Manual of Procedures

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DOCUMENT CONTROL NOTICE

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AMENDMENT HISTORY

Not applicable.

Version 1.0 to 2.0 (Date)	
Summary of Change	Reason for Change
Change 1	Reason 1
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Version 2.0 to 3.0 (Date)	
Summary of Change	Reason for Change
Change 1	Reason 1
Change 2	Reason 2

1. DOCUMENT OVERVIEW

This manual defines the data required for competition judging. Data not collected or submitted per this manual will not be considered for final evaluation unless specifically requested in the event of a tie.

This document has been drafted to support the XPRIZE Healthspan Rules and Regulations and Competition guidelines.

Additional information for finalist teams can be found on the XPRIZE Healthspan Resource Hub.

1.1 ACRONYMS

6MWT	6-Minute Walk Test
AE	Adverse Event
BP	Blood Pressure
BPM	Beats Per Minute
BV	Baseline Visit
CBC	Complete Blood Count
CDE	Common Data Element
CITI	Collaborative Institutional Training Initiative
Co-I	Co-investigator
cm	Centimeter
CMV	Cytomegalovirus Assay
CPET	Cardiopulmonary Exercise Testing
CV	Curriculum Vitae
DCC	Data Coordinating Center
DSMB	Data and Safety Monitoring Board
FV	Follow-up Visit
GCP	Good Clinical Practice
HR	Heart Rate
ID	Identification
IRB	Institutional Review Board
kg	Kilogram
LMS	Learning Management System
LV	Low Volume
mL	Milliliter
mmHg	Millimeters of Mercury
mo	Month
MV	Mid-point Visit
PBMCs	Peripheral Blood Mononuclear Cells
REDCap	Research Electronic Data Capture

SAE	Serious Adverse Event
SOE	Schedule of Events
UP	Unanticipated Problem

2. STUDY TEAM REQUIREMENTS

2.1 TEAM ROLES

Each Finalist Team will be required to name a **Lead Team Investigator** and a **DCC Liaison**. The responsibilities of these roles and system access associated with each role are listed below.

2.1.1 LEAD TEAM INVESTIGATOR

The Lead Investigator is responsible for the oversight of the trial. This individual is accountable for appropriate study conduct, timely reporting of safety events and protocol deviations, and escalation of all relevant issues to the Utah DCC.

Access: The Lead Investigator will have access to their team-specific Data Access Group in the XPRIZE Healthspan Database, DCC Florence eBinder, and Jira Helpdesk. At any time, they can submit questions to the Utah DCC.

2.1.2 LIAISON TO THE DCC

Each Finalist Team will appoint one primary DCC Liaison. This individual is responsible for entering data into the XPRIZE Healthspan Database, resolving data queries, uploading additional information in DCC Florence eBinder (as requested), and submitting Jira Helpdesk Tickets with any questions related to the database, protocols, or reports.

Backup DCC Liaison: Each Finalist Team may also designate one backup DCC Liaison to ensure continuity when the primary DCC Liaison is unavailable (e.g., leave of absence, role transition, or other unforeseen circumstances). The backup DCC Liaison may be granted the same system access and may assume DCC Liaison responsibilities as needed.

Access: The DCC Liaison and, if designated, the backup DCC Liaison, will have access to the XPRIZE Healthspan Database, Query Manager, DCC Florence eBinder, and Jira Helpdesk. At any time, they can submit questions to the Utah DCC.

2.1.3 CENTRAL LAB LIAISON

Each Clinical Hub will designate a site-based point of contact for specimen-related data management and logistics. Depending on the site's staffing structure, this role may be assigned to the DCC Liaison, Site Coordinator, or a dedicated laboratory/specimen coordinator. The Central Lab Liaison serves as the primary point of contact between the Clinical Hub and the XPRIZE Central Laboratory and is responsible for ensuring timely, accurate, and complete specimen documentation and communication. Responsibilities include real-time entry of specimen collection, processing, and tracking data into

LabKey; maintenance of specimen inventory and freezer logs; coordination of specimen shipments through World Courier; identification, documentation, and initial management of specimen-related deviations; and communication of specimen status, shipment updates, and operational issues to the Central Laboratory team.

Access: The Central Lab Liaison will have access to the Central Lab LIMS system. Access and instruction will be provided by the Central Lab.

2.1.4 SITE COORDINATOR

Each team will have multiple Site Coordinators. The coordinators are responsible for enrollment, participant engagement, study visits, and biospecimen collection. All staff involved in research procedures should have adequate training before performing study-related responsibilities. All study personnel training should be maintained on a study training log that can be made available if requested by XPRIZE or the Utah DCC.

Access: Study staff will not have access to the XPRIZE Healthspan Database, DCC Florence eBinder, or Jira Helpdesk. All inquiries should be routed through the DCC Liaison.

2.2 TRAINING

The Lead Team Investigator and the DCC Liaison will be required to complete the XPRIZE protocol training, REDCap data entry training, and Query Manager training. If live training cannot be attended, this requirement may be fulfilled by watching the videos available in the DCC Resource Hub. In addition, they should have current CVs, medical licenses (as applicable), and CITI/GCP training certificates (or equivalent) readily available if requested by XPRIZE or the Utah DCC.

	Access					**Training**			
Role	Database	Query Manager	DCC Florence eBinder	Central Lab LIMS	Jira Help Desk	Protocol Training	REDCap Training	Query Manager Training	Human Subjects Training
Lead Team Investigator	X				X	X	X		O
DCC Liaison	X	X	X		X	X	X	X	O

Central Lab Liaison				X		X			O
Study Staff/Co-Is						X			O

X=required

O=readily available if requested by XPRIZE or the Utah DCC

Each Finalist Team is responsible for maintaining a current and accurate study training log documenting all personnel who have completed study-specific training. The training log should be updated promptly as new personnel join the study, training is completed, or study responsibilities change.

For endpoint assessment measures, each examiner who conducts assessments should complete the applicable XPRIZE training on standard protocols. Training should be documented for each examiner conducting assessments to ensure adherence and consistency.

2.3 REGULATORY AND DOCUMENTATION

Finalist teams are required to maintain their own regulatory documents for their trial. XPRIZE and the Utah DCC may request regulatory documentation at any time, and the finalist teams should be prepared to provide the documentation as requested. Requested documentation may include but is not limited to:

- Final approved protocol and amendments
- Approval from applicable Regulatory Oversight Committee (e.g., Institutional Review Board (IRB) or Independent Ethics Committee (EC))
- Protocol deviation narratives
- CVs and medical licenses, as applicable
- Human subject protection, CITI, and/or GCP training certificates, as applicable
- Training logs and delegation of authority logs
- Participant screening logs
- Equipment or machine calibration reports
- Independent Data and Safety Monitoring Board (DSMB) reports, letters, and recommendations
- Laboratory reference ranges
- Approved informed consent documents
- Adverse event narratives

If documentation is requested, please upload documents here: DCC Florence eBinder.

