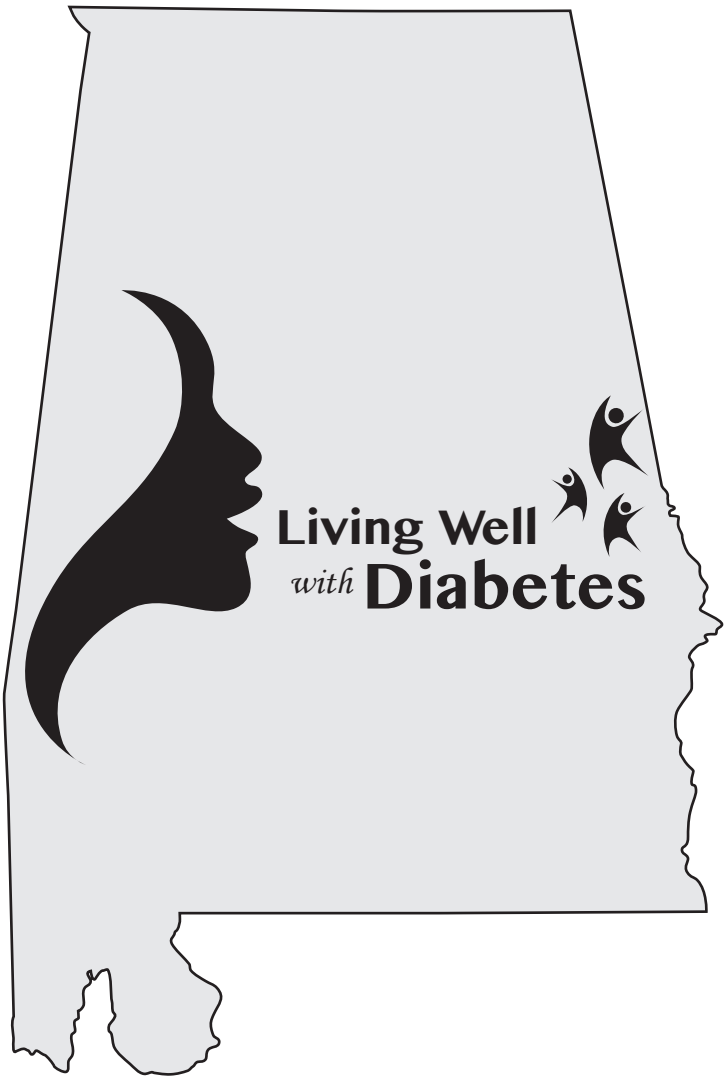
Appendix F. Biometric Protocol, Consent Form, In-Person Data Collection Form, Health Report Card

Anthropopomorphic and Biometric Measurements Protocol



Protocol Version 2016-March

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Introduction

The Living Well with Diabetes Study is a randomized controlled trial enrolling 500 participants in rural Alabama.

Your role of as a data collector is very important to this study. The information that you collect will help us better understand the day-to-day experiences of individuals living with diabetes and pain. The information will also determine what effects the program has on the health and well-being of study participants.

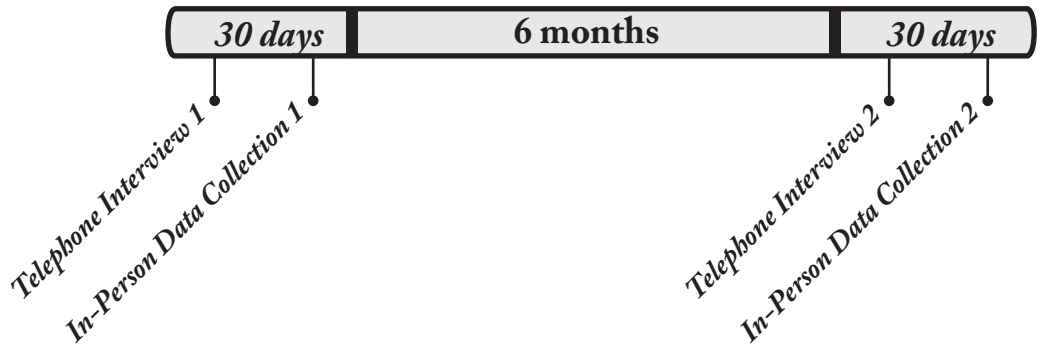
The information that you gather will help the study investigators make important decisions. The information that you gather will help us make important decisions. Therefore, we have to have confidence in the conclusions that we make. We get that confidence from knowing that the data was collected in a ***standard, reliable way***.

The in-person data collection will consist of 3 types of activitie:

- Gathering baseline measurements (blood pressure, A1c, LDL-Cholesterol, weight, height)
- Generating a participant medication list
- Providing the participant with their measurements in the form of a report card.

1. Baseline Measurements

Among the goals of the Living Well Study is to determine if the program improve HbA1c, blood pressure, weight, and physical function. These values will be measured at the beginning of the study and after the 12-week program.



Measurements on each participant will be made at a community venue or in the participant's home. Measurements will be made in a separate room or, at minimum, in an area properly screened from other participants. Participants should be wearing a loose fitting shirt that allows full access to the arm for blood pressure measurement.

If asked, the research assistant measuring and recording the values may tell the participant their values at the time of measurement. ***Remind the participant that they will receive a "report card" with the measurement values and an explanation of the values.***

2. Medication List

The investigators and Peer Advisors require an accurate list of all medications taken by the participants. The participants will be notified prior to the in-person data collection visit that you will making this list. You will be writing down the names, dosages, and frequencies of the participant's medications.

3. Report Card

Participants will receive a report card and an explanation of what the values mean in general terms.

This manual will provide details on how each of the activities should be completed. Since Living Well is a research study, we all all Biometric personnel to strictly follow these protocols so that we can be certain these measurements are accurate the precise.

Blood Pressure

It will take approximately 10-15 minutes to make two blood pressure measurements including the initial 5-minute rest. The BP measurements will be the first measurement taken during the in-person data collection visit.

1. Equipment and Supplies.

- LifeSource Blood Pressure Monitor (Model UA 789)
- Blood pressure cuffs (medium, large, extra large sizes)
- Tape measure
- Eyebrow pencil
- Chair with back support
- Table to rest arm

1.1. Maintenance of Equipment

With each use:

- Device is turned off at the completion of each participant's examination.
- Squeeze all air from the cuff
- Confirm that the connection of the cuff to the tubing is secure and tubing is not kinked.

Monhtly:

- Inspect cuff and tubing for cracks or tears. If a leak is suspeced, place the cuff around an unopened, full, 12-ounce can, start the monitor, and submerge the cuff in water. If there is a leak, air bubbles will start to rise from the area of the leak. Replace the cuff if a leak is detected.
- Wipe the exterior of the monitor with a clean cloth slightly dampened with mild detergents.
- Check the blood pressure cuffs to assure all sizes of cuffs are available.
- Inspect the measuring tape used to measure arm circumference for damage or wear.

2. Participant Preparation.

Participants should not drink any caffeine (from coffee, tea, or soda), should not eat or do any heavy physical activity, smoke, ingest alcohol for 30 minutes prior to recording the blood pressure.

2.1. Arm Circumference

The blood pressure is taken on the right arm. If the participant's right arm is injured or missing, or if the participant reports a compelling reason to avoid measurement in this arm, such as a mastectomy on the right side, use the left arm for the blood pressure measurement. Measure the participant's arm to determine the appropriate cuff size before allowing the participant to rest. Use the following procedures to measure the participant's arm and determine the appropriate cuff size:

- Proper measurement requires that the participant's arm is bare to the shoulder. The participant should be wearing a loose-fitting top.
- Request the participant to stand facing away from the examiner with the right elbow bent 90 degrees at the elbow with the hand on the stomach. The upper arm should be at a 90-degree angle to the lower arm.
- Measure arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow (olecranon process) using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm with an eyebrow pencil.
- Ask the participant to relax their arm along the side of the body.
- Wrap the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin. Make the measurement to the nearest 0.5 cm (round down).
- Use the measurement to determine the correct cuff size. Wipe pencil mark off participant's skin

Do not use the markings on the blood pressure cuff for reference. Instead, use the criteria in the chart below for determining the appropriate cuff size for the participant.

Arm Circumference		Cuff Size
24 - 35.5 cm	9.4 - 14.1 in	Medium Cuff
36 - 42 cm	14.2 - 16.5 in	Large Cuff
> 42 cm	> 16.5 in	Extra Large Cuff

3. Measurement Procedures.

The blood pressure can be measured after any period where the participant has been sitting quietly (no talking or completing forms) for 5 or more minutes, and at least 30 minutes after ingestion of caffeine. After applying the appropriate sized blood pressure cuff, the participant should sit for 5 minutes with his/her feet flat on the floor and legs and ankles uncrossed. Two blood pressure readings will be obtained.

