

# Hockey FIT Pilot: Screening & Measurement Procedures Manual



## **Important Notes for the Screening and Assessment Sessions**

Baseline measurement sessions should ideally be conducted directly following a successful screen. If a successful screen cannot be followed by a baseline measurement session, the baseline should be conducted within 3 weeks after the screen. A maximum of 4 weeks should pass between the baseline assessments and the start of the Hockey FIT program.

Ensure all headers and footers (i.e. ID#'s, Dates, etc.) are completed on all study documents. During the screening and measurement sessions – one of the head assessors should check and sign off that everything within the Case Report Forms are complete.

For sensitive measurements (e.g., weight, BMI, waist circumference), male research staff (assessors) should perform assessments wherever possible.

## 1. Screening and Measurement Sessions Schedule

Measurement	Screening	Baseline	12-week	12-month {IG only}
Participant Log	X			
Pre-Randomization ID #	X			
Letter of Information & Consent Form	X			
PAR-Q	X			
Health Care Provider Clearance Form	X			
Gender	X			
Age	X	X*		
Height	X	X*	X	X
Weight	X	X*	X	X
Body Mass Index	X	X*	X	X
Eligibility Form	X			
Group Allocation		X**		
Participant ID#		X**		
Demographic & Health Related Information		X		
International Physical Activity Questionnaire		X	X	X
Starting the Conversation		X	X	X
Modified DINE		X	X	X
7-Day Alcohol Recall		X	X	X
Rosenberg Self-Esteem Scale		X	X	X
Positive and Negative Affect Schedule		X	X	X
EQ-5D-3L		X	X	X
Blood Pressure		X	X	X
Waist Circumference		X	X	X
Step Count Outcome Tracking Form		X	X	X

\* Use number recorded at Screening Session

\*\* Occurs at Allocation & Enrollment Session

## 2. Initial Contact & Pre-Screening

For the purpose of the research study, we want to be able to track whether an individual:

- i) contacted the site to learn more about the study;
- ii) if contacted the site, is then interested in the study; and,
- iii) if interested, is eligible to participate.

We will track this information using the **Participant Log**. The “*initial contact*” portion of the log will be completed by the designated Hockey FIT Coach responsible for fielding all recruitment communications.

- a) A specific **telephone script/email script** will be followed when communicating with potential participants:

### Telephone Script (when returning a call):

*Hi (insert the name of the potential participant here) my name is (insert your name) and I am one of the Hockey Fans in Training coaches. I received your message and am returning your call regarding your interest in the study. If you have a few moments I'd like to tell you a bit more about the study and to ask you a few questions. Would that be okay?*

*\*If they are no longer interested in the study, thank them for their time, and complete Sections {A}, {B}, and {C} of the **Participant Log***

*\*If yes, continue with the following...*

*The Hockey Fans in Training study or Hockey FIT is a 12-week exercise and healthy living program that is run in collaboration with (insert hockey club here) and aims to improve weight loss, exercise, and healthy eating behaviour of male hockey fans.*

*For men who are interested in the study, we will be conducting an in-person screening session to see if they are eligible to participate. However, as an initial pre-screen, would you mind if I asked you a few questions to assess whether you are eligible to attend the in-person screening?*

- *Are you a male aged 35-65 years? (record in Section {D} of the **Participant Log**)*
- *What is your height and weight? (record in Section {D} of the **Participant Log**)*
  - *Coach is to determine BMI from this information using **STEP Test & BMI Calculations** document*
- *Would you be available to attend the Hockey FIT program sessions that will take place every {insert day of week} from {insert time} starting {insert date}?*

*\*If the participant answers “no” to the gender or age criterion; clearly does not have a BMI  $\geq 28 \text{ kg/m}^2$ ; or is not available on the days the program sessions will run, they do not clear the pre-screen. Thank them for their time and ensure sections {A}, {B}, {C}, and {D} of the **Participant Log** are complete. End the call. Notes: 1) if BMI is close to cut-off, schedule potential participant for a screening session so that height and weight can be objectively measured; and 2) we are looking to find out if participants are generally available for the Hockey FIT program if randomized to the intervention group – 100% attendance over 12 weeks is not required but strongly encouraged.*

*\*If they answer “yes” to the gender and age criterion; have a BMI  $\geq 28$  kg/m<sup>2</sup>; and are available on the days the program sessions will run, they have cleared the pre-screen. Complete section {D} of the **Participant Log** and continue with the following...*

*As you have cleared the pre-screen, we would like to invite you to attend an in-person screening session. The in-person screening session serves two main purposes. The first is for you and other interested men to come along and ask questions and get a good understanding of the study, its history, what results we are looking for and any other questions you may have. The second purpose of the screening session is that it gives us the chance to determine your eligibility for the study. This is done through a couple of questionnaires and some physical measurements (e.g., height and weight). Would you be interested in attending an in-person screening session? By attending, you are not by any means committed to participating.*

*\*If no, thank them for their time and ensure sections {A}, {B}, {C} and {D} of the **Participant Log** are complete.*

*\*If yes, complete Section {D} of the **Participant Log** and continue with booking a screening appointment. Let the participant know that if they are deemed eligible to participate at the screening session, they will be invited to complete a baseline assessment immediately after (i.e., on the same day). Finish the call by ensuring sections {A}, {B}, and {C} of the **Participant Log** are complete.*

### Email Script

*Hi (insert the name of the potential participant here) my name is (insert your name) and I am one of the Hockey Fans in Training (Hockey FIT) coaches. I am returning your email message about your interest in our Hockey FIT study. I'd like to start off by telling you a bit more about the study and then asking you a few questions.*

*The Hockey Fans in Training study or Hockey FIT is a 12-week exercise and healthy living program that is run in collaboration with (insert hockey club here) and aims to improve weight loss, exercise, and healthy eating behaviour of male hockey fans.*

*For men who are interested in the study, we will be conducting an in-person screening session to see if they are eligible to participate. However, as an initial pre-screen, we would like you to answer a few questions:*

- *Are you male? {Please respond with “YES “or “NO”}*
- *Are you aged 35-65 years? {Please respond with YES “or “NO”}*
- *What is your height (in cm or inches)?*
- *What is your weight (in pounds or kilograms)?*
- *Would you be available to attend the Hockey FIT program sessions that will take place every {insert day of week} from {insert time} starting {insert date}? {Please respond with “YES “or “NO”}*