3. FINALS DATA COLLECTION FRAMEWORK

The XPRIZE Healthspan competition will utilize a centralized data collection and common data element list for all finalist teams. Data will be collected through REDCap. All data entered into the XPRIZE Healthspan database should be fully de-identified. Protected health information (PHI) and personal identifiable information (PII) is prohibited and must not be entered into the database. Every participant record will be assigned a unique study ID that should be used to identify that participant when you are communicating with the Utah DCC, XPRIZE, or the Central Lab.

The XPRIZE Healthspan data collection includes measures that are required and several measurements that are optional but recommended.

3.1 SCHEDULE OF EVENTS (SOE) AND TIMEPOINTS:

Visit	**BV1**	**BV2**	**MV1**	**MV2**	**FV1**	**FV2**
Study Month	**-1mo**	**0mo**	**6mo**	**9mo**	**11mo**	**12mo**
Determination of Participant Characteristics, Safety, Tertiary Endpoints						
Screening (team discretion)						
Participant Characteristics Questionnaires	X					X
Self-Reported Heath, Symptoms, and Event Reports	X	X	X	X	X	X
Complete Blood Count *(local lab)*	X	X	X		X	X
Participant Vitals Collection	X	X	X	X	X	X
Determination of Primary Endpoint Assessments (Muscle, Cognition)						
6-minute Walk Test (6MWT)	X	X			X	X
Cardiopulmonary Exercise Test (CPET)**	X	X			X	X
Lower-Body Power	X	X			X	X
Cogstate Computerized Cognitive Assessment	X	X			X	X
Biospecimen Collections for Central Labs & Biorepository (Immune Endpoints and Biomarkers)						
Whole blood, dried blood spot, plasma, serum	X	X	X	X	X	X
PBMCs	X	X	X		X	X
Nucleic Acid stabilizer tube		X				X
Urine (cup)		X	X			X
**Assessment measures denoted with double asterisks are strongly recommended but optional						

3.2 RECOMMENDED ORDER OF EVENTS FOR STUDY VISITS:

This section outlines the recommended order of events for each study visit. While minor adjustments may be made to accommodate participant needs or site workflows, the sequence should be followed as closely as possible to ensure protocol compliance, participant safety, and consistency across study sites. Refer to the study protocol for any assessment-specific requirements or exceptions.

Figure 1. Finals Study Design Schematic

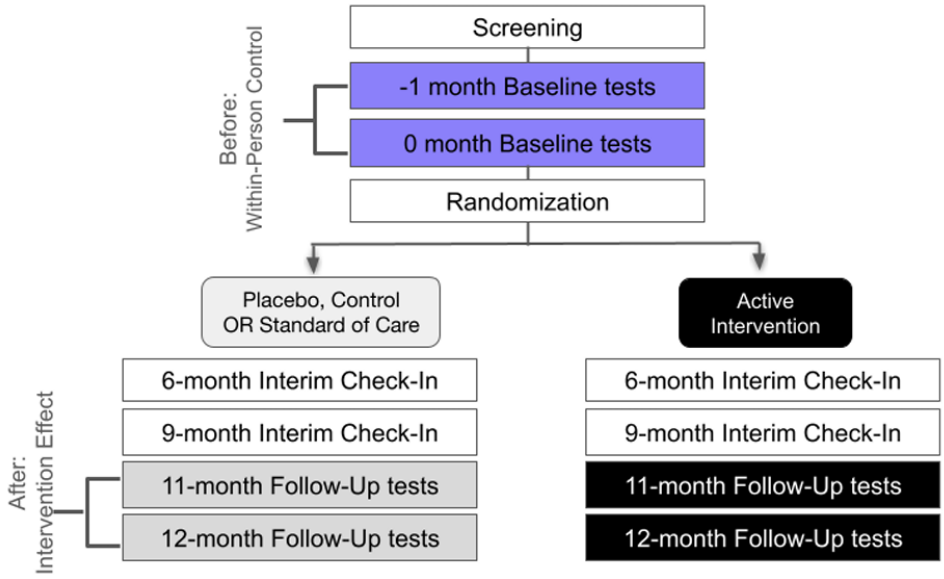

*Figure from the Rules and Regulations Document

3.2.1 SCREENING

Screening and consent for XPRIZE may occur at a designated screening visit or at the beginning of Baseline Visit 1. All individuals who are assessed for eligibility must be recorded on the site's local screening and enrollment log, regardless of screening outcome. For each screening attempt, the log must document the outcome (e.g., ineligible, consented, enrolled) and, for individuals who are not enrolled, the specific reason for exclusion. Entries must include enough detail to support reconstruction of a CONSORT-style flow diagram for monitoring, judging, and audit. Individuals may be re-screened at the site's discretion, but each screening and rescreening attempt must be clearly documented as a separate event in the log. An individual may only be enrolled once in the trial. Only participants who meet all inclusion criteria should be entered into XPRIZE Healthspan Database and assigned a unique study ID; individuals who do not meet inclusion criteria must remain documented on the local screening log and must not be entered into REDCap.

INCLUSION CRITERIA

The participant must meet inclusion criteria to be eligible for the XPRIZE competition:

1. Age: 50-<90 years old
2. Medication stability: If taking medications, has the participant been on a stable medication regimen for at least 3 months prior to enrollment, with no clinically significant medication changes anticipated at the time of enrollment?
    a. Medication changes include starting a new medication, stopping a medication, changing dose, changing frequency, changing route, or changing schedule. Temporary or minor changes that are not clinically significant, such as short-term medications for an acute condition, may be reviewed by the investigator or medically qualified designee.
    b. Medication includes prescription medications, over-the-counter medications, vitamins or multivitamins, dietary supplements, herbal products, and hormone or biologic therapies.