3.1 Application of the cuff

- Ensure that the participant is seated comfortably in a chair with back supported and both feet are flat on the floor.
- Make sure that the participant's arm is resting on the table at a 90-degree angle with the palm facing up.
- Palpate the brachial artery.
- Mark the brachial artery with an eyebrow pencil.
- Attach the appropriate-sized cuff to the monitor by firmly inserting the Air Connector Plug of the blood pressure cuff into the Air Socket of the monitor.
- Place the cuff around the upper right arm, approximately at heart level, with the participant's palm facing upward (the participant may rest their forearm and elbow on a table or arm of the chair). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of the elbow.
- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area that it overlaps the cuff. You should be able to insert the first joint of two fingers under the cuff.
- If it is not feasible to measure blood pressure using the right arm, the left arm will be used. Mark which arm is used for the measurement on the Biometric Data Collection Form.

3.2 Performing the blood pressure measurement

- After the 5 minute rest, press "Start" on the monitor
- On the Data Form under "1st Reading" record: time, armed used (L or R), systolic value, diastolic value, pulse
- Allow 1 minute rest.
- Press "Start"
- On the Data Collection Form under "2nd Reading" record: time, systolic value, diastolic value, pulse
- Wipe pencil mark off participant's skin

3.3 Interruptions

If the blood pressure measurement is interrupt and requires the participant to move from the seated position, the participant will be required to repeat the 5-minute rest and another 2 blood pressures must be performed. 4.1 Training requirements

4. Quality Assurance

Clinical experience with blood pressure measurement is required. In addition, training should include:

- Read and study manual and data collection packet
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with program coordinator

4.2 Certification requirements

- Complete training requirements
- Explain and demonstrate daily and monthly checks of blood pressure monitor
- Explain procedure if measurement is interrupted
- Performs exam according to protocol

4.3 Quality assurance checklist

- Explains procedure
- Measures for cuff size
- Wraps cuff snugly, centering bladder over brachial artery
- Five minute rest period before measurement
- Records the systolic and diastolic readings as they appear on the digital display
- Deflates bladder
- Reviews forms for completeness
- Completes Data Collection Form appropriately

Acknowledgments:

- Women's Health Initiative Operations Manual. Volume 2, Section 9.2: Blood Pressure. 8/30/95.
- WHAS Operations Manual. Section 3.5 Blood Pressure Measurements. 6/18/93.
- MOST Operations Manual Vol. IV Chapter 3E, Version 1.0. 4/3/09
- Mr.OS Visit 3 Operations Manual Version 1.5. 07/25/2007

Obtaining Blood Samples

For the A1c measurement, blood samples will be collected. Instructions for the fingerstick are given here while instructions on use of the A1c machine and recording the data are in the following section.

1. Equipment and Supplies.

- Lancet
- Alcohol wipes
- Gauze
- Bandaid
- Gloves
- Sharps Container

2. Participant Preparation and Sample Collection.

- Put on gloves.
- Clean the participant's finger, just lateral to the fingertip pad with an alcohol wipe, and allow it to dry.
- (Use the lancet as direct). Accu-check Safe-T-Pro Plus Lancet directions: Holding the lancet, twist off the blue protective lancet cap. Press the lancet lightly against the cleaned lateral side of the fingertip. Press the blue button.
- Dispose of lancet in sharps container
- "Milk" finger by gently applying pressure from the base to the tip of the finger.
- Wipe away first drop of blood with gauze and use subsequent blood drops for testing.
- After sample is collected, apply light pressure with gauze. If needed, apply bandage.

3. Quality Assurance.

3.1 Training requirements

The technician requires no special qualifications for performing this assessment. Training includes:

- Read and study manual and data collection packet
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with program coordinator

3.2 Certification requirements

- Complete training requirements
- Explain procedure
- Performs exam according to protocol

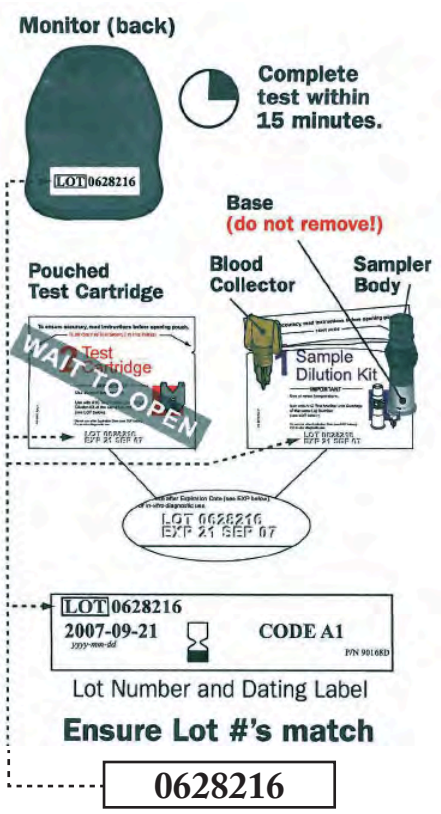
3.3 Quality assurance checklist

- Explains procedure
- Wears gloves
- Cleans finger with alcohol, correct use and disposal of lancet
- Obtains sample from lateral side of fingertip, wipes first drop of blood
- Ascertains bleeding has stopped

A1c Measurement

1. Equipment and Supplies.

- Alcohol wipe
- Gauze
- Bandaid
- A1cNow+ Test System (each system includes 3 items)
  - Monitor
  - 1. Sample Dilution Kit
  - 2. Test Cartridge



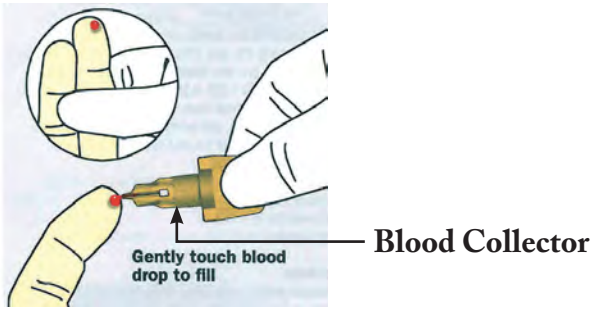
1.1. Before You Begin: Preparation of Test System

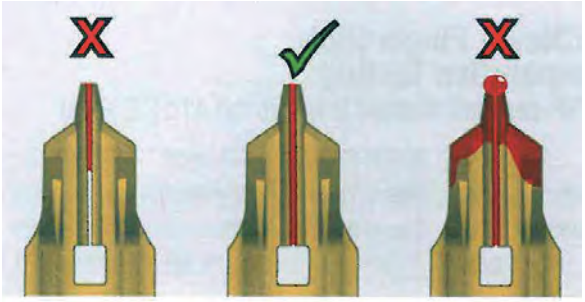
- Ensure all parts of the test kits are at the same temperature.
- All test parts are within the specified range. (Between 64 - 82 degrees F).
- NOTE: If the kit has recently been at high temperature (above 82 degress) or in the refrigerator, keep the kit at room temperature for at least one hour before use.
- NOTE: avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold. Quality control materials should be used to confirm the test kit is working properly. See Troubleshooting Section for more information.
- IMPORTANT! The Lot numbers should match the monitor, dilution kit, and test cartridge (DO NOT OPEN!).

2. Participant Preparation and A1c Measurement.

2.1. Collect Blood

- Use the lancet to draw blood.
- Wipe away the first drop of blood.
- Take blood collector and gently touch blood drop to fill.