*Once I receive your responses to the above questions, I will let you know if you are eligible to attend an in-person screening session.*

*In the event that you are eligible to attend, I have provided additional information about the in-person screening session below:*

*The in-person screening session serves two main purposes. The first is for you and other interested men to come along and ask questions and get a good understanding of the study, its history, what results we are looking for and any other questions you may have. The second purpose of the screening session is that it gives us the chance to determine your eligibility for the study. This is done through a couple of questionnaires and some physical measurements (e.g., height and weight). By attending, you are not by any means committed to participating.*




*Thank you for answering the questions in this email and I will be in touch shortly to let you know if you are eligible to attend the in-person screening session. **Please note: If you prefer to answer these questions over the phone, please send me your phone number and possible day/times that would work for me to call you.***

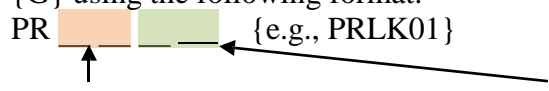
*Cheers*

**\*Ensure sections {A}, {B}, {C}, and {D} of the *Participant Log* are complete for both eligible and ineligible participants after the pre-screen when corresponding with potential participants through email\***

**b) Pre-Randomization ID #**

- Every individual who is scheduled for an in-person screening session receives a Pre-Randomization ID#
- Assign and record the individual's Pre-Randomization ID # on the *Participant Log* {G} using the following format:

PR    {e.g., PRLK01}



Site ID:  
LK = London  
SS = Sarnia

Participant number: Numbers are to be given out sequentially in the order that the individual is scheduled (e.g., 01, 02....)

- Ensure the Pre-Randomization ID# is included in the header of each page of the *Screening Session CRF*.

### 3. Screening Session

Refer to *Screening Session Case Report Form (CRF)*. Note the start and end time of the session on the front page of the CRF. **ENSURE the Pre-Randomization ID # and Date of the Visit is in the header of each page of the CRF.** Leave the Participant ID# field blank at this time (this will be assigned following group allocation).

Each participant will be provided with a screening folder (containing all screening documents) that he will carry from station to station, as outlined in the corresponding flow diagram (see Appendix A, Diagram 1). Approximately 3 men will be scheduled every 15 minutes with a maximum of 9 men scheduled per hour (i.e., 3 at 0 minutes; 3 at 15 minutes; 3 at 30 minutes). The plan is that all eligible participants' will continue with baseline measurement session immediately following the screen.

#### a) Participant Log

The “screening” portion of the *Participant Log* will be completed by the Hockey FIT assessors during the in-person Screening Session.

#### b) Letter of Information & Consent Form

- Provide participant with 2 copies of the *Letter of Information* and *Consent Form*
- Allow participant time to read through the *Letter of Information* and *Consent Form* – answer any questions that they might have.
- Ask the participant to provide written consent to participate in the study on both copies of the *Consent Form*.
- Ensure the participant initials each page of the *Information Letter* on both copies
- Keep one copy of the initialled *Letter of Information* and signed *Consent Form* in the participant's folder. The other copy is for the participant to take home with them.
- Record consent status on the *Participant Log {E}*.

#### c) Physical Activity Readiness Questionnaire (PAR-Q)

- Have participant read and fill out PAR-Q.
- Once participant is finished completing the PAR-Q, the assessor must review. If “Yes” is checked for any of the questions on the *PAR-Q*, a Health Care Provider (HCP) must give clearance before the individual can participate in any activity and therefore be eligible for the study.
- If a HCP is available (e.g., the Study Principal Investigator or other Clinical Designee), ask for clearance immediately using the *HCP Clearance Form*.
- If a HCP is not available, the participant must take the *HCP Clearance Form* and have a HCP complete. The participant must receive clearance within 3 weeks of issuing in order to continue with baseline assessment. If contact is not made within 1 week, a Hockey FIT assessor should contact the individual to check in. Record the status of HCP clearance on the *Participant Log {F}*.
- If “No” is checked for all of the questions then participant has cleared the PAR-Q and there is no need to complete a HCP Clearance Form. Record clearance of the PAR-Q on the *Eligibility Form* and on the *Participant Log {F}*.

**d) Health Care Provider (HCP) Clearance Form**

- The Hockey FIT assessor should fill-out the top part of the form including: i) their name as the assessor; and ii) the specific concern from the PAR-Q.
- Once the **HCP Clearance Form** is complete, if any of the following have been checked by the HCP, a note should be made on the participant’s study file so that the Hockey FIT coach is aware of the physical activity capabilities of this individual:
  - *Unrestricted physical activity based on the Canadian Physical Activity Guidelines - start slowly and build up gradually*
  - *Progressive physical activity: a) With avoidance of; b) With inclusion of*
  - *Only a medically-supervised exercise program until further medical clearance*
- If the following has been checked by the HCP then the participant is ineligible for the study: *No physical Activity.*
- Record status of HCP Clearance on the **Participant Log {F}**

**e) Gender**

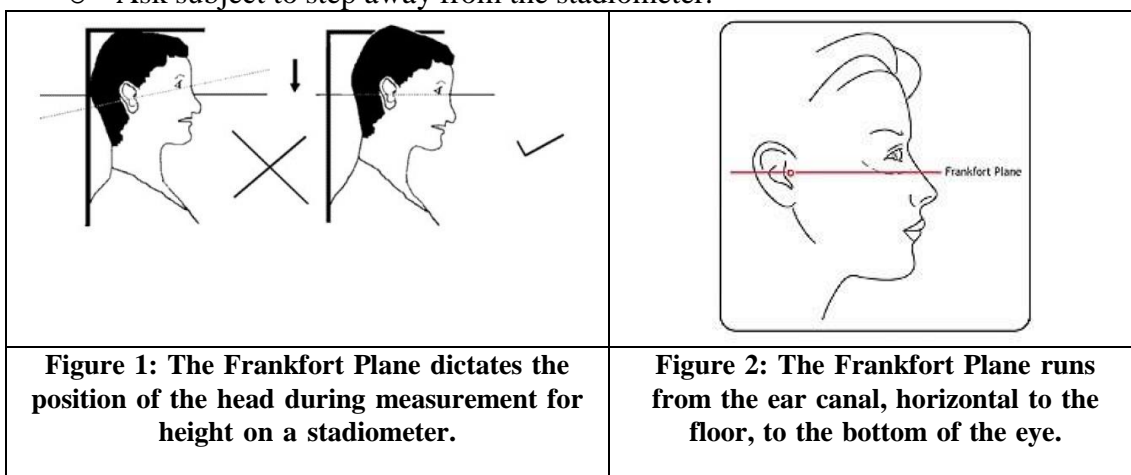
- The individual needs to be male to be eligible for the study. Record eligibility related to gender on the **Eligibility Form**.