EXCLUSION CRITERIA

1. Severe, unstable, or uncontrolled medial conditions: Does the participant have any severe, unstable, or uncontrolled medical conditions?
    a. Examples include, but are not limited to advanced cardiovascular disease, kidney failure awaiting transplant or dialysis, uncontrolled diabetes, severe chronic obstructive pulmonary disease, active, untreatable, or terminal cancer, unstable angina, myocardial infarction within the past 6 months, and uncontrolled hypertension.
2. Physical disability: Is the participant unable to perform study measures required to test primary endpoint muscle function assessment?
3. Cognitive impairment: Does the participant have significant cognitive impairment or diagnosed dementia that interferes with their ability to provide informed consent or comply with study procedures?
4. Major surgery: Has the participant had a major surgery in the past 6 months?
5. Major surgery: Does the participant plan to have a major surgery during the study period?
6. Major surgery: Does the participant have a severe orthopedic disease awaiting replacement surgery?
7. Severe psychiatric condition: Does the participant have a severe psychiatric condition, such as major depression, schizophrenia, or bipolar disorder, that is not well controlled or on a stable medication regimen?
8. Substance abuse: Does the participant have a history of substance abuse or dependence within the past 6 months?
9. Allergy to intervention: Does the participant have known allergies or adverse reactions to the intervention(s) being tested in the study?

10. Pregnancy: Is the participant pregnant, planning to become pregnant, or breastfeeding during the study period?
    a. Pregnancy test is not required.
11. Immediately life-threatening condition or any condition, that in the principal investigator's judgement, is expected to limit life expectancy during study period.
12. Life expectancy: The participant has a life expectancy of at least 5 years, as assessed by the principal investigator based on medical history and current health status.
    a. Study investigator(s) may use the ePrognosis Combined Lee Schonberg Index to inform assessment of life expectancy (https://eprognosis.ucsf.edu/leeschonberg-result.php). XPRIZE recommends considering participants with a predicted 5-year mortality of 60% or greater on the Combined Lee Schonberg Index as meeting the life-expectancy exclusion criterion.

STUDY ID GENERATION

All participants screened that meet the XPRIZE Healthspan inclusion criteria must be assigned a unique Study ID to ensure consistent identification throughout the study while protecting participant confidentiality.

Each team will be provided with a unique URL to a Study ID survey by the DCC. This survey will be open to all study staff who participate in screening. To generate a Participant's Study ID, the study coordinator at each site will:

1. Navigate to their team's Screening Survey using the unique team URL.
2. Complete and eligibility questions in the survey
3. **Submit** the Eligibility Survey.
4. A unique Study ID will be generated for that participant.

Participant Study IDs follow a standardized study-specific format (e.g., 5214-12). The first 4 digits will identify the team, the number following the dash will identify the participant. Study IDs must not be modified and will never have leading zeros (e.g. 5214-0012) or spaces (e.g. 5214 – 12).

Once assigned, the Participant's Study ID must be used on all study records, data collection forms, biospecimen samples, and correspondence within the XPRIZE Healthspan database. The Participant's Study ID must remain associated with the participant for the duration of the study and must not be reassigned or reused.

The assigned Study ID will be used by the Utah DCC to link data from the Central Laboratory and Cogstate to the XPRIZE REDCap. Consistently identifying the same participant across all study-related systems and processes with a single Study ID is essential.

3.2.2 CONSENT

If a potential participant is deemed eligible by meeting all inclusion criteria and no exclusion criteria, they may be consented into the trial in accordance with the approved local protocol and applicable ethics requirement. All participants must provide consent before any research procedures are conducted.

3.2.3 VISIT PROCEDURES

The recommended order of procedures for each visit is listed below. A link to the protocol for each procedure is included when appropriate. Study staff should adhere to the XPRIZE protocols when possible and should document each time they deviate from the protocols on the Protocol Deviation Case Report Form in REDCap.

If a participant is unable to complete all the procedures at a given visit, they may come back for an unscheduled visit to complete the outstanding procedures. The research coordinator should be sure to document the date that each procedure is completed inside the applicable REDCAP visit event.

BASELINE VISIT 1 (BV1)

The first baseline visit should occur between 3 and 6 weeks before randomization.

- Vitals
  - Body temp
  - Height
  - Weight
  - Blood pressure
  - Pulse rate
  - Waist circumference
  - Hip circumference
- Fasted Blood Draw
  - Clinical Labs on Site: CMP, Hemoglobin A1c, CMV, Whole Blood for CBC
  - Central Lab Samples: Plasma, Serum, Whole Blood, Dried Blood Spot, PBMCs, Proteomic Stabilizer Blood, Function Health Sample
- Snack Opportunity
- Participant Survey
  - Participant Characteristics
  - Intrinsic Capacity
  - Lifestyle
  - Self-reported Health Events
- Symptoms, Safety Event Reporting, and Medication Changes

- Six-Minute Walk Test (6MWT)
- Lower Body Power
- Cogstate Computerized Cognitive Assessments
- CPET (Optional but recommended)

BASELINE VISIT 2 (BV2, AT OR PRIOR TO RANDOMIZATION)

The second baseline visit must occur within 3-6 weeks of the first baseline visit. If it is conducted outside of this window, a protocol deviation should be documented.

- Vitals
  - Body temp
  - Height
  - Weight
  - Blood pressure
  - Pulse rate
  - Waist circumference
  - Hip circumference
- Fasted Blood Draw
  - Clinical Labs on Site: CMP, Hemoglobin A1c, CMV, Whole Blood for CBC
  - Central Lab Samples: Plasma, Serum, Whole Blood, Dried Blood Spot, PBMCs, Proteomic Stabilizer Blood, Function Health Sample, Nucleic Acid Stabilizer Tube
- Urine Collection
- Snack Opportunity
- Participant Survey
  - Lifestyle
  - Self-reported Health Events
- Symptoms, Safety Event Reporting, and Medication Changes
- 6MWT
- Lower Body Power
- Cogstate Computerized Cognitive Assessments
- CPET (Optional but recommended)

RANDOMIZATION

Randomization will occur at the conclusion of BV2. Specific randomization procedures will be developed at the team level, and finalist teams should follow their study protocol. When possible, Study Coordinators and Lead Investigators should remain blinded to the randomization; however, the DCC Liaison will need the ability to enter the participant's randomization assignment into the XPRIZE database for analysis purposes and will therefore be unblinded.

MID-POINT VISIT 1 (MV1, 6 MONTHS POST-RANDOMIZATION)

The first mid-point visit should occur within 6 months after randomization. If this visit is not conducted, a protocol deviation should be documented.

