze
- If the yield is insufficient you may re-insert the trocar up to three times through the same hole in the fascia but at slightly different angles in the numbed area, as long as the participant is comfortable and consents to repeated passes.
- Hold firm direct pressure over incision site for at least 5 minutes or longer until external bleeding has ceased
- Approximate the incision edges and close the incision with a sterile liquid bonding agent (such as Dermabond) or butterfly bandage. This will help prevent bleeding and scarring.
- Apply a small dab of triple antibiotic over the incision (once glue is dry if using). Apply a single folded sterile gauze on top of the incision and cover with Tegaderm.
- Wrap with elastic wrap and place an ice bag on the incision site for 15 to 30 minutes to reduce swelling and pain, unless prohibited by study protocol.
- Study coordinator: Record procedure stop time.
- Study coordinator: Record approximate amount of 2% lidocaine injected.
- Study coordinator: Record whether or not there were any adverse reactions during or post procedure.
- Study coordinator: Record whether or not any muscle tissue sample was collected.
- Study coordinator: The total amount of time that the participant will be in the clinic for this procedure is approximately 45 minutes to 1 hour. This includes about 15 minutes of interaction with the study physician for the site preparation and the biopsy itself; 10 to 15 minutes to wait for the lidocaine to take effect, about 15 minutes for icing the area after the biopsy; and 15 minutes for a snack/recovery. Be sure to offer the snack as soon as possible after the biopsy.

Recommended Tray/Room setup

Tray setup must be done 45 minutes to 15 minutes prior to biopsy and out of sight of the research participant. The biopsy tray should be prepared, covered until use, and used during the procedure away from the participant's field of observation.

Sterile field must be maintained during tray setup. Sterile gloves must be worn or sterilized ring (sponge) forceps (handle non-sterile, tips sterile) used when handling sterile items.

Assemble the following items for the tray:

(2) non-fenestrated sterile drapes (one for lining tray and one for draping over set-up tray)
(1) fenestrated sterile drape
(1) biopsy needle (all parts-trocar, cannula, plunger. Numbers must match) [sterilized]
(1) standard bore 27-33" IV extension tubing
(1) Sterile 3-way stopcock (if assistant preference)
(1) tweezers [sterilized] if not packaged with biopsy needle
(5-8) sterile 3x3 or 4x4 gauze pads
(1) No. 11 safety scalpel
(1) 23 g 1¼" safety needle
(1) 16 g 1" safety needle
(1) 60 cc syringe
(1) 10 cc syringe
(1) pack of sterile skin glue such as Indermil or Dermabond (kept in refrigerator in Sample Processing Room)
(1) sterile medium butterfly bandage (if not using glue)
(1) sterile transparent dressing (tegaderm) appropriate for needed coverage
(1) Bottle of 2% buffered lidocaine containing at least 10ml

(1) Sterile Alcohol pad

Two-person tray assembly:

1. The non-sterile assistant dons exam gloves. The sterile assistant dons sterile gloves
2. The non-sterile assistant opens 1 non-fenestrated drape, pulling the corners of the packaging back so the sterile person can remove the item without touching the outside of the packaging.
3. The sterile person unfolds the drape and places the drape over the tray, blue side down, without touching the tray with their gloves
4. The non-sterile assistant continues to open each sterile item in the manner previously described and the sterile person places them on the sterile field.
5. The sterile person assembles the biopsy needle and assures the pieces fit together, then attaches the tubing, stopcock (if using) and 60 ml syringe
6. The sterile person attaches the 16G draw needle to the 10ml syringe
7. The non-sterile assistant cleans the stopper of the lidocaine with a sterile alcohol pad, allowing the alcohol to evaporate.
8. The assistant then inverts the bottle and holds it steady while the sterile person draws up 10ml of lidocaine.
9. The sterile person activates the safety device on the needle and directly discards the needle in an open sharps container. The 23G needle is then attached to the syringe to maintain sterility and avoid leakage
10. The sterile person unfolds the 2nd non-fenestrated drape and lays it over tray, blue side up.
11. Holding the tray by the drape covered edges, the sterile person transports the tray to a tray holder in the biopsy room. The non-sterile assistant may be needed to open doors.

One-person tray assembly:

Lidocaine will not be drawn up with this assembly so make sure that it's available in the biopsy room

With exam gloves on:

1. Open 1 non-fenestrated drape, and handling only the corners lay it on sanitized surgical tray (blue side up).
2. Open each pack of sterile instruments or dry supplies and drop on to draped tray; make sure that items are not handled directly.

Don surgical gloves (keeping gloves sterile at all time)

3. Maintaining the sterile field, reposition biopsy tray contents and assemble needles
4. Unfold second non-fenestrated drape and lay over tray, blue side down
5. Holding the tray by the drape covered edges, the sterile person transports the tray to a tray stand in the biopsy room

Materials in the Room

(2) chloroprep swabs
(2) pairs of sterile surgical gloves-for surgeon
(2) pairs of sterile surgical gloves-for biopsy assistant
(1) box of exam gloves (S/M/L) for non-sterile assistant
(1) bottle of 2% lidocaine (to be stored in processing lab per DOH exclusion when not in use)
(1) bottle of 1% carbocaine (to be stored in processing lab per DOH exclusion when not in use)
(1) spray bottle of Gebauer's Pain Ease (Nonflammable Instant Topical Anesthetic)
(1) alcohol prep pad
(1) pouch triple antibiotic
(1) tegaderm
(1) sterile butterfly bandage
(1) pack of bandaids
(1) roll of lab tape
(1) box of sterile gauze pads
(2) Instant ice packs
(2) Elastic (ACE or Coband) wrap
(2) standard bore 27-33" IV extension tubing
(1) biopsy needle (all parts-trocar, cannula, plunger. Numbers must match) [sterilized]
(1)Scissors [sterilized]
Pillow cases
Blue absorbent leak-proof pads (chux)
Exam shorts