**f) Age**

- The individual needs to be between the ages of 35-65 during the 2015 calendar year to be eligible for the study. Record the individual’s age and their eligibility related to age on the **Eligibility Form**.

**g) Height**

- Height will be measured using a portable stadiometer (Model: SECA 213).
- Measurement procedure (1):
  - Ask individual to stand with back, buttocks and heels against the stadiometer. Subject’s feet should be together and flat on the floor at base of the stadiometer.
  - Place individual’s head in the Frankfort plane (see Figure 1 and 2).
  - Instruct individual to take and hold a deep breath. At the same time place the headboard firmly down on the vertex, pushing down the hair as much as possible. Ensure that the feet do not come off the ground and that the position of the head is maintained in the Frankfort plane.
  - Record measurement at the end of the subject’s deep inward breath – record stature to the nearest 0.1 cm on the **Eligibility Form**.
  - Ask subject to step away from the stadiometer.



**h) Weight**

- Weight will be measured using a digital weight scale (Model: Tanita HD 351)
- Measurement procedure (1):
  - Weigh subject with minimal clothing and with shoes removed.
  - Check the scale is reading zero.
  - Ask subject to stand on the centre of scale, without support and with their weight distributed evenly on both feet – record body mass to nearest 0.1 kg on the *Eligibility Form*.
  - Ask subject to step off the scale.

**i) Body Mass Index (BMI)**

- Use formula in excel spreadsheet (*STEP Test & BMI Calculations*) to calculate BMI (in  $\text{kg/m}^2$ )
- The individual's BMI must be greater than or equal to  $28 \text{ kg/m}^2$  to be eligible. Record the individual's BMI and their eligibility related to BMI on the *Eligibility Form*.

**j) Eligibility Form**

- Ensure the *Eligibility Form* is complete.
- Indicate the individual's eligibility at the bottom of the form (in the shaded box)
- If individual is eligible – schedule/conduct baseline assessment.



#### 4. Measurement Sessions {Baseline, 12 weeks, 12 months (IG only)}

Refer to the *Measurement Sessions Case Report Form (CRF)*. Ensure that in the header of the CRF, the correct time period for data collection is checked (i.e., baseline, 12-week, 12-month) and the date of the visit is recorded. Also ensure that the Participant Pre-Randomization ID# (baseline only) and Participant ID# (after baseline, 12-week, and 12-month) are recorded. Finally, note the start and end time of the visit on the first page of the CRF.

Each participant will be provided with a measurement session folder (containing all measurement documents) that he will carry from station to station, as outlined in the corresponding flow diagram (see Appendix A, Diagram 2). Note: the flow for follow-up measurement sessions will be similar to that outlined for the baseline session.

Before asking the men to self-complete the questionnaires, the Hockey FIT assessor should overview the different sections of the questionnaire. Below is a brief script:

*You are being asked to complete a questionnaire that will capture information on your demographics (such as age, occupation, and ethnicity) as well as your physical and mental health, diet and physical activity levels. Please take your time and review the instructions for each question carefully and answer each question as honestly and accurately as possible. If you have questions or need clarification, please ask a Hockey FIT Assessor. Please also ensure that you are only selecting one answer for each question and are following the skip patterns accordingly.*

##### a) Demographics and Health Related Information

- This questionnaire **only** needs to be completed at **baseline** (V0).
- A paper-based version of the questionnaire will be given to participants for self-completion.

##### b) International Physical Activity Questionnaire (IPAQ) – Short Version

- A paper-based version of the questionnaire will be given to participants for self-completion. Participants answer this questionnaire by recalling their physical activity over the previous 7 days. The questionnaire is separated into sections that focus on: 1) vigorous activities; 2) moderate activities; 3) walking; and 4) sitting.
- The development of this measure commenced in Geneva in 1998 and extensive reliability and validity testing was undertaken across 12 countries in 2000.(2)
- We will follow the recommended scoring protocol to calculate a total physical activity continuous score, which is expressed in MET-minutes/week. These numbers can then be translated into classifications of low, moderate and high physical activity levels.
- We will also collect the total time spent in sedentary activity per day (minutes).
- Note: All scoring for this questionnaire will be done at the data analysis stage

##### c) Starting the Conversation (STC)

- A paper-based version of the questionnaire will be given to participants for self-completion.
- The STC is an 8-item simplified food frequency instrument designed for use in primary care and health-promotion settings. Validity, robustness, stability and

sensitivity to change were evaluated and results indicate that the eight STC items and summary score performed well and importantly showed sensitivity to change.(3) The tool is available in English and Spanish and is in the public domain.

**Scoring Protocol:**

- Answers selected in the Left column; 0 points.
- Answers selected in the Middle column; 1 point.
- Answers selected in the Right column; 2 points.
- A summary score is calculated at the end by the Hockey FIT Assessor and recorded. Points for each item are summed to obtain the summary score.

**d) Modified Dietary Instrument for Nutrition Education (DINE)**

- A paper-based version of the questionnaire will be given to participants for self-completion
- The full Dietary Instrument for Nutrition Education (DINE)(4) can take a considerable amount of time to complete and can be difficult for some participants.
- We will use an adapted version of the DINE and follow the methods used by Football Fans in Training (5) to calculate three separate dietary intake scores for fatty food, sugary food and fruit and vegetables.
- Participants answer this questionnaire by recalling their diet over the previous 7 days.
- High scores are indicative of high consumption.