- Vitals
  - Body temp
  - Weight
  - Blood pressure
  - Pulse rate
- Fasted Blood Draw
  - Clinical Labs on Site: CMP, Hemoglobin A1c, CMV, Whole Blood for CBC
  - Central Lab Samples: Plasma, Serum, Whole Blood, Dried Blood Spot, PBMCs
- Urine Collection
- Snack Opportunity
- Participant Survey
  - Lifestyle
  - Self-reported Health Events
- Symptoms, Safety Event Reporting, and Medication Changes

MID-POINT VISIT 2 (MV2, 9 MONTH POST-RANDOMIZATION)

The second mid-point visit should occur within 9 months after randomization. If this visit is not conducted, a protocol deviation should be documented.

- Vitals
  - Body temp
  - Weight
  - Blood pressure
  - Pulse rate
- Fasted Blood Draw
  - Clinical Labs on Site: CMP, Hemoglobin A1c, CMV, Whole Blood for CBC
  - Central Lab Samples: Plasma, Serum, Whole Blood, Dried Blood Spot
- Snack Opportunity
- Participant Survey
  - Lifestyle
  - Self-reported Health Events
- Symptoms, Safety Event Reporting, and Medication Changes

FOLLOW-UP VISIT 1 (FV1, 11 MONTH POST-RANDOMIZATION)

The first follow-up visit should occur within 11 months after randomization. If this visit is not conducted, a protocol deviation should be documented.

- Vitals
  - Body temp
  - Height
  - Weight
  - Blood pressure
  - Pulse rate
  - Waist circumference
  - Hip circumference
- Fasted Blood Draw
  - Clinical Labs on Site: CMP, Hemoglobin A1c, CMV, Whole Blood for CBC
  - Central Lab Samples: Plasma, Serum, Whole Blood, Dried Blood Spot, PBMCs, Proteomic Stabilizer Blood, Function Health Sample,
- Snack Opportunity
- Participant Survey
  - Lifestyle
  - Self-reported Health Events
- Symptoms, Safety Event Reporting, and Medication Changes
- 6MWT
- Lower Body Power
- Cogstate Computerized Cognitive Assessments
- CPET (Optional but recommended)

FOLLOW-UP VISIT 2/FINAL VISIT (FV2)

The second follow-up visit should occur within 11 months after randomization. If this visit is not conducted, a protocol deviation should be documented.

- Vitals
  - Body temp
  - Height
  - Weight
  - Blood pressure
  - Pulse rate
  - Waist circumference
  - Hip circumference
- Fasted Blood Draw
  - Clinical Labs on Site: CMP, Hemoglobin A1c, CMV, Whole Blood for CBC

    - Central Lab Samples: Plasma, Serum, Whole Blood, Dried Blood Spot, PBMCs, Proteomic Stabilizer Blood, Function Health Sample, Nucleic Acid Stabilizer Tube
- Urine Collection
- Snack Opportunity
- Participant Survey
    - Participant Characteristics
    - Intrinsic Capacity
    - Lifestyle
    - Self-reported Health Events
- Symptoms, Safety Event Reporting, and Medication Changes
- 6MWT
- Lower Body Power
- Cogstate Computerized Cognitive Assessments
- CPET (Optional but recommended)

3.3 UNSCHEDULED OR MISSED VISITS

An unscheduled visit may be needed to complete or re-do an endpoint assessment due to experimental failure, address safety concerns, conduct additional monitoring of symptoms, or other unexpected reasons.

The team should report unscheduled visits to the XPRIZE-Utah DCC and note the reason for the unscheduled visit, noting deviations from protocol. The acceptable window for unscheduled visits is within 2 weeks before or after the initial visit is scheduled.

If a participant missed a scheduled visit, the team should report this to the XPRIZE-Utah DCC and note the reason the participant missed the visit.

4. REQUIRED DATA COLLECTION

This section provides protocols for the mandatory assessments for participants. To know what assessments to administer at each visit refer to the SOE table above.

4.1 VITAL SIGNS

Reference Appendix A for the full vital signs protocol, including information on approved equipment and calibration scheduling.

Prior to collecting vital signs, make sure to complete the **pre-measurement requirements:**

- Physical rest
- Substance restriction
- Bladder status
- Environmental control

When collecting vital signs, make sure you are using the approved, calibrated equipment.

Vitals are **required** to be collected in the following order:

Vital Sign	Equipment
Blood Pressure	Automated clinical-grade oscillometric monitor with appropriately sized cuffs
Heart Rate	Automated clinical-grade oscillometric monitor with appropriately sized cuffs
Body Temperature	Digital oral thermometer with disposable probe covers or non-contact infrared thermometer
Height	Wall-mounted mechanical or digital stadiometer
Weight	Calibrated medical-grade digital scale with a flat, non-carpeted surface
Waist Circumference	Flexible, non-elastic anthropometric measuring tape
Hip Circumference	Flexible, non-elastic anthropometric measuring tape

4.2 FASTED BLOOD DRAWS

For information on required steps for blood collection, processing, and shipment, please refer to the UCSD manual of operations.

4.3 SNACK OPPORTUNITY

Following sample collection, participants may be offered a snack before continuing with the rest of the visit. Before allowing the participant to eat, make sure that all samples have already been collected.

4.4 PARTICIPANT SURVEY

This is a survey that should be administered to each study participant. The survey should be completed by the participant to the best of their ability. A trained study team member should be available during survey administration to provide clarification, answer participant questions, and assist as needed without influencing or directing participant responses. Study staff should ensure that participants have adequate time to complete the survey and should review the survey upon completion to confirm that all required items have been addressed.

The survey includes validated questionnaires that should be administered in paper format in accordance with the study protocol and the validated administration procedures for each instrument.

It is the finalist team's responsibility to ensure participant responses are provided to the DCC Liaison for REDCap data entry.

Validated Questionnaire Licensure: Licensing has been secured for the use of validated questionnaires within the XPRIZE Healthspan Competition only. Any use of these questionnaires outside of the competition, including for commercial or other purposes, requires the user to independently register with the instrument owner, obtain the appropriate license, and pay any applicable licensing fees.

4.5 SYMPTOMS, SAFETY EVENT REPORTING, AND MEDICATION CHANGES

At the baseline visit, the site study team will collect and document each study participant's baseline symptoms, current safety status, and concomitant medications. At each subsequent study visit, the site study team will assess and document any changes in the participant's clinical status since the previous visit. This assessment will include changes in symptoms, the occurrence of any safety events (including adverse events, as applicable), and any changes to concomitant medications. Information will be obtained directly from the study participant.

4.6 MUSCLE FUNCTION

The following table lays out the required and optional muscle function tests to perform.