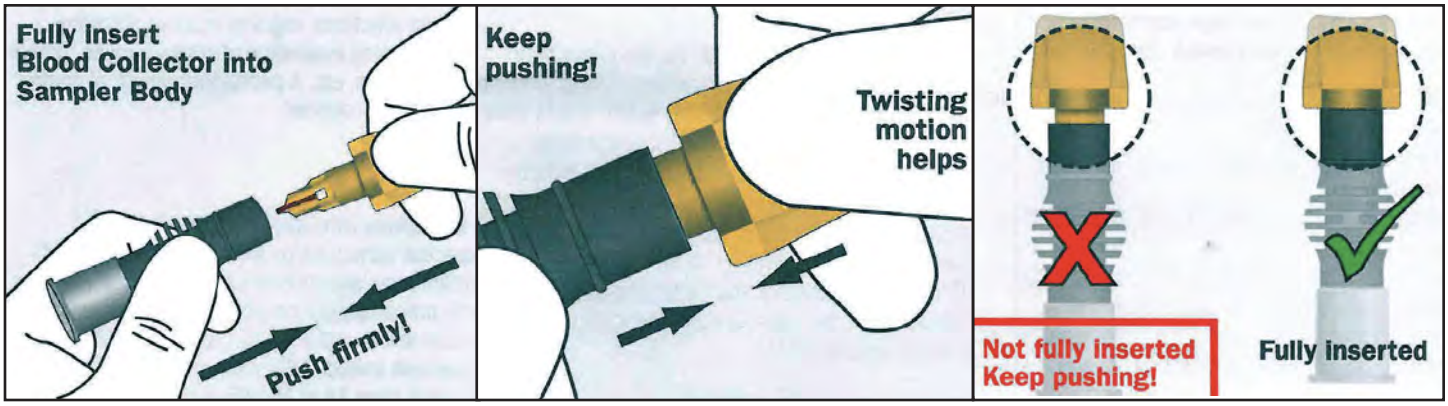
Too Little *Add More*

Just Right

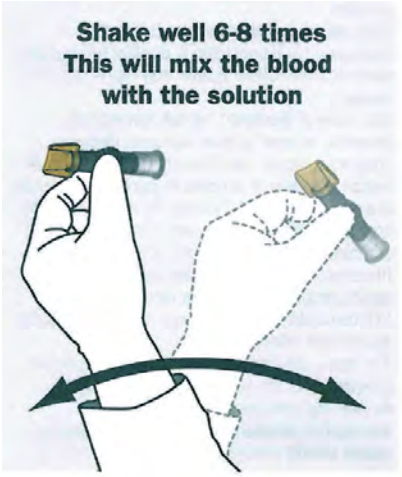
Too Much *Wipe Away*

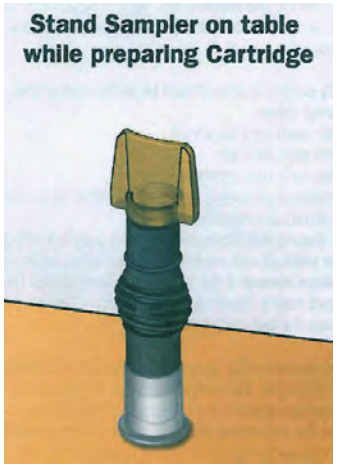
2.2. Insert Blood Collector

- Fully insert Blood Collector into Sampler Body.



- Shake well 6-8 times to mix the blood with the solution.
- Stand the sampler on the table while preparing the Cartridge.





2.3. Insert Cartridge

- Open the Test Cartridge packet now. IMPORTANT: Must use the cartridge within 2 minutes.
- "Click" Test Cartridge into place. Monitor and Test Cartridge codes must match.

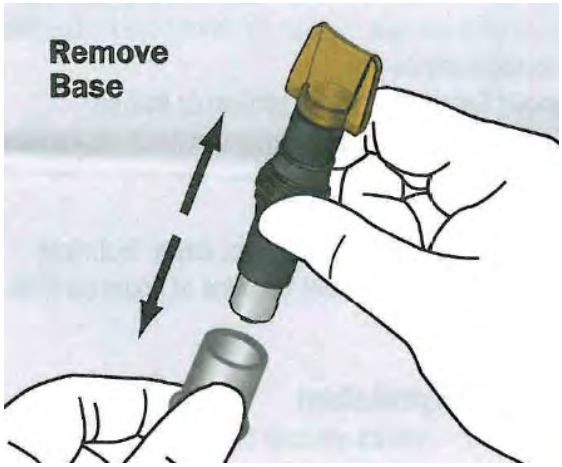
2.4. Prepare Monitor

- After clicking the test cartridge into place, monitor's display will say "WAIT".
- Wait until the display says "SMPL".
- When the display says "SMPL", the monitor is ready.

WAIT for SMPL to display

Ready for Sampler

- Ensure that the monitor is on a level surface.
- Remove the base from the blood collector.



2.5. Dispense Sample into Cartridge

- Push down the blood collector completely on the cartridge completely to dispense diluted sample. Remove quickly.
- IMPORTANT! Do not handle the monitor again until the test is complete.

Push down completely to dispense diluted sample Remove quickly

Do not handle Monitor again until test is complete!

2.6. Results

- It will take 5 minutes to display the results.
- The display will count down.
- After the 5 minutes, 3 items will be displayed.
  - "QCOK" - QC test result
  - "00.0" - A1c test result
  - "00TL" - Number of tests left
- This result cycle remains displayed for 60 minutes or until the next Test Cartridge is inserted.
- If "QCOK" is not displayed, please see the Troubleshooting section.
- Record A1c value in the data collection packet.

2.7. Troubleshooting

- See the table below for a description of A1cNOW+ operating and error codes.
- OR = Out of Range / QC = Quality Control / E = Monitor Error

Message	Description and Resolution
OR 1	The blood sample may have too little hemoglobin (less than 20% hematocrit), not enough blood was collected, or the blood was not well mixed inside the Sampler.* You may wish to check hematocrit by another method.
OR 2	The blood sample may have too much hemoglobin (greater than 60% hematocrit), or excess blood was collected.* You may wish to check hematocrit by another method.
OR 3	The blood sample may have too little A1C, or insufficient blood was collected.*
OR 4	The blood sample may have too much A1C, or excess blood was collected.*
OR 5	The Monitor temperature is below 180C (640F). Repeat the test at room temperature.
OR 6	The Monitor temperature is above 280C (820F). Repeat the test at room temperature.
<4.0	The %A1C is less than 4%.
>13.0	The %A1C is greater than 13%.
QC 2	Occurs when you insert a Test Cartridge that already has sample added to it. Do not remove and reinsert Test Cartridge after adding sample.*
QC 6	Sample was added to Test Cartridge before "SMPL" display. This counts down one test on the Monitor. Remove and discard Test Cartridge. To avoid this error, do not add sample until the "WAIT" prompt clears and "SMPL" appears.
QC 7	The Test Cartridge remained in the Monitor without sample addition for 2 minutes after "SMPL" prompt. This counts down one test on the Monitor. Discard the Test Cartridge and insert a fresh one when you are ready to dispense the Sampler.
QC 30-33	The Monitor was unable to obtain a valid initial reading. Be sure to remove the Sampler within one second after dispensing it into the sample port, and do not disturb the Monitor while the test is running. *
QC 50-51 QC 55-56	Insufficient sample was delivered to the Test Cartridge. To avoid this error be sure to fully insert the Blood Collector into the Sampler and shake immediately.*
All other QC codes	The quality control checks did not pass. Call Bayer Technical Support toll-free at 877-212-4968 x 1. The test will have to be repeated with another Test Cartridge and Sample Dilution Kit.
E1-E99	The Monitor has a Fatal Error. Call Bayer Technical Support toll-free at 877-212-4968 x 1.
**Carefully repeat the test using a new Test Cartridge and a new Sample Dilution Kit.*	

2.7. Reuse Monitor

- The Monitor is reusable (either 20 or 10 tests per test system).
- To run another test, use a new sampler and test cartridge from the same kit.
- Discard the test cartridge.

3. Quality Assurance.

3.1 Training requirements

The technician requires no special qualifications for performing this assessment. Training includes:

- Read and study manual and data collection packet
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with program coordinator

3.2 Certification requirements

- Complete training requirements
- Explain procedure and measure A1c on 2 volunteers according to protocol.

3.3 Quality assurance checklist

- Obtains sample per "obtaining blood sample" section of manual.
- Properly measures and records A1c measurementt.

3.4 Control

- Use liquid control solution to calibrate machine.
- Each A1CNow+ Monitor performs over 50 internal chemical and electronic quality control checks, including potential hardware and software errors (e.g. cartridge alignment, programming), and potential reagent strip errors (e.g. insufficient sample volume, invalid calculations). The Monitor has been programmed to report an error code if these quality checks are not passed.
- Quality control testing should be performed at the following times:
  - With each new shipment.
  - With each new lot.
  - With each new operator.
  - Whenever problems (storage, operator, instrument, or other) are identified.
  - To ensure that storage conditions have not affected the product, run a control sample before running a patient sample if the test kit has been stored for more than a month and it has been at least a month since the last control testing.
- The measured value should be within the acceptable limits stated for the control material. If the results obtained are outside the acceptable limit, please review the procedure and re-test the control material. If the measured value continues to fall outside the acceptable limit, please refrain from analyzing additional patient samples and contact Bayer Technical Support (877-212-4968).
- Good laboratory practices include a complete quality control program. This entails proper sample collection and handling practices, ongoing training of testing personnel, ongoing evaluation of control results, proper storage of test kits, etc. A permanent record of control results should be retained.