**Scoring Protocol:**

Scoring Food Frequencies

DINE food frequency categories will be converted to scores as follows:

- Cheese, beef burgers or sausages, beef, pork or lamb, chips, fried food:
  - No times = 1
  - 1-2 times = 2
  - 3-5 times = 6
  - 6 or more times = 9
- Pies, quiches, pastries:
  - No times = 1
  - 1-2 times = 2
  - 3-5 times = 5
  - 6 or more times = 8
- Bacon or processed meat, crisps:
  - No times = 1
  - 1-2 times = 2
  - 3-5 times = 5
  - 6 or more times = 6
- Milk amount:
  - Less than half a cup = 1
  - About half a cup = 2
  - About a cup = 3
  - Two or more cups = 4
- Milk type:
  - Whole = 3
  - Partly-skimmed = 2
  - Skimmed = 1

- Sugary drinks:
  - Less than once a day = 1
  - 1-2 times a day = 2
  - 3-5 times a day = 3
  - 6 or more times a day = 4
- Biscuits, chocolate and sweets:
  - Less than once a day = 1
  - 1-2 times a day = 2
  - 3-5 times a day = 4
  - 6 or more times a day = 6
- Fruit and vegetables:
  - Less than once a day = 0.5
  - 1-2 times a day = 1.5
  - 3-5 times a day = 4
  - 6 or more times a day = 6

Summary Scores for Fatty Food, Fruit and Vegetable, and Sugary Food:

- From these variables we will calculate a fatty food score, a sugary food score and a fruit and vegetable score.
- *Fatty food score*: includes scores from 8 variables. Cheese score + beef burger or sausages + beef, pork or lamb + bacon or processed meat + pies, quiches, pastries + crisps + (fried food + chips/2) + (milk frequency x milk type). Possible range = 8 - 68.
- *Sugary food score*: includes scores from three variables. Sugary drinks + biscuits + chocolate, sweets. Possible range = 3 - 16.
- *Fruit and vegetable score*: included score only from the fruit and vegetable variable. Possible range = 0.5 - 6.

**e) 7-Day Alcohol Recall**

- Alcohol intake will be measured using a paper-based 7-day alcohol recall diary.
- Participants will be asked to recall the number of “drinks” they consumed over the past 7-day period and record this number in the provided table.
- Participants work backwards recording how many drinks (from the 5 categories) they have had each day over the past 7 days (i.e., they start with the previous day and work back through the week).

***Scoring Protocol***

- A total number of weekly drinks will be calculated by the Hockey FIT Assessor. This number will be calculated by summing the total number of drinks (across the 5 categories) for each day of the week.

**f) Rosenberg Self Esteem Scale (RSES)**

- A paper-based version of the questionnaire will be given to participants for self-completion.
- The RSES consists of 10 items assessing global self-esteem (e.g., “On the whole, I am satisfied with myself”). Previous studies have reported alpha reliabilities for the RSE ranging from .72 to .88. Five of the items have positively worded statements and five have negatively worded ones. The scale measures state self-esteem by asking the respondents to reflect on their current feelings.(6,7)

- Higher scores indicate higher self-esteem.

**Scoring Protocol:**

- A summary score will be calculated by the Hockey FIT Assessor to provide a measure of self-esteem. The score is calculated by summing the points for each item together.
- For items A, C, D, G and J: Strongly Agree (1 points); Agree (2 points); Disagree (3 points); Strongly Disagree (4 points).
- For items B, E, F, H and I (which are reversed scored): Strongly Agree (4 points); Agree (3 points); Disagree (2 points); Strongly Disagree (1 point).

**g) International Positive And Negative Affect Scale (PANAS) Schedule Short Form (I-PANAS-SF)**

- A paper-based version of the questionnaire will be given to participants for self-completion
- The I-PANAS-SF consists of 10 words that describe different feelings or emotions. Respondents rate to what extent they have felt that way from “1=never” to “5 = always. Half of the words contribute to the positive affect score and the other half contribute to the negative affect score.(8)

**Scoring Protocol:**

- Summary scores will be calculated by the Hockey FIT Assessor to provide a measure of positive affect and negative affect.
- Scoring: 1- Never selected (1 point); 2 selected (2 points); 3 selected (3 points); 4 selected (4 points); 5 – Always selected (5 points)
- Positive affect sub-scale score (sum of items C,E,G,H and J) – higher scores represent higher levels of positive affect (score will range from 5-25)
- Negative affect sub-scale score (sum of items A,B,D,F and I) – lower scores represent lower levels of negative affect (score will range from 5-25)

**h) Health Related Quality of Life (EQ-5D-3L)**

- Health-Related Quality of Life will be captured using a paper-based version of the European Quality of Life 5 Dimensions (EQ-5D).
- The EQ-5D is a 6-item generic measure that captures self-reported health-related quality of life in 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.(9)

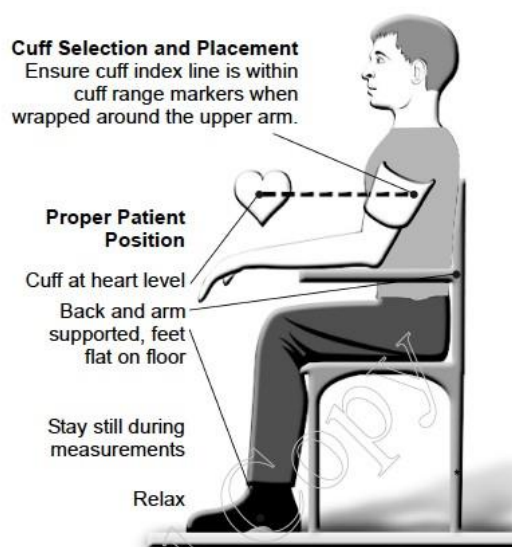
**Scoring Protocol:**

- A summary score for Descriptive Health State (A-E) and for VAS will be calculated by the Hockey FIT Assessor
- Questions A-E scoring: First answer = 1 point; Second answer = 2 points; Third answer = 3 points). The score is the digits listed in order.
- Question F: Participants receive points relating to where they marked on the scale. For example, if they selected 70 then their score on the VAS is 70.