MUSCLE ENDPOINT ASSESSMENTS			
Order of events	**Time to conduct test**	**Location of protocol**	**Required**
Endurance Capacity			
Six-Minute Walk Test (6MWT)	20 minutes	Resource Hub	Yes
Cardiopulmonary Exercise Test (CPET)	45 minutes	Resource Hub	No, strongly recommended
Lower Body Power – choose 1 of the following tests			
Knee Extensor Isokinetic Power Assessment	20 minutes	Resource Hub	Yes
Leg Extension / Leg Press Power Assessment	25 minutes	Resource Hub	Yes

4.7 COGNITIVE FUNCTION: COGSTATE

Cognitive function will be assessed using the electronic Cogstate assessment platform. The assessment consists of multiple test batteries designed to evaluate various domains of cognitive function and must be administered to all study participants.

Participants should complete the assessment independently and to the best of their ability. Study staff designated as Cogstate Test Supervisors must complete the required training through the Cogstate Learning Management System (LMS) before administering any Cogstate assessments.

Prior to administering the assessment, study staff should:

1. Verify that a stable internet (Wi-Fi) connection is available.
2. Confirm that the participant is prepared to complete the assessment (e.g., has reading glasses, hearing aids, or other necessary assistive devices available).

Study staff should ensure that participants have sufficient time to complete the assessment in a quiet environment with minimal distractions. Participants should be encouraged to complete the full sequence of assessments. If a participant pauses or requests a break, they should be encouraged to

resume and complete the assessment whenever appropriate, unless there is a valid reason to discontinue the session.

Detailed instructions for administering Cogstate assessments are provided in the Cogstate resources and should be followed for all assessments.

Questions regarding Cogstate assessments should be directed to XPRIZE@cogstate.com.

Quantitative CT can be used to assess the muscle area from a single slice or muscle volume from a stack of slices covering a whole muscle, following segmentation. MRI may be used coupled with analysis algorithms for muscle mass assessment or body composition analysis.

5. OPTIONAL BUT RECOMMENDED MEASUREMENTS

Required assessments will be used in the adjudication of the Grand Prize and must be conducted according to their specified protocols. Additional assessments are “recommended but optional”. These may provide valuable information for understanding broader impacts of interventions and alignment with other global programs, but they will not influence judging or the determination of whether trial endpoints have been achieved. Optional assessments will not influence judging or the determination of whether trial endpoints have been achieved. Finalist teams may choose to include these recommended but optional measurements.

6. SAFETY DATA COLLECTION

Safety information identified during the study will be reported to XPRIZE in accordance with the procedures and timelines specified in this MOP and the Rules and Regulations. Most safety data will be entered in the XPRIZE Database. Regulatory oversight documents will be submitted to the XPRIZE-Utah DCC through DCC Florence eBinder when requested. Study sites are responsible for ensuring that all safety events are recorded and reported for their individual clinical trial. This includes meeting all applicable local requirements for reporting to the DSMB, IRB/EC, or other regulatory authorities, as well as the XPRIZE study-specific reporting requirements.

The XPRIZE-Utah DCC will provide applicable safety information to the XPRIZE Safety Committee and Judging Panel in accordance with established reporting procedures. The DCC's safety review activities support competition oversight and do not replace finalist teams' responsibility for clinical care, safety monitoring, or local regulatory reporting.

There will be four different types of safety data reported for the XPRIZE protocol. These include:

1. Baseline medical assessments (recorded in XPRIZE REDCap by DCC Liaisons)
2. Out-of-range laboratory values (recorded automatically during Central Lab data transfers)
3. Adverse events (AEs) and Unanticipated problems (UPs) (recorded in XPRIZE REDCap by DCC Liaisons)
4. Regulatory oversight determinations and decisions (DSMB, IRB/EC, or regulatory authority determinations and/or decisions) (provided to XPRIZE DCC in electronic format/secure document sharing system)

6.1 BASELINE MEDICAL ASSESSMENTS

Baseline medical assessments should be reviewed and documented prior to participant randomization and/or study intervention. These assessments are performed to establish each participant's baseline clinical status, confirm eligibility, and identify any pre-existing medical conditions or abnormalities. Any clinically significant findings identified before study participation should be documented as baseline conditions and should not be reported as AEs unless they worsen after enrollment or otherwise meet protocol-defined reporting criteria.

6.2 OUT-OF-RANGE LABORATORY VALUES

Each finalist team will provide their pre-defined clinically significant (for their study population, intervention, etc.) laboratory out-of-range values to the XPRIZE-Central lab prior to study initiation.

All out-of-range values (as reported by local laboratories) should be reviewed by the investigator or appropriately delegated qualified study clinician for clinical significance. Laboratory values outside the team's reference range should be documented according to institutional practice and protocol requirements. An out-of-range (local laboratory value) alone does not constitute an AE. An out-of-range value pre-specified by the finalist team as clinically significant does constitute an AE.

All laboratory results will be imported to the DCC from the central lab, with central laboratory out-of-range values flagged, and pre-defined finalist team out-of-range values automatically coded as adverse events.

6.3 ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Apart from out-of-range lab values, the DCC Liaison will be responsible for entering AE data and Unanticipated Problem (UP) data into the XPRIZE REDCap. Finalist teams must notify the XPRIZE-Utah DCC of each serious adverse event (SAE) within 7 calendar days after the site becomes aware of the event. The XPRIZE-Utah DCC will report SAEs to XPRIZE within 7 calendar days after receiving notification from the Finalist Team. The XPRIZE DCC and/or Safety Committee may ask for additional information to be uploaded to an alternate secure document sharing platform to describe additional details regarding SAEs or UPs.

6.3.1 ADVERSE EVENT (AE)

An AE is any untoward medical occurrence (sign, symptom, or diagnosis) that occurs during experienced by a participant during the XPRIZE study monitoring window. An untoward medical experience can be described as any change from the participant's baseline condition that is not an improvement toward better health. AEs may or may not be related to the study intervention. AEs that meet the definition of serious are referred to as SAEs.

6.3.2 SERIOUS ADVERSE EVENT (SAE)

An SAE is an AE that:

- Results in death; or
- Is life-threatening (the participant was, in the view of the site investigator, in immediate danger of death from the event as it occurred); or
- Requires inpatient hospitalization or prolongs an existing hospitalization; or
- Results in persistent or significant disability or incapacity or permanent impairment of a body structure or body function; or
- Results in fetal distress, fetal death, or congenital anomaly/birth defect; or
- Results in medical or surgical intervention to prevent permanent impairment of a body function, or to prevent permanent damage of a body structure due to the use of a medical product; or

- Other medically important event not covered by other serious criteria.