LDL Measurement

1. Equipment and Supplies

- CardioChek® Analyzer
- PTS Panels™ Test Strips
- Lot specific MEMo Chip™
- Sterile lancet
- Capillary blood collector or pipet
- Gauze
- Alcohol wipe

1.1 Maintenance

Each Day:

- Dampen a cloth with water and wipe the surfaces and the display area as needed. Be careful not to get the Test Strip Insert Opening (where the test strip is inserted) wet.
- Wipe the Test Strip Insert Opening with a clean, damp (not wet), lint-free tissue or cloth. Make sure the glass is very clean with no dust or fingerprints. The glass must be completely dry before running a test.
- Handle the gray Check Strip by the base of the plastic strip. Be careful not to scratch or damage the surface. Store the Instrument Check Strip in the analyzer carrying case when not in use. Do not store in the instrument.
- Check your analyzer with the Instrument Check Strip to verify proper functioning of the CardioChek's electronic and optical systems when:
  - You first receive it.
  - You drop the analyzer.
  - You get a result that is not expected.

How to Use the Instrument Check Strip:

1. Turn the analyzer ON by pressing either button.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. Press Enter when CK STRIP is displayed.
4. Insert the Check Strip, ribbed side up, into the Test Strip Insert opening when INSERT STRIP is displayed.
5. The analyzer should display PASSED. (If the display reads FAILED, see the NOTE at end of this section.)
6. Remove the Check Strip and store it in the analyzer carrying case.
7. Press Next until EXIT is displayed. Press Enter.
8. Press Next until RUN TEST is displayed.
9. Press Enter. The analyzer is ready to run tests.

Note — If the analyzer displayed FAILED:

1. Clean the CardioChek Test Strip Insert Opening (where the strip is inserted into the analyzer) with a soft, lint-free, damp cloth.
2. Inspect the Check Strip to make sure it is not dirty or damaged. Use the spare Check Strip and repeat.

2. Participant Preparation and Equipment Preparation

2.1 Participant preparation:

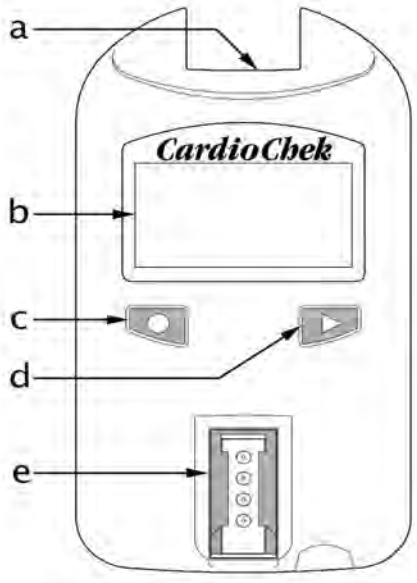
- Refer to “Obtaining Blood Samples” section of the protocol manual.

2.2 Equipment storage and operating conditions:

- Store the analyzer at room temperature (68-77°F) and 20-80% Relative Humidity.
- Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp or by a window. Direct light may adversely effect test results. If room temperature falls below 64.4°F, allow analyzer to warm up at least 30 minutes – 1 hour before testing.

2.3 Parts of the CardioChek Test System:

- CardioChek Analyzer



MEMo Chip Port (a)
The MEMo Chip Port is on the top of the analyzer. A lot specific MEMo Chip is inserted into this port.

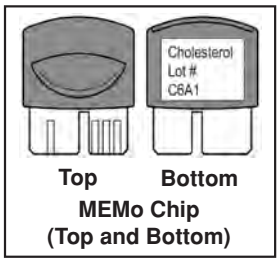
Display (b)
Display shows test results, messages, time, date, and stored results.

ENTER Button (c)
Press this button to turn the analyzer ON or to accept the current menu choice.

NEXT Button (d)
Press this button to turn the analyzer ON or to advance to the next menu option.

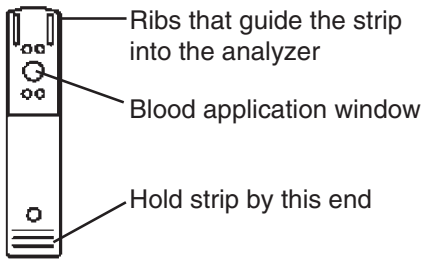
Test Strip Insert Opening (e)
The Test Strip Insert Opening is positioned in the lower front of the analyzer. The strip is inserted here with the raised lines facing up.

- MEMo Chip



MEMo Chip
The color-coded MEMo Chip contains the settings for each test. The top of the MEMo Chip has a finger notch. The bottom has a label with the test name and lot number.

- Test Strip



3. Measurement Procedures

3.1 Insert MEMo Chip

- Insert MEMo Chip with lot number that matches Test Strip vial lot number. Press either button to turn the CardioChek ON. Analyzer will display lot code.

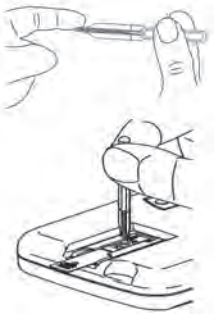
Insert MEMo Chip with finger notch (top) side up, lot number code facing down.

2.2 Insert Strip

- When INSERT STRIP is displayed, hold by the raised lines and insert strip into the analyzer as far as it will go.

2.3. Apply Sample

- When APPLY SAMPLE is displayed, apply whole blood sample with a capillary pipet to blood application window.
- Use the Test Strip and lancet one time only. Dispose of properly.



Obtain a blood sample with capillary pipet (to black mark).

2.4. Results

- Within two minutes the result will appear on the display. Remove and discard strip. Do not add more blood to a Test Strip that has been used.

IMPORTANT ***Do not leave a used Test Strip or Check Strip in the analyzer Test Strip Opening. This prevents the analyzer from automatically shutting down and shortens battery life.***

2.5. Record Value

- Using the appropriate form, record value and time on Biometric Data Collection Form next to “LDL”. Initial the technician space.

2.6. How to review results stored in memory

Test results are automatically stored in the analyzer's memory. CardioChek can store up to 30 results of each chemistry and at least 10 results of each control test. The analyzer allows review of the results in order from the most recent to the oldest. Each result is displayed with time and date. Results stored in memory are not deleted when the batteries are changed.

1. Press either button to turn the analyzer ON. If the display reads, INSTALL MEMO CHIP, go to Step 2. If the display reads, INSERT STRIP, press Enter.
2. Press Next until MEMORY is displayed.
3. Press Enter. CHEM is displayed.
4. Press Enter, then Next to select the desired chemistry. (Note: Until the chemistry has been run at least once, the test name is not displayed.)
5. Press Enter to view the test result including time and date.
   a. To recall Control results, press Next until EXIT is displayed. Press Enter. Press Next until CONTROLS is displayed.
   b. Press Enter when the desired Control test is displayed.
   c. For example, to review Lipid Panel results, from the CHEM display, press NEXT until LIPIDS is displayed, then ENTER. The time and date will be displayed. Press ENTER when the desired test time and date is displayed. Press NEXT to scroll through results.
6. To exit, press Next until the display reads EXIT, then press Enter. Repeat this step until you return to RUN TEST.

3. Quality Assurance

3.1 Training requirements

The technician requires no special qualifications for performing this assessment. Training includes:

- Read and study manual
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with local expert

3.2 Certification requirements

- Complete training requirements
- Measure LDL on 2 volunteers according to protocol

3.3 Quality assurance checklist

- Explains procedure
- Obtains sample per "Obtaining Blood Samples" section of manual
- Obtains adequate blood sample
- Properly inserts Test Strip into analyzer
- Properly applies blood to the Test Strip
- Records LDL value on the Biometric Data Collection Form appropriately
- Discards used Test Strip
- Removes and discards Strip prior to obtaining next sample

Acknowledgments:
CardioChek® Brand Analyzers User Guide. PS-002450E Rev. 0 (06/06).

Weight Measurement

1. Equipment and Supplies

- Homedics SC-540 LCD 400 lb/180 kg Capacity Bath Scale

1.1 Maintenance

- When not in use the scale should be set to “off”
- Do not store anything on top of the scale
- At the end of each day, and as needed, wipe exposed parts with soft, slightly damp cloth

1.2 Accuracy Check

- On a monthly basis, the scale should be checked against a known 50kg weight
- Notify principal investigator there is great than a 1.0 pound discrepancy

2. Participant and Exam Room Preparation

The scale should be placed on a level, uncarpeted floor. If bare floor is unavailable, firm, non-compressible carpeting (e.g., indoor-outdoor) is acceptable.