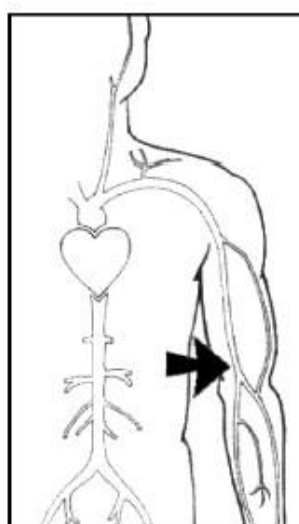
**See Appendix B for sample scoring.**

### i) Blood Pressure (BP)

- Blood pressure will be measured using an automated sphygmomanometer (BpTRU devices). *Note: no calibration is required to use BpTRU.*
- Three BP measurements will be taken in total and recorded.
- The first measurement should be taken after a 2-minute rest (sitting) period. *Note: 2 minutes is used instead of 5 minutes since participants will already be sitting while filling out questionnaires (otherwise 5 minutes is necessary).*
- There should be 2 minutes in between each measurement (*note: this is automated using the BpTRU*).
- Ensure the participant's feet are flat, and that their back and arms are supported. Arm should be free of clothing (e.g., do not place cuff over a sweater). Cuff should be at the level of the heart and arm resting. See **Figure 3** below.
- Always measure on left arm unless not medically indicated (record which arm and repeat on same arm at next assessment).
- **Cuff placement:** align the artery indicator on the cuff with the patient's brachial artery as shown in **Figure 4** below. Ensure cuff is tight but allow two fingers to be inserted between the cuff and the arm.
- No talking to the participant during the measurement and try to do in a quiet area.



**Figure 3: Proper participant positioning**



**Figure 4: Proper BP cuff placement**

**Average of Reading 2 and 3:** Calculated by the Hockey FIT Assessor. To calculate the average systolic BP: add Reading 2 systolic and Reading 3 systolic together and divide by 2. Do the same for diastolic BP.

### j) Waist Circumference (WC)

- Two waist circumference measurements will be taken initially. If the difference between reading 1 and 2 is  $\geq 0.5$  cm a third reading will be taken. Record readings.
- Clear the abdominal area of any clothing, belts or accessories. Stand upright with feet shoulder-width apart and the stomach relaxed. Wrap the measuring tape around the waist.
- Use the borders of your hands and index fingers – not your fingertips – to find the uppermost edge of your hipbones by pressing upwards and inwards along the hip bones. **Tip:** Many people mistake an easily felt part of the hip bone located toward the

front of the body as the top of their hips. This part of the bone is in fact not the top of the hip bones, but by following this spot upward and back toward the sides of the body, you should be able to locate the true top of the hip bones.

- Align the bottom edge of the measuring tape with the top of the hip bones on both sides of your body.
- Make sure the tape is parallel to the floor and is not twisted.
- Ask the participant to relax and take two normal breaths. After the second breath out, tighten the tape around the waist. The tape should fit comfortably snug around the waist without depressing the skin. **Tip:** Remember to keep asking the participant to keep their stomach relaxed at this point.
- With the participant still breathing normally, take the reading on the tape (in cm).
- Go to the following link for a video on how to correctly measure waist circumference: <http://www.heartandstroke.com/site/?c=ikIQLcMWJtE&b=3876195>(10)

**Average of recorded WC measurements:** To be recorded by Hockey FIT assessor. Add readings 1 and 2 together and divide by 2 for the average. If a third reading was taken, add all 3 readings together and divide by 3.

**k) Height**

- See protocol on Page 7 of this Manual
- For the Baseline Session only – use height recorded at Screening Session.

**l) Weight**

- See protocol on Page 8 of this Manual
- For the Baseline Session only – use weight recorded at Screening Session.

**m) Body Mass Index (BMI)**

- See protocol on Page 8 of this Manual
- For the Baseline Session only – use body mass index recorded at Screening Session.

**n) Step Count**

- Provide participant with *pedometer* as well as the *Step Count Outcome Tracking Form*
- Review placement of pedometer on body with participant and how to use
- Review instructions about completing the tracking form with the participant; stress the importance of tracking daily steps on each of the 7 days in the monitoring period and recording on the form.
- The Assessor is to circle the start date of tracking for the participant and complete the dates (mm/dd/yy) accordingly.
- The Assessor should also indicate in the shaded box the measurement period for tracking (i.e., baseline, 12-week, 12-month)

## 5. ALLOCATION & ENROLLMENT SESSION

At this session, individual participants will arrive for their scheduled 15-minute appointment. Appendix A – Diagram 3 outlines the flow for this session.

### a) Pedometer & Step Count

- Collect *pedometer* and *Step Count Outcome Tracking Form* from the participant
- The Assessor will review *Step Count Outcome Tracking Form* with participant to ensure values are legible and that there are no outstanding questions. Next, the Assessor will transfer the 7-day step count data to the participant's measurement session CRF and file the *Step Count Outcome Tracking Form* in the participant's folder as a back-up of the raw step data.
- At this point, it is unknown as to whether the participant will leave with their pedometer (i.e., if allocated to the Hockey FIT group); thus, the assessor should clip the pedometer to the folder and ask participant to carry folder and pedometer to the next station.

### b) Group Allocation

- One of the head Hockey FIT Assessors will conduct this important task
- Once the participant is seated, the Hockey FIT assessor will take the participant's folder (and pedometer) and then take out the next sequentially numbered, opaque envelope from the box.
- The assessor will then write the participant's name and pre-randomization ID on the front of the envelope
- Next, the assessor will open the envelope in front of the participant and show the participant their group allocation and explain what it means:
  - 1) **Hockey FIT Group:**
    - Start Hockey FIT program immediately (i.e., as scheduled per calendar)
    - Complete both 12-week and 12-month measurement sessions
  - 2) **Wait-List Control Group:**
    - Continue with usual activities/daily routine without any intervention from the study team
    - Complete 12-week measurement session
    - Offered opportunity to start Hockey FIT program in September

### c) Information and Pedometer Provided

- The Assessor will review the weight and BMI measurements with each individual participant (regardless of group allocation).
  - The *Health Canada BMI Nomogram* (11) will be used to visually show each male where he falls according to Canadian guidelines. On the Nomogram, use a straight edge to locate the point of the chart where height (cm) and weight (kg) intersect. Share the number on the dashed line closest to this point and explain to the participant what this means.
- There will be four different types of participant packages created that will be site (London or Sarnia) and group (Hockey FIT or Control) specific; these will be added to a pre-made folder that contains the participant's consent form. The packages will include a participant information sheet, and for the control group only, copies of Canada's Food Guide and the CSEP Physical Activity Guidelines.
- The assessor will provide the participant with the correct folder and ensure that they highlight both the site and group allocation on the participant information sheet. The

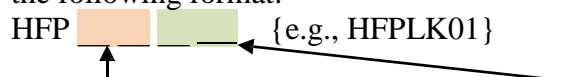
assessor should briefly review the participant information sheet with each participant, including the importance of reporting adverse events. The assessor should also briefly review the other materials in the folder.