6.3.3 UNANTICIPATED PROBLEMS (UPS)

UPs are defined as any incident, experience or outcome that meets all of the criteria below:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studies; AND
2. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) or if the event or problem possibly or definitely affects the safety, rights, and welfare of current participants; AND
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

For any UP identified, the finalist team must document the event in REDCap. Documentation must include the name or description of the UP, the date the event occurred, and the date on which the study site became aware of the event. The XPRIZE DCC and/or Safety Committee may ask for additional information to be uploaded to an alternate secure document sharing platform to describe additional detail about the UP.

6.4 REGULATORY OVERSIGHT

Safety oversight activities conducted by the DSMB, IRB/EC, sponsor, or other regulatory authorities should be documented throughout the study. Finalist teams are responsible for reviewing and implementing applicable recommendations, determinations, protocol modifications, or other required actions resulting from these oversight activities. Documentation of reports, correspondence, approvals, recommendations, and resulting study actions should be maintained in the study regulatory files and implemented in accordance with protocol requirements and applicable regulations. Finalist teams must notify XPRIZE-Utah DCC within 7 calendar days of any decision or action to halt, pause, suspend, or terminate a study site or study. All regulatory safety oversight communications will be uploaded to an alternate secure document sharing platform for XPRIZE DCC and/or Safety Committee review.

7. DATA STANDARDS IN REDCAP

7.1 VALIDATION RULES AND DATA CHECKS

To promote accurate and consistent data entry, validation rules will be implemented for applicable fields within the REDCap database. Validation rules are used to restrict data entry to predefined formats, ranges, or allowable values whenever appropriate. Data will be collected in parallel between sites so dates, times, and units will remain the same throughout the study. We will also use controlled terminology throughout the database for uniform data collection, including coded values (1,2,3) or open text for “other” fields. The database will be consistent in capturing required fields which will be marked by a red asterisk. Certain fields may contain branching logic so if a question is answered with a datapoint asking yes/no, if answered with a yes, another clarifying question may be asked.

Routine data quality checks will be conducted throughout the study to identify incomplete, inconsistent, missing, or potentially inaccurate data. REDCap's built-in Data Quality tools, custom reports, and data exports may be used to support these reviews. Some data checks will be instant and may pop up to say a value is out of expected range or inappropriate characters. This may happen if a date of birth is entered in a date of visit data field where we wouldn’t expect the year of visit to be within the same range as a birth year.

Standardized medical terminology shall be used to support consistent coding, review, analysis, and reporting of clinical trial data. The XPRIZE-Utah DCC shall use The Medical Dictionary for Regulatory Activities (MedDRA) to code adverse events, serious adverse events, medical history, and other protocol-specified medical concepts. WHODrug Global will be used to code prior and concomitant medications and other protocol-specified medicinal products. DCC Liaisons shall enter the reported information into REDCap as verbatim text. Coding will be done by a certified clinical data manager and shall not replace, overwrite, or otherwise alter the original reported value.

7.2 HANDLING OF MISSING, UNKNOWN OF INCOMPLETE VARIABLES

Study personnel should make every effort to collect complete and accurate data at the time of data entry. When data are unavailable, the appropriate study-defined response (e.g., "Unknown," "Not Done," "Not Applicable," or "Participant Declined") should be selected when available. Fields should only be left blank when permitted by the study design or data collection instrument. The original collection instrument will be called the study data source document, this may be a form for an assessment that was filled out by the person conducting the test or even an intake form for the subject completing these tests depending on the nature of the data. These source documents should be completed in a legible and complete manner in order to input data into the database.

Missing or incomplete data identified during routine data quality reviews should be verified against source documentation and corrected by authorized study personnel when appropriate. If a lab value is deemed inaccurate, the contracted study lab will be notified for correction. If the information cannot be obtained, the missing value will remain documented according to study-specific conventions. Data will not be estimated or imputed unless specified in the study protocol or statistical analysis plan.

7.3 REDCAP ALERTS

REDCap notifications may be used to automate study communications and support study workflow. These notifications will come in the form of an email and may be site/study specific and not contain Protected Health Information (PHI). Please do not reply to these emails as this is an unmonitored email account, please reach out to your designated study personnel if you have questions about the alert.

7.4 QUERY MANAGER

Data queries for this study are managed through Query Manager, the DCC's discrepancy management application used to monitor REDCap data for quality, completeness, and consistency. Query Manager runs nightly to identify missing, inconsistent, or out-of-range data based on study-specific validation rules. When discrepancies are identified, queries are generated and assigned to the appropriate study site or the DCC for review. Site staff should review released queries regularly (preferably daily) and use their DCC/REDCap credentials to access Query Manager after completing the required training. The Query Manager application will send an email if you have open queries that need attention but please log in periodically to check for outstanding queries as well.

To resolve a query, review the discrepancy described in Query Manager and verify the corresponding data in REDCap. If an error is identified, update the data directly in REDCap; the query will automatically resolve during the next nightly system refresh once the discrepancy no longer exists. If the data is correct or the query cannot be resolved through changes in REDCap (e.g., data are truly unavailable), provide a brief explanation in the query message field and select Request DCC Review so the DCC can evaluate and manually resolve the query, if appropriate.

REDCap and Query Manager work on the same username and passwords, please have all site users log in every 30 days to maintain an active account and password. If you are prompted to reset your password for either application, please utilize the password reset site at: https://reset.utahdcc.org/showLogin.cc or contact your designated study personnel.

7.5 DATA LOCK PROCEDURES

The database will be checked periodically for routine data review and cleaning, safety or medical monitoring, interim or final analysis, regulatory reporting, external lab result transfers, and data snapshots. These checks may prompt a temporary database lock and then at the end of the study, a

final study lock and archival. The study team will alert the study teams when these snapshots or locks may happen and ask for all queries to be resolved within a specified amount of time. The study database will be reviewed for completeness and accuracy prior to data lock. These snapshots and locks are to ensure all expected records and visits are present, required forms are complete or their status is documented, data validation checks have been run and reviewed, critical queries are resolved or documented as outstanding external laboratory transferred data have been loaded and reconciled, adverse event and medication coding is sufficiently complete, safety and clinical databases have been reconciled, protocol deviations and eligibility data have been reviewed. After a snapshot has occurred, if missing data is found or data is updated, a change to the previous data may require a comment to be changed and will be entered into the database through a pop-up box prompt.