Weight is measured without shoes or heavy jewelry. Study participants will be encouraged to empty their bladders and/or bowels prior to the measurement.

3. Measurement Procedures

Script: *“The measurement that we are about to take is more accurate if you use the bathroom before we measure you. If you need to use the bathroom it is down the hall.”*

1) Ask participant to step on the scale, positioning feet evenly on the scale platform
2) Display will show “HI”
3) Ask participant to stay still while weight is determined
4) Display will flash and then show weight
5) Repeat to confirm reading
6) Record value on Biometric Data Collection Form next to “weight”

Note: if the on/off button is pressed prior to standing on the scale, the scale will be prepared to measure body composition. Press on/off or wait 30 seconds for the scale to turn off and follow instructions above.

If a participant requires support from a cane while being weighed, weigh yourself with and without the participant’s cane, etc., to determine its weight. Subtract the weight of the aid from the participant’s weight before recording. In the event that it is necessary for the examiner to support the participant during weighing, provide the minimum support that is safe.

Error messages on scale

Err	Weight Mode: unstable weight, begin again
0_Ld	Weight overload, remove weight immediately
Lo	Low battery, replace

4.1 Training requirements

The technician requires no special qualifications for performing this assessment. Training includes:

- Read and study manual
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with local expert

4.2 Certification requirements

- Complete training requirements
- Conduct exam on 2 volunteers

4.3 Quality assurance checklist

- Participant encouraged to use bathroom prior to measurement
- Explains procedure
- Measurement made without shoes, heavy jewelry, or other clothing
- Ensures that participant stands still in center of platform
- Completes Biometric Data Collection Form appropriately

Acknowledgments:
Mr OS Visit 3 Operation Manuals Version 1.0. 1/18/2007

Height Measurement

1. Equipment and Supplies

- Seca 214 Portable Stadiometer

2. Participant and Exam Room Preparation

Assemble Seca 214 Stadiometer by firmly inserting the height rod into the floor plate and affixing the horizontal arm to the height rod. The stadiometer should be placed on a level, uncarpeted floor. If bare floor is unavailable, firm, non-compressible carpeting (e.g., indoor-outdoor) is acceptable. There should be about a foot or more of unoccupied wall space on either side of the stadiometer.

The participant should be relaxed. He should also be barefoot or wearing thin socks or stockings. Ask the participant to remove any hairpiece or rearrange any hair styling that might interfere with firm contact between the headboard and the scalp.

3. Measurement Procedures

3.1 General Issues

To perform this measurement accurately, it is important that the recorder observe both the position of the participant and of the stadiometer. The participant should be instructed to avoid slouching and the stadiometer brought down in the midline of the head.

3.2 Administration

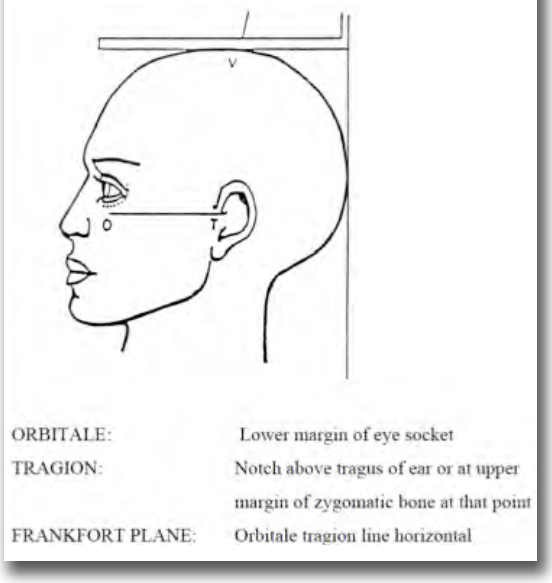
1) Have the participant stand in the center of the foot plate with their heels together and their back against the height rod. The back (scapulae), buttocks and both heels should be touching the height rod. Be sure that the participant maintains the correct posture during the measurement.

Script: *"Please stand with your back against the board mounted on this wall. Your legs should be together and your heels, your buttocks and your back should be touching the wallplate. Look straight ahead and stand tall." If necessary to achieve Frankfort Horizonal Plane: "Please raise/lower your chin."*

Note: The participant should be standing with head erect and in the Frankfort horizontal plane (see Figure 2), but, in general, the back of the head does not need to be in contact with the wall-plate. Check that the participant is in the correct position, starting with the heels and checking each point of contact with the wall-plate.

Check that the arms are relaxed and hanging loosely at the sides and that the shoulders are relaxed by running your hands over them and feeling the relaxed trapezius muscle. The head should be in the "Frankfort Horizontal Plane" in which the lowest point on the inferior orbital margin (orbitale) and the upper margin of the external auditory meatus (tragion) form a horizontal line (Figure 2). To verify that the head is in the Frankfort plane, hold the base of a clear plastic right angle (or T of a T-square) against the wall and make sure that the edge perpendicular to the wall is parallel to the "Frankfort Horizontal Plane".

Figure 2. Frankfort Plane for Measuring Body Height



2) Bring the horizontal bar down firmly onto the top of the participant's head. It may be necessary, upon occasion, to alter the hair styling of some of the participants for the horizontal arm to make contact with the top of the scalp.

3) Have the participant breathe in deeply. They should not alter their position by, for example, raising the heels off the floor as they breathe in.

   Script: *"Take a deep breath."*

4) Just before the participant exhales, note the reading on the stadiometer to the nearest 0.5cm (round down).

   Script: *"Breathe out."*

5) Have the participant step away from the stadiometer, then step back in to the measurement position. Repeat steps 1 - 4 and take a second measurement.

6) If the two measurements differ by ≥ 4 mm, take an additional two measurements.

7) Record value on Biometric Data Collection Form next to "height" in inches and centimeters.

3.3 Deviations and exceptions to standard positioning:

Obese participants and those with a kyphotic posture may be unable to place heels, buttocks, and scapulae in a single vertical plane. These participants may be positioned so that only the buttocks, and possibly the scapula, are in contact with the wall-plate. The essential point is that the participant stand erect with the buttocks in contact with the wall plate and the legs as close together as possible. In very obese participants, if it is not possible to obtain contact between the headboard and the top of the skull, then the participant may need to lean back slightly (without tilting the head) until proper contact can be made.

For participants with severe spinal curvature, if the spine protrudes farthest, then that should be the part that is touching the wall plate, together with heels and buttocks. For participants with extreme kyphotic posture, it may not be possible to obtain contact between the headboard and scalp when the participant's back is against the wall-plate. In this case, measure height with the participant standing sideways (side of arm and shoulder in contact with the wall-plate) and positioned so that the headboard contacts the scalp. If the participant has 'knock-knees' then have them separate the heels so that the knees are in contact but do not overlap. Obese participants may also not be able to stand comfortably with the heels touching and may stand with the legs together and the heels separated.

4. Quality Assurance

4.1 Training requirements

The technician requires no special qualifications for performing this assessment. Training includes:

- Read and study manual
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with local expert

4.2 Certification requirements

- Complete training requirements
- Conduct exam on 2 volunteers

4.3 Quality assurance checklist

- Correct assembly of Seca 214 Stadiometer
- Explains procedure
- Hairpiece removed, hair style altered, if necessary
- Checks that heels are together
- Checks for heels, buttock, scapula touching wall-plate (all touching if possible)
- Two more measurements made if first two differ by ≥ 4 mm
- Completes Biometric Data Collection Form appropriately

Acknowledgments:
Mr OS Visit 3 Operation Manuals Version 1.0 1/19/2007

Medication List

The investigators and Peers require an accurate list of medications taken by the participants. This is a seemingly simple task, but can actually be challenging because participants may bring in medications they no longer take, not bring their insulin, take their medications in a way different than written on the prescription, or not bring their medications with them. There are special instructions for aspirin and insulin below.