- The assessor will also return the pedometer to participants allocated to the **Hockey FIT group only** and explain that it is to be used throughout the Hockey FIT program and will be collected upon study completion (12 months).

**d) Participant ID #**

- Once allocated, the participant is officially enrolled in the Hockey FIT pilot RCT and should now be assigned a participant ID #. The Pre-Randomization # is no longer used.
- Assign and record the individual's Participant ID # on the *Participant Log* {G} using the following format:

HFP   {e.g., HFPLK01}



**Site ID:**

LK = London  
SS = Sarnia

**Participant number:** Numbers must match the number that is indicated on the outside of the allocation envelope (e.g., 01, 02....)

- *Note: the participant ID# will not necessarily (and likely will not) match the pre-randomization ID #.*
- The Assessor now needs to go back and record the Participant ID# in the header of each page of the *Screening Session CRF and the Measurement Session CRF*.

\*Upon return to the study office, the head assessors will create a master excel document linking participant names and Participant ID#. This document will then be passed to the Project Coordinator for recording of group allocation and storage.

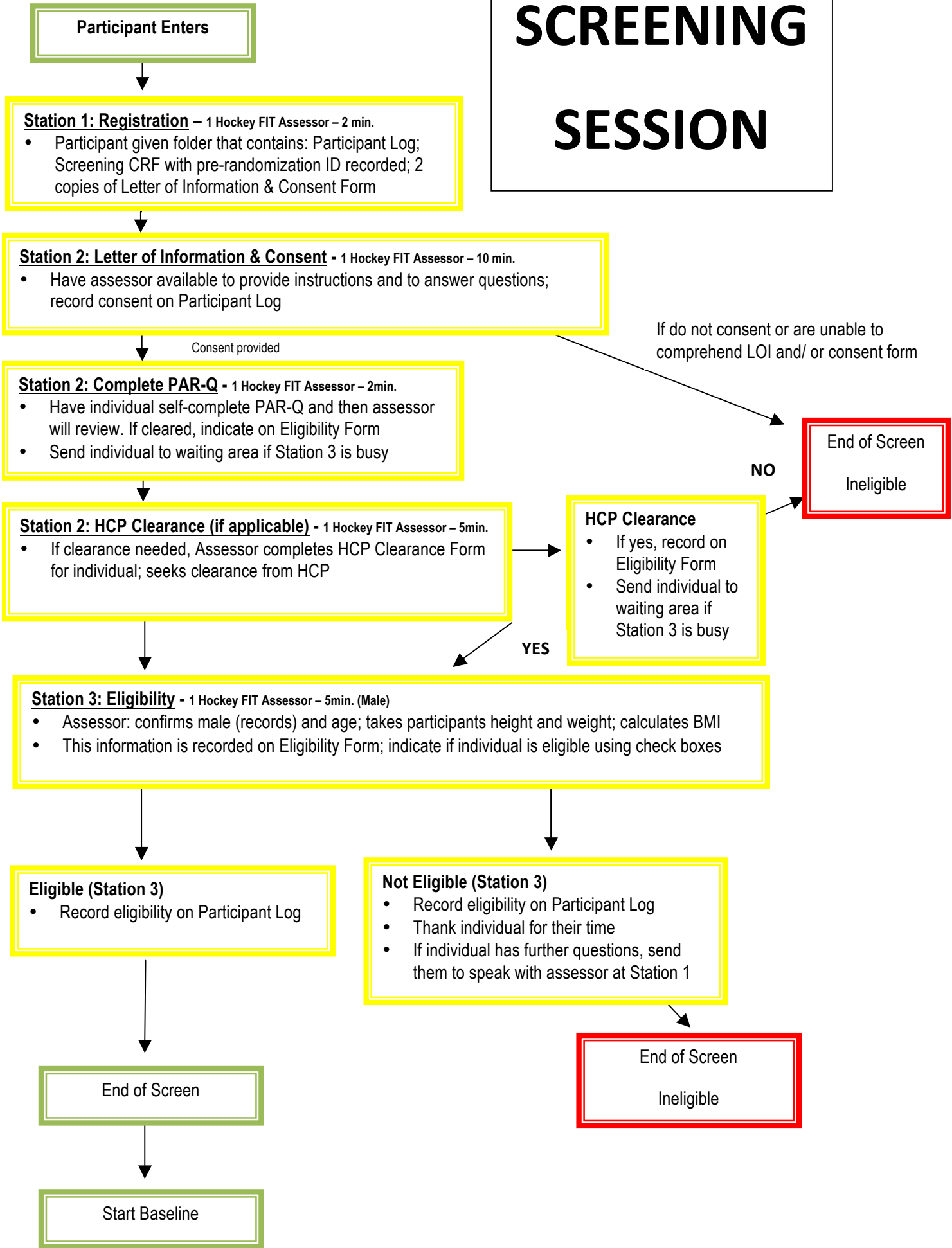


## References:

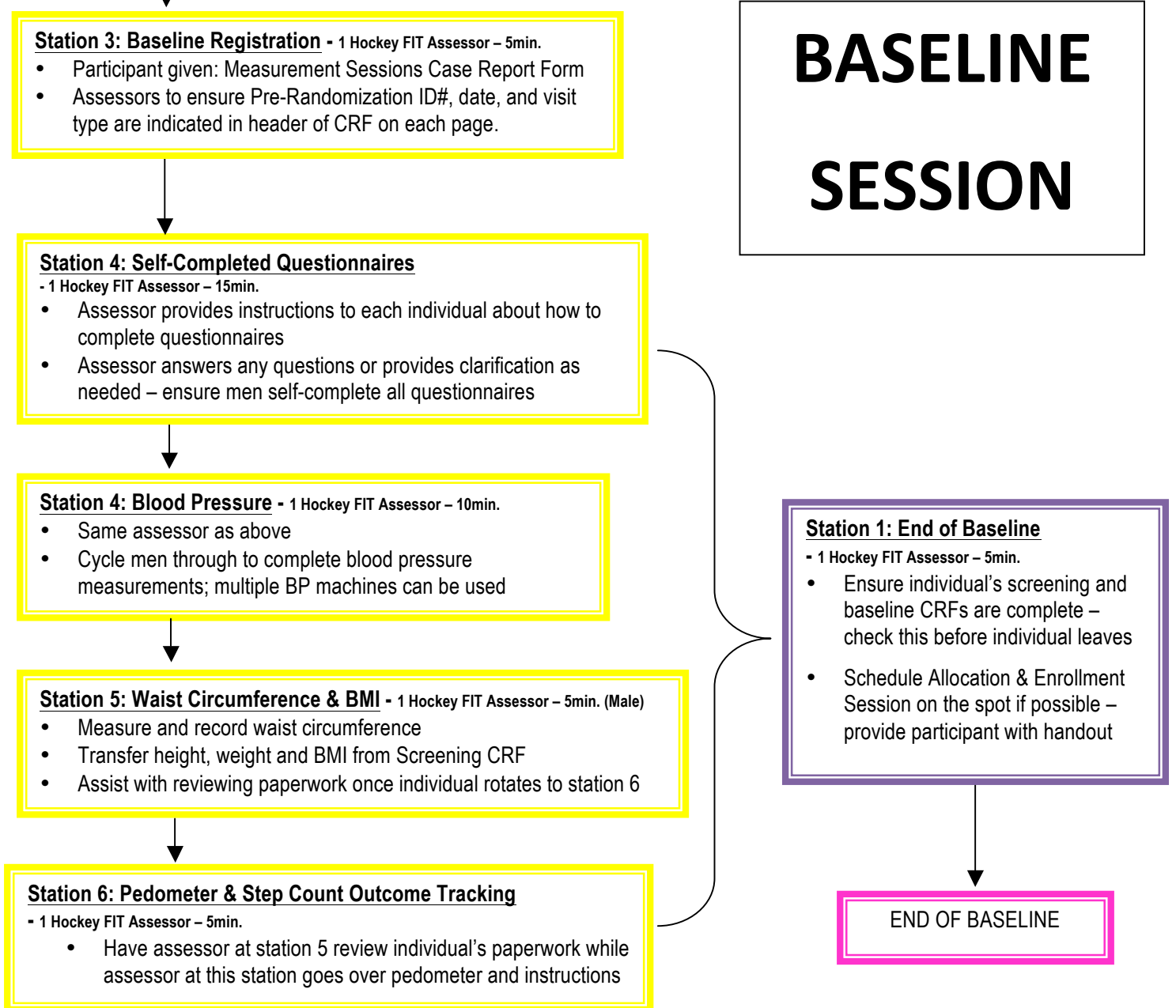
1. Ross WD, Marfell-Jones MJ. Kinanthropometry. In: MacDougall JD, Wenger HA, Green HJ, editors. *Physiological Testing of the High-Performance Athlete*. 2nd ed. Champaign, IL: Human Kinetics Books; 1991. pp. 223–308.
2. Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. *Medicine & Science in Sports & Exercise*. 2003 Aug;35(8):1381–95.
3. Paxton AE, Strycker LA, Toobert DJ, Ammerman AS, Glasgow RE. Starting The Conversation. *American Journal of Preventive Medicine*. Elsevier Inc; 2011 Jan 1;40(1):67–71.