Final database lock is the formal point after which the clinical database is considered complete and ready for final analysis. Once data review is complete and all required approvals have been obtained, the REDCap project will be placed in Data Lock/Archival mode or otherwise restricted to prevent further data modifications. Any changes requested after database lock must be documented, approved by the study leadership, and implemented in accordance with study-specific procedures. These procedures are intended to protect data confidentiality, integrity, traceability, and reproducibility throughout the trial. REDCap provides role-based data-export controls and logs data exports, data modifications, report activity, and changes to user permissions in its audit trail so many study personnel may never see the exports or database lock results.

8. PROTOCOL DEVIATIONS

A protocol deviation is any departure, divergence, or unplanned variation from the approved study protocol, study procedures, or applicable regulatory requirements that occur during the conduct of the trial.

All deviations related to XPRIZE competition-specific study procedures must be documented and managed in accordance with the processes outlined below. For the purposes of this competition, protocol deviations are categorized as either expected deviations or unexpected deviations.

8.1 EXPECTED DEVIATIONS (PRIOR APPROVAL REQUIRED)

Expected deviations are anticipated departures from XPRIZE study procedures that are identified before they occur. Expected deviations must be pre-approved by XPRIZE. Should a participating team identify that they are unable to follow the approved study protocol, study procedures, or applicable regulatory requirements, the team must submit a request for approval through the JIRA Helpdesk. The request will include details about the expected deviation. XPRIZE will evaluate the request, determine whether the deviation is acceptable, and communicate the final decision to the submitting site. Approved expected deviations should be implemented only after receiving formal approval from XPRIZE.

8.2 UNEXPECTED DEVIATIONS

Unexpected deviations are unplanned departures from either the XPRIZE-specific study protocol, the team-specific study protocol, or established study procedures. These may include errors, omissions, or other deviations that occur during trial conduct. All unexpected deviations must be documented on a local protocol deviation log maintained by each site.

A subset of unexpected deviations must be entered in REDCap using the Protocol Deviation Log data form. The following unexpected deviations must be entered into REDCap:

- Any **deviation from the XPRIZE-specific study protocol or XPRIZE-specific procedures**. This includes the MOP, Rules/Regulations, Central Lab manual, and XPRIZE clinical protocols.
- Any deviation that qualifies as an **important deviation**. The study team should refer to the pre-defined categories for important deviations (refer to section 8.4) to assess whether the deviation is important or non-important.

Unexpected deviations that 1) relate solely to team-specific study procedures and 2) are determined to be non-important, do not need to be entered into REDCap. These deviations must be documented on a local protocol deviation log maintained by the study site and retained according to site recordkeeping requirements.

8.2.1 DEVIATION FROM XPRIZE-SPECIFIC PROCEDURES

Deviations related to XPRIZE-specific study procedures must be documented in REDCap and classified into one of the following categories:

1. **Unscheduled Visit** – A visit conducted outside the planned XPRIZE study schedule.
2. **Out-of-Window Visit / Timeline Adherence** – A study visit or procedure performed outside the XPRIZE protocol-defined time window.
3. **Withdrawal / Early Termination** – Participant withdrawal or early discontinuation from study activities.
4. **Unblinding** – Premature unblinding that is not otherwise permitted by the protocol.
5. **Protocol-Specific Deviation** – A deviation from a XPRIZE study-specific protocol procedure. The applicable protocol area should be specified (e.g., muscle, cognitive, or immune assessments).

8.2.2 IMPORTANT DEVIATIONS

An important deviation is one that may affect participant safety, rights, welfare, data integrity, or the scientific validity of the study. Important deviations must be categorized as follows:

1. **Intervention** – Deviations related to the administration or delivery of the intervention, participant exposure, concomitant treatments, or other intervention-related procedures.
2. **Safety** – Deviations that impact participant safety or well-being, or deviations implemented to eliminate an immediate hazard to a participant.
3. **Data Integrity** – Deviations resulting in the failure to collect data necessary for evaluating study endpoints, or deviations that may significantly affect the completeness, accuracy, reliability, or interpretability of study data.

9. COMMUNICATION EXPECTATIONS

9.1 JIRA HELP DESK

The Utah DCC XPRIZE Healthspan Help Desk is the main point of contact to the Utah DCC for Finalist Teams, the Judging Panel, and the Scientific Advisory Board. Users submit tickets into the Help Desk and the Utah DCC provides support and resolves issues. Questions relating to the protocol or procedures, reports, database, data entry, etc. will be included.

Users will need to create or use an established Atlassian Cloud account to open a ticket. Finalist Teams will identify a DCC Liaison to open tickets and communicate resolutions on behalf of the full study team.

The Utah DCC XPRIZE Heatlhspan Help Desk can be accessed at the below link and is also accessible from the XPRIZE Healthspan Resource Hub.

Utah DCC XPRIZE Healthspan Help Desk: https://xprizeutahdcc.atlassian.net/servicedesk

9.2 COMMUNICATION PLAN FOR ESCALATION OF ISSUES

The DCC Liaison will be the point of contact between teams and XPRIZE or the DCC. If there are any issues that arise that need to be reported to XPRIZE and the DCC, the DCC Liaison will submit a ticket through the JIRA help desk.

9.3 RESPONSE EXPECTATION

Throughout the study, XPRIZE and/or the DCC may request supplementary information. It is the team's responsibility to respond within 1 week of the request.

Lack of response from each team will trigger an escalation communication to the lead site PI and XPRIZE leadership.

9.4 UTAH DCC AD PASSWORD RESET

If you need to reset your Utah DCC AD account password, please use the following link: https://reset.utahdcc.org.

Please note that Utah DCC AD account passwords must be changed every 90 days.

1.1 APPENDIX A

VITAL SIGNS XPRIZE HEALTHSPAN PROTOCOL

The purpose of this section is to standardize the collection of vital signs (blood pressure, heart rate, body temperature, weight, and height) for all participants enrolled in the XPRIZE Healthspan competition.

EQUIPMENT AND MAINTENANCE

All participating sites must use the approved, calibrated equipment specified below. No substitutions are permitted without prior approval from the Data Coordinating Center.

- **Blood Pressure/Heart Rate:** Automated clinical-grade oscillometric monitor with appropriately sized cuffs.
- **Body Temperature:** Digital oral thermometer with disposable probe covers or non-contact infrared thermometer.
- **Weight:** Calibrated medical-grade digital scale on a flat non-carpeted surface.
- **Height:** Wall-mounted mechanical or digital stadiometer.
- **Waist Circumference:** Flexible, non-elastic anthropometric measuring tape
- **Hip Circumference:** Flexible, non-elastic anthropometric measuring tape.