The biometrics personnel must:

1. Generate as accurate a medication list as possible
2. Keep one copy for the researchers, make a copy for the participant, and if the participant is assigned a Peer, make a copy for the Peer

1. Instructions

If the participant has brought their medications, check the "Yes" box next to "Brought Medications" and for each medication:

1. Ask if the participant takes that medication
2. Ask if the participant take it as it is written on the prescription bottle.
   This is not meant to be a negative question and should not be asked in a way that assumes non-adherence. Sometimes doctors prescribe twice the dose and ask the patient to cut it in half to save the patient money, or they write for it to be take daily even though the patient only takes it "as needed" so that a "one month" supply lasts longer.
3. Record the medication (start on the #1 line, unless the medication is aspirin or insulin)
   a. Name
   b. Dose
   c. How often taken
4. Ask if the patient takes any other medications, either prescription or over-the-counter
   a. If so, follow directions for participant's who did not bring their medications (below)
5. If aspirin has not already been documented, ask if the patient takes aspirin
   a. If not, check the "no" box next to "Aspirin"
   b. If so, check the "yes" box follow and directions for aspirin (below)
6. If insulin has not already been documented, ask if the patient takes insulin
   a. If not, check the "no" box next to "Insulin"
   b. If so, check the "yes" box and follow directions for insulin (below)

Brought medications	☐ No	☐ Yes		
Aspirin	☐ No	☐ Yes	81 mg per day or _____ *(circle)*	☐ from memory
Insulin	☐ No	☐ Yes		

If the participant did not bring their medications check the "no" box next to "brought medications" and:

1. Ask if the participant knows his/her medications
   a. If yes, write down as much as the participant knows of the medications'
      i. Name
      ii. Dose
      iii. How often take
   b. Check the "From memory" box on each line in which the medication information is based solely on participant recall
2. Prompt for prescription, over-the-counter medication, aspirin, and insulin.

Aspirin, people often do not consider aspirin as a real medication and they often do not bring it with them. So the top of the Medication List has a space specifically to prompt about aspirin. Most people with diabetes should be taking an aspirin and most will be taking 81mg daily.

1. If the participant brought aspirin, check the "yes" box next to "Aspirin" and
   a. circle "81mg per day" if correct
   b. or cross out "81mg per day" and write in the dose/frequency the patient is taking
2. If the participant did not bring aspirin ask if the participant takes aspirin and check the boxes accordingly

Insulin, since insulin is stored in a glass vial and in the fridge, participants often forget to bring their insulin. And the directions are often not written on the insulin, so you will have to ask the participant how the insulin(s) are taken. Most people take one or two types of insulin (insulin names are listed below). We have left 3 lines for insulin at the top of the medication list.

1. Ask if the participant takes insulin and check the appropriate box.

If "yes",

2. If the participant brought insulin(s)
   a. Write the name
   b. Ask how much and how often the insulin is injected
      i. If the participant knows, record and do not check the "From Memory" box
      ii. If the participant does not know either the dose or the frequency
         1. Record what the participant does know
         2. Write "?" for information the participant doesn't know
         3. Check the "From Memory" box

3. If the participant did not bring insulin,
   a. Ask if the participant knows the type, dose, and frequency of insulin(s) taken
      i. If participant knows all 3, record and do not check "From Memory" box
      ii. If the participant does not know
         1. Record what the participant does know
         2. Write "?" for information the participant doesn't know
         3. Check the "From Memory" box
         4. You may prompt participant with names of different insulins if he/she thinks that will help them remember

4. Sliding scales. Some participants may not be on a fixed insulin dose, but may take a different amount of insulin depending on their glucose reading. Those people usually are also taking a fixed-dose long-acting insulin. Record the fixed doses and write S/S for sliding scale (example on next page). Do <u>not</u> check "From Memory" box.

5. Insulin pump. Some participants may be using an insulin pump. We do not need dosages or frequencies for those participants (example on next page). Do not check "From Memory" box, even if they do <u>not</u> know the name of the insulin in their pump.

Types of Insulins, trade name (and generic name)

<u>Combination insulins usually taken once or twice per day</u>

- Humalin 70/30 (NPH/regular insulin)
- Humalin 50/50 (NPH/regular insulin)
- Novalog 70/30 (insulin aspart protamine/ insulin aspart)
- Humalog 50/50 (insulin lispro protamine/ insulin lispro)
- Humalog 75/25 (insulin lispro protamine/ insulin lispro)

<u>Long-acting insulins usually taken one or twice per day</u>

- Humalin N (NPH insulin)
- Novalin N (NPH insulin)
- Lantus (insulin glargine)
- Levemir (insulin detemir)

<u>Short-acting insulins usually taken several times per day or used in an insulin pump</u>

- Humalin R (regular insulin)
- Novalin R (regular insulin)
- Humalog (insulin lispro)
- Novalog (insulin aspart)
- Apirdra (insulin glulisine)

Knows the name and frequency, but not the dose

	medication	dose	frequency	notes	from memory
insulin	70/30	?	Twice a day		X
					☐
					☐

Knows frequency and dose, but not the name

	medication	dose	frequency	notes	from memory
insulin	?	10 units	at night		X
	?	5 units	with meals		X
					☐

Only knows dosage

	medication	dose	frequency	notes	from memory
insulin	?	10 units	?		X
					☐
					☐

Only knows frequency

	medication	dose	frequency	notes	from memory
insulin	?	?	twice a day		X
					☐
					☐

Sliding scales

	medication	dose	frequency	notes	from memory
insulin	Lantus	20 units	every night		☐
	Novolog	s/s	twice a day		☐
	Novolog	s/s	as needed		☐

Insulin pump and doesn't know the type of insulin

	medication	dose	frequency	notes	from memory
insulin	?	pump	pump		☐
					☐
					☐

3. Quality Assurance

3.1 Training requirements

The technician requires no special qualifications for performing this assessment. Training includes:

- Read and study manual
- Attend Living Well training session on techniques
- Practice on other staff or volunteers
- Discuss problems and questions with local expert

3.2 Certification requirements

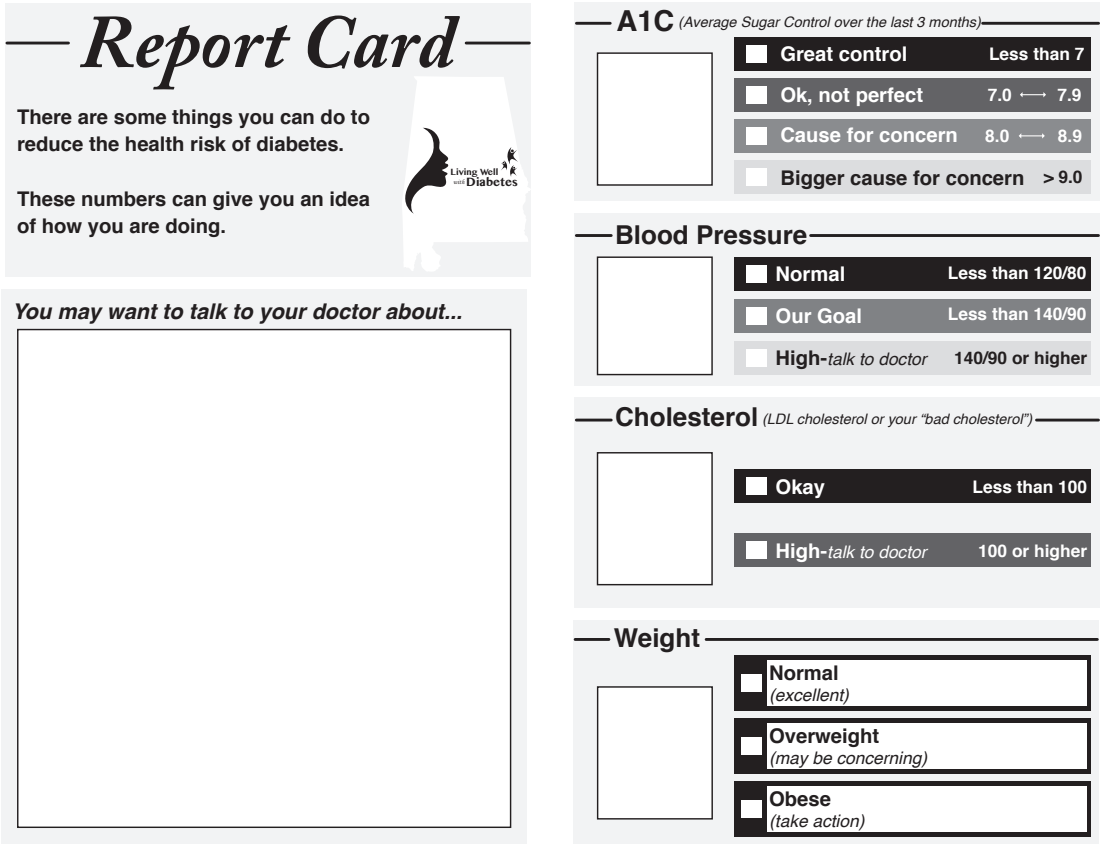
- Complete training requirements
- Generate a medication list for 2 volunteers according to protocol

3.3 Quality assurance checklist

- Ascertains if the participant brought his/her medications
- Ascertains if the participant takes his/her medications as written on the bottles
- Probes for over-the-counter, aspirin, and insulin use
- Gathers as much information as possible if participant did not bring medications
- Checks the “from memory” box when the participant did not bring medications
- Completes Medication List form appropriately

Report Card

The participants will receive a report card providing the results from the biometrics exam. Biometrics personnel will also provide basic interpretation of the values, but in depth questions need to be referred to the participant's physician.