4. Roe L, Strong C, Whitesdie C, Neil A, Mant D. Dietary Intervention in Primary Care: Validity of the DINE Method for Diet Assessment. *Family practice*. 1994 Jan 1;11(4):375–81.
5. Hunt K, Wyke S, Gray CM, Anderson AS, Brady A, Bunn C, et al. A gender-sensitised weight loss and healthy living programme for overweight and obese men delivered by Scottish Premier League football clubs (FFIT): a pragmatic randomised controlled trial. *Lancet*. 2014 Apr 5;383(9924):1211–21.
6. Rosenberg M. *Society and adolescent self-image*. Princeton, NJ: Princeton University Press; 1965.
7. Gray-Little B, Williams V, Hancock T. An Item Response Theory Analysis of the Rosenberg Self-Esteem Scale. *Personality and Social Psychology Bulletin*. 1997 Dec 15;23(5):443–51.
8. Thompson ER. Development and Validation of an Internationally Reliable Short-Form of the Positive and Negative Affect Schedule (PANAS). *Journal of Cross-Cultural Psychology*. 2007 Mar 1;38(2):227–42.
9. Dyer MT, Goldsmith KA, Sharples LS, Buxton MJ. A review of health utilities using the EQ-5D in studies of cardiovascular disease. *Health Qual Life Outcomes*. 2010;8(1):13.
10. Healthy waists [Internet]. Heart and Stroke Foundation of Canada; [cited 2015 Apr 9]. Available from: [http://www.heartandstroke.com/site/c.ikiQLcMWJtE/b.3876195/k.87BF/Healthy\\_Waists.htm](http://www.heartandstroke.com/site/c.ikiQLcMWJtE/b.3876195/k.87BF/Healthy_Waists.htm)
11. Canadian Guidelines for Body Weight Classification in Adults [Internet]. Health Canada; [cited 2015 Apr 14]. Available from: [http://www.hc-sc.gc.ca/fn-an/alt\\_formats/hpfb-dgpsa/pdf/nutrition/cg\\_quick\\_ref-ldc\\_rapide\\_ref-eng.pdf](http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/nutrition/cg_quick_ref-ldc_rapide_ref-eng.pdf)