CALIBRATION SCHEDULE

All scales and blood pressure monitors must undergo calibration validation within the past 6 months. Results must be documented in the site's Equipment Calibration Log held locally at the site. If a device fails validation, it must be removed from service immediately. Logs should be made available when requested, if needed for monitoring.

PRE-MEASUREMENT REQUIREMENTS

Before initiating any vital sign measurements, the study coordinator must verify and document that the participant meets the following prerequisites:

1. **Physical Rest:** The participant must not have engaged in vigorous physical exercise for at least 2 hours prior to the assessment.
2. **Substance Restriction:** The participant must not have consumed caffeine, nicotine, or alcohol within 2 hours prior to the assessment.
3. **Bladder Status:** The participant must empty their bladder immediately prior to sitting down for the assessment.

4. **Environmental Control:** Measurements must be conducted in a quiet, climate-controlled room (20°C–24°C) to prevent ambient temperature from affecting vascular tone or body temperature.

MEASUREMENT SEQUENCE AND PROCEDURES

To prevent physical exertion from confounding cardiovascular metrics, vital signs must be collected in the exact order listed below.

BLOOD PRESSURE (BP) AND HEART RATE (HR)

- **Preparation:** Seat the participant in a chair with back support. Ensure feet are flat on the floor (legs uncrossed), and the bare upper arm is supported on a flat surface at heart level.
- **Rest Period:** Instruct the participant to sit quietly for **exactly 5 minutes**. No talking, reading, or phone use is permitted by the participant or the coordinator during this time.
- **Cuff Selection:** Measure the participant's mid-upper arm circumference and apply the correct cuff size. Place the lower edge of the cuff 1–2 cm above the antecubital fossa.
- **First Reading:** Initiate the automated monitor cycle. Record the systolic BP, diastolic BP, and HR in the source documentation.
- **Interval Rest:** Wait 2 minutes. The participant must remain seated and quiet.
- **Second Reading:** Initiate the second automated cycle. Record the values.
- **Data Recording:** Calculate and record the average of the two readings.
    - *Protocol Exception (Arrhythmia):* If the automated machine displays an error code twice due to an irregular pulse (common in ages 50–80), the coordinator must switch to a manual sphygmomanometer and stethoscope to obtain the reading. Record "Manual Method" in the Case Report Form (CRF).
    - *Protocol Exception (Discrepancy):* If the two systolic readings differ by >5mmHg, take a third reading, discard the first, and average the second and third readings.

BODY TEMPERATURE

- Verify the participant has not consumed hot or cold liquids, chewed gum, or smoked within the past 15 minutes.
- Apply a clean, disposable probe cover to the digital oral thermometer or use a non-contact infrared thermometer.

If using an oral thermometer,

- Place the thermometer probe under the participant’s tongue in the **posterior sublingual pocket** (left or right side).
- Instruct the participant to close their mouth completely and breathe through their nose.

- Leave the probe in place until the device signals completion. Record the value to the nearest 0.1°C.

BODY WEIGHT

- Ensure the scale is positioned near a wall or stable counter.
- Instruct the participant to remove shoes, heavy outerwear (jackets, sweaters), and empty all heavy items from their pockets.
- Verify the digital scale reads 0.0.
- Instruct the participant to step onto the center of the scale, stand still with weight evenly distributed, and look straight ahead.
- The participant must not touch or lean against any surface while the scale locks the weight reading.
- Record the measurement to the nearest 0.1 kg.

HEIGHT

- Instruct the participant to remove shoes, heavy socks, and any hair accessories or hairstyles that add height.
- Position the participant on the stadiometer platform facing away from the wall.
- Attempt to align the heels, buttocks, upper back, and back of the head against the vertical backboard.
    - If the participant has age-related spinal curvature (kyphosis) and cannot touch all four points comfortably, do not force compliance. Prioritize keeping the feet flat on the floor and adjusting the head to the Frankfort Horizontal Plane.
- Ensure the participant's gaze is straight ahead, with an imaginary horizontal line linking the lower orbit of the eye to the external auditory meatus (ear canal) parallel to the floor.
- Instruct the participant to take a deep breath, hold it, and stand as tall as possible without lifting their heels.
- Lower the stadiometer headpiece firmly but gently until it makes contact with the crown of the head, compressing any hair.
- Record the height to the nearest 0.1 cm before the participant steps away.

HIP CIRCUMFERENCE

- Use a flexible, non-elastic anthropometric measuring tape with measurements displayed in centimeters (cm).
- Instruct the participant to stand upright with feet shoulder-width apart, arms relaxed at their sides, abdomen relaxed, and weight evenly distributed between both feet.
- Ensure the participant has removed bulky clothing, belts, or other items that may interfere with the measurement. Direct skin measurement is preferred whenever possible.

- Position the measuring tape horizontally around the abdomen at the midpoint between the lowest palpable rib and the top of the iliac crest (hip bone).
- Ensure the measuring tape is level around the entire waist and fits snugly without compressing the skin or underlying soft tissue.
- Instruct the participant to breathe normally. Obtain the measurement at the end of a normal exhalation.
- Record the waist circumference to the nearest 0.1 cm.

WAIST CIRCUMFERENCE

- Use a flexible, non-elastic anthropometric measuring tape with measurements displayed in centimeters (cm).
- Instruct the participant to stand upright with feet together (or approximately 10 cm apart if needed for balance) and weight evenly distributed between both feet.
- Ensure the participant has removed bulky clothing or items that may interfere with the measurement. Direct skin measurement is preferred whenever possible.
- Position the measuring tape horizontally around the widest portion of the buttocks, typically at the level of the greater trochanters.
- Ensure the measuring tape is level around the hips and fits snugly without compressing the skin or underlying soft tissue.
- Record the hip circumference to the nearest 0.1 cm.

VITAL ELIGIBILITY FOR MUSCLE TESTS

Heart Rate:

	Heart Rate		
	<40bpm	40-120bpm	>120bpm
6MWT			
Leg Extensor			
Knee Power			

Blood Pressure:

	Systolic Blood Pressure			
	<90mmHg	90-180mmHg	180-220mmHg	>220mmHg
6MWT				
Leg Extensor				
Knee Power				

	Diastolic Blood Pressure		
	<100mmHg	>100-110mmHg	>110-115mmHg
6MWT			
Leg Extensor			
Knee Power			