Report Card

There are some things you can do to reduce the health risk of diabetes.

These numbers can give you an idea of how you are doing.

Living Well with Diabetes

You may want to talk to your doctor about...

A1C *(Average Sugar Control over the last 3 months)*

☐ Great control	Less than 7
☐ Ok, not perfect	7.0 ⟷ 7.9
☐ Cause for concern	8.0 ⟷ 8.9
☐ Bigger cause for concern	> 9.0

Blood Pressure

☐ Normal	Less than 120/80
☐ Our Goal	Less than 140/90
☐ High-*talk to doctor*	140/90 or higher

Cholesterol *(LDL cholesterol or your "bad cholesterol")*

☐ Okay	Less than 100
☐ High-*talk to doctor*	100 or higher

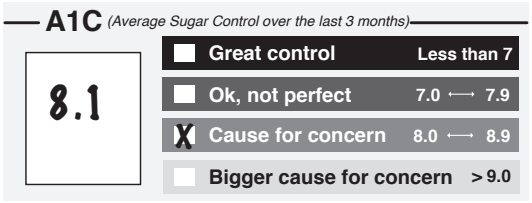
Weight

☐ **Normal** *(excellent)*
☐ **Overweight** *(may be concerning)*
☐ **Obese** *(take action)*

1. Completing the Report Card

1) A1c

- Transcribe the A1c value from the Biometric Data Collection Form onto the Report Card
- Place a check mark in the appropriate box (if A1c < 7.0 great control, 7-7.9 okay, 8-9 Concerning, and >9 bigger concern).



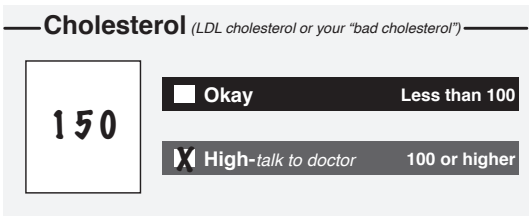
A1C *(Average Sugar Control over the last 3 months)*

8.1

☐ Great control	Less than 7
☐ Ok, not perfect	7.0 ⟷ 7.9
☒ Cause for concern	8.0 ⟷ 8.9
☐ Bigger cause for concern	> 9.0

2) LDL

- Transcribe the LDL value from the Biometric Data Collection Form onto the Report Card
- Place a check mark in the appropriate box.



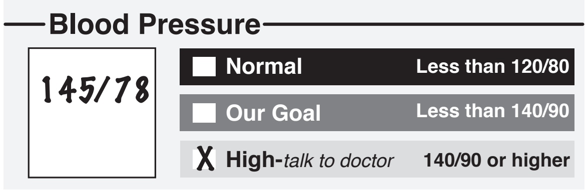
Cholesterol *(LDL cholesterol or your "bad cholesterol")*

150

☐ Okay	Less than 100
☒ High-*talk to doctor*	100 or higher

3) Blood Pressure

- Transcribe the lowest of the 2 research blood pressure reading values from the Biometric Data Collection Form onto the Report Card.
- Use the systolic value to determine the blood pressure category and place a check mark in the appropriate box (if SPB < 120 normal, <140 our goal, and >140 High)



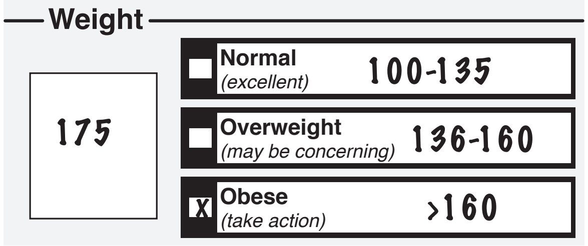
Blood Pressure

145/78

☐ **Normal** Less than 120/80
☐ **Our Goal** Less than 140/90
X **High**-*talk to doctor* 140/90 or higher

4) Weight

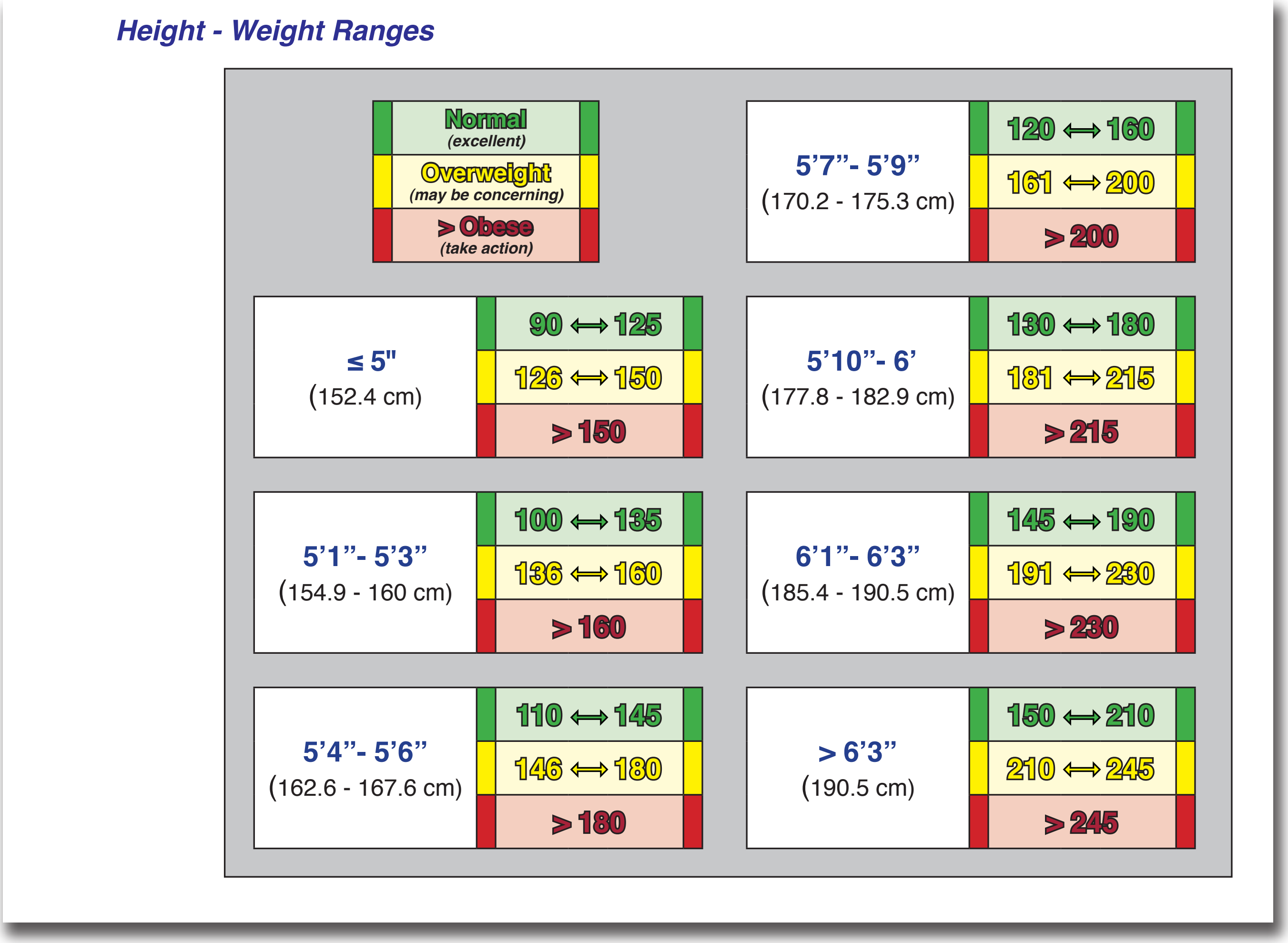
- Transcribe the weight in pounds from the Biometric Data Collection Form onto the Report Card.
- Find the participant's height on the Height-Weight Reference Sheet and write the ranges next to Normal, Overweight, and Obese.
- Place a check mark in the appropriate box for Normal, Overweight, and Obese.