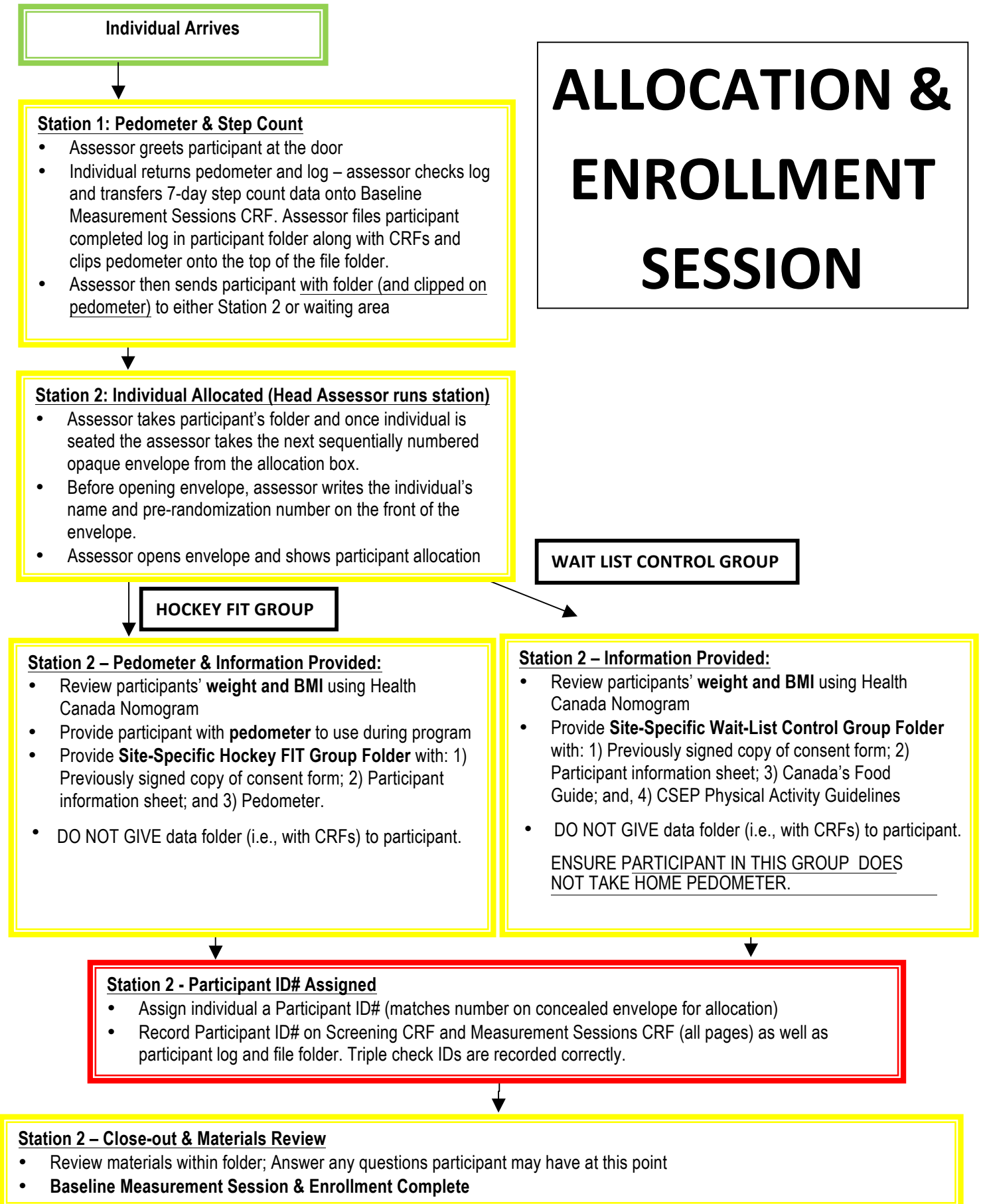
Appendix A: Diagram 1

# SCREENING SESSION



## Appendix A: Diagram 2





## Appendix B: Sample Scoring of EQ-5D

### 2. Scoring the EQ-5D-3L descriptive system

The EQ-5D-3L descriptive system should be scored as follows:

<p>By placing a tick in one box in each group, please indicate which statements best describe your health today.</p>		Levels of perceived problems are coded as follows:
<p><b>Mobility</b></p> <p>I have no problems in walking about <input checked="" type="checkbox"/></p> <p>I have some problems in walking about <input type="checkbox"/></p> <p>I am confined to bed <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Level 1 is coded as a '1'</p> <p><input type="checkbox"/></p>	
<p><b>Self-Care</b></p> <p>I have no problems with self-care <input checked="" type="checkbox"/></p> <p>I have some problems washing or dressing myself <input type="checkbox"/></p> <p>I am unable to wash or dress myself <input type="checkbox"/></p>	<p><input type="checkbox"/> Level 2 is coded as a '2'</p> <p><input checked="" type="checkbox"/></p>	
<p><b>Usual Activities</b> (e.g. work, study, housework, family or leisure activities)</p> <p>I have no problems with performing my usual activities <input type="checkbox"/></p> <p>I have some problems with performing my usual activities <input checked="" type="checkbox"/></p> <p>I am unable to perform my usual activities <input type="checkbox"/></p>	<p><input type="checkbox"/> Level 3 is coded as a '3'</p> <p><input checked="" type="checkbox"/></p>	
<p><b>Pain/Discomfort</b></p> <p>I have no pain or discomfort <input type="checkbox"/></p> <p>I have moderate pain or discomfort <input type="checkbox"/></p> <p>I have extreme pain or discomfort <input checked="" type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Level 3 is coded as a '3'</p> <p><input checked="" type="checkbox"/></p>	
<p><b>Anxiety/Depression</b></p> <p>I am not anxious or depressed <input checked="" type="checkbox"/></p> <p>I am moderately anxious or depressed <input type="checkbox"/></p> <p>I am extremely anxious or depressed <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/></p>	
<p><i>NB: There should be only <u>one</u> response for each dimension.</i></p>		

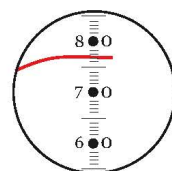
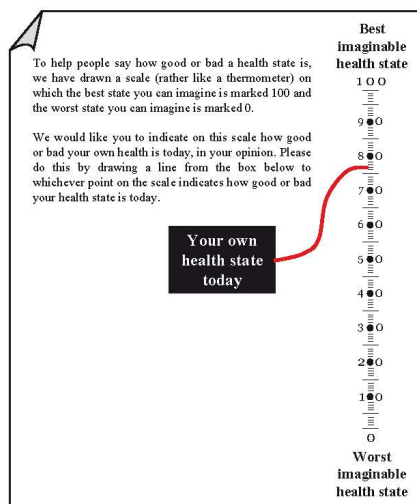
This example identifies the state 11232.

**NB: Missing values** can be coded as '9'.

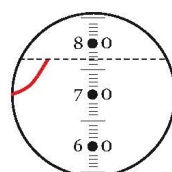
**NB: Ambiguous values** (e.g. 2 boxes are ticked for a single dimension) should be treated as missing values.

### 3. Scoring the EQ VAS

The EQ VAS should be scored as follows:



For example this response should be coded as 77



Even though the line does not cross the VAS this response can still be scored by drawing a horizontal line from the end point of the response to the VAS. In this example the response should be coded as 77

**NB: Missing values** should be coded as '999'.

**NB: Ambiguous values** (e.g. the line crosses the VAS twice) should be treated as missing values.