Weight

175

☐ **Normal** *(excellent)* 100-135
☐ **Overweight** *(may be concerning)* 136-160
☒ **Obese** *(take action)* >160



Height - Weight Ranges

Height	Normal *(excellent)*	Overweight *(may be concerning)*	> Obese *(take action)*
≤ 5" (152.4 cm)	90 ⟷ 125	126 ⟷ 150	> 150
5'1"- 5'3" (154.9 - 160 cm)	100 ⟷ 135	136 ⟷ 160	> 160
5'4"- 5'6" (162.6 - 167.6 cm)	110 ⟷ 145	146 ⟷ 180	> 180
5'7"- 5'9" (170.2 - 175.3 cm)	120 ⟷ 160	161 ⟷ 200	> 200
5'10"- 6' (177.8 - 182.9 cm)	130 ⟷ 180	181 ⟷ 215	> 215
6'1"- 6'3" (185.4 - 190.5 cm)	145 ⟷ 190	191 ⟷ 230	> 230
> 6'3" (190.5 cm)	150 ⟷ 210	210 ⟷ 245	> 245

6) You may want to talk to your doctor…

- Write the conditions which are in the "concerning" or "take action" ranges.

2. Interpreting Values for Participants

Living Well personnel should provide the results of the biometric measurements and explain what the numbers mean. Their role is not to provide medical advice. If participants have questions beyond the explanation of the values and the risks that may be associated with elevated values, participants should be instructed to talk to their health care providers. Below are suggested explanatory scripts.

1) A1c

Read the following text until the participant's A1c range is reached. For example, read the first 3 bullets for someone with an A1c of 6.5.]

A1c, also called hemoglobin A1c or glycosylated hemoglobin, indicates how well a person's diabetes is controlled. A1c is a blood test that indicates a person's glucose level over the last 2-3 months. Doctors order this test once a year if a person has excellent control of their diabetes and every 3 months when diabetes is not well controlled.

- People without diabetes have an A1c of about 5.
- A person with diabetes who has an A1c less than 7 is under excellent control. Their risk for diabetic complications such as damage to the blood vessels in the eyes, kidneys, heart, and brain (which can cause blindness, kidney failure, heart attack, and stroke) is low.
- Experts agree that when a person has an A1c from 7 to 8, they should do something. It may be changing their diet and exercise, starting medication, or increasing medication.
- A person with an A1c greater than 8 has poorly controlled diabetes. They are at risk for complications of diabetes. Experts recommend people with poorly controlled diabetes should have their medications increased or new medications should be started.

2) Blood pressure

Having high blood pressure, or hypertension, is especially troublesome when a person has diabetes. Research has shown that in people with diabetes, to protect the heart, kidneys, and brain, it is more important to control blood pressure than to control glucose. For this reason, experts suggest lower blood pressure goals for people with diabetes compared to people without diabetes. Doctors should check blood pressure at every visit.

- Although we look at both the top number, the systolic blood pressure, and the lower number, the diastolic blood pressure, a person's risk for complications is more associated with systolic blood pressure
- Your systolic blood pressure is [read only the statement coinciding to the participant's value]
  - o less than 120. So you don't need to be doing anything more than what you are already doing.
  - o less than 140 is your goal. Keep checking your blood pressure regularly, and if it goes over 140, you should speak with your doctor.
  - o greater than 140. Experts suggest that you and your doctor should take some action to decrease your blood pressure.

NOTE*: In the event of a hypertensive participant, the following protocol will be taken.*

- *Any participant with a blood pressure reading between 140/90 – 159/99 will be advised to talk to their doctor about their high blood pressure at their next visit with their doctor.*
- *Any participant with a BP reading between 160/100 – 179/109 will be advised to call their doctor on the same day if possible.*
- *For participant with a BP ready over 180/110, the research staff will stop and call Dr. Cherrington. Dr. Cherrington will speak with the participant develop a plan for the participant to obtain immediate medical attention.*

3) Weight

The weight ranges on this card are for a person of your height. Obesity makes it harder to control diabetes and places a person at increased risk for several medical problems including high blood pressure, arthritis and even some cancers. [Read only the statement coinciding to the participant's value.]

- Your weight is in the "normal" range for your height. This is considered a healthy weight. Starting or continuing healthy habits now can help prevent future weight gain and help you to maintain this healthy weight.
- Your weight is in the "overweight" range, which puts a person at higher risk for going on to become obese. Fortunately, incorporating healthy behaviors now can help prevent future weight gain.
- Your weight is in the "obese" range. The extra weight makes it is harder to control diabetes and increases the risk of heart disease and other diseases. Fortunately medical studies have shown that even a drop of 5% of body weight can lower the risk for developing many of these problems.

4) You may want to talk to your doctor…

- If all values are in the "Excellent/Good" ranges: You are doing great. You may want to talk to your doctor about healthy habits to keep yourself healthy.
- [*Read list of conditions in the "Concerning/Take Action" ranges.*]

REMINDER

Living Well personnel should not offer medical advice. If participants have questions more in depth than what has been stated in this script, they should be referred to their doctors.

Consent Form

CONSENT FORM

TITLE OF RESEARCH:	Living Well (Improving Medication Adherence in the Alabama Black Belt)-AIM 2
IRB PROTOCOL NO.:	X160301010
INVESTIGATOR:	Andrea Cherrington, MD MPH
SPONSOR:	Patient Centered Outcomes Research Institute (PCORI)
SPONSOR PROTOCOL NO.:	AD-1306-03565

Purpose of the Research

We are asking you to take part in a research study. This research study will test if Peer Advisors can help patients with diabetes better care for his or her diabetes to improve blood sugar levels, blood pressure, and quality of life. Peer advisors come from the same community as participants and have been trained to help people with diabetes. This study will enroll 500 participants. 250 participants will work with a peer advisor for 6 months and 250 participants in the general education group will receive health education videos. Which program you receive will depend on a random assignment process.

Explanation of Procedures

If you agree to participate in this study, you will be asked to take part in a telephone interview with a UAB study research assistants that will last approximately 45-60 minutes. During this call, you will be asked questions about you, your diabetes, your overall health, and topics related to your health such as your doctor, health care access, health knowledge, and current health behaviors. You do not have to answer any questions that you don't want to or that make your feel uncomfortable.

After the telephone interview, you will be asked to complete an in-person data collection visit that will last approximately 45-60 minutes. The data collection will be scheduled within 30 days of completing the telephone interview. The data collection visit will be conducted at a location in your community or in you home, depending of your preference. During the in person data collection visit, trained UAB study research assistants will conduct the following activities:

1. Test your blood sugar levels and your cholesterol levels by drawing blood from your finger
2. Measure your blood pressure 2 times
3. Measure your weight and height.
4. Make a list of all of your medications, including the doses and the frequency that you take the medicines.
5. Give you a health report card that provides you with the results of your blood sugar levels, cholesterol levels, blood pressure, and your weight.

Wearing a loose fitting shirt is recommended to the in-person data collection visit so that we are able to measure your blood pressure. We ask that you do not to not drink any caffeine (from coffee, tea, or soda), do not eat or do any heavy physical activity, smoke, ingest alcohol for 30 minutes prior to the in person data collection visit.

After the in-person data collection visit, you will start your 6-month program. You will receive one of two programs. Which program you receive will be determined by chance.

The first program is called the General Health Program. If you receive this program, you will receive health education videos. The videos cover the following topics: Dementia and Alzheimer's, Breast Cancer, Colorectal Cancer, Osteoporosis and Fall Prevention, Eye Health, Oral Health, Foot Care, and Driving Safety. The videos last between 15 to 30 minutes. If you are in this program, UAB study staff will call you on the phone 3 times during months 1, 3, and 5 to make sure the program is going well and to answer any questions you may have. These calls will last around 5 minutes. You will also receive post cards from UAB staff during months 2, 4, 6, and for holidays.

The second program is called the Living Well Program. In this program, you will be matched with a peer advisor. The peer advisor you are matched to depends on yours and peer advisor's availability. Your peer advisor will contact you on the phone within 2 weeks. You will watch videos that cover the following topics: diabetes basics, healthy eating, physical activity, stress reduction, and diabetes, cholesterol, blood pressure medications. The videos last between 20 to 40 minutes. You will then talk with your peer advisor on the phone using your study activity goal. During the phone calls with your peer advisor, you will set health goals and talk about the content covered in the videos. You will speak weekly for the first 8 weeks, bi-weekly for 1 month, and 1-3 times for month for the final 3 months. For the first 3 months, the calls with your peer advisor will last between 30-45 minutes. For the months 3-6, the calls with your peer advisor will last between 10-15 minutes. The total number of times and your peer advisor speak will be determined by you and your peer advisor but you will talk with your peer advisor around 13-16 times. If you are in this program, UAB study staff will call you on the phone 2 times during months 2 and 5 to make sure the program is going well and to answer any questions you may have. These calls will last around 5 minutes. You may also receive postcards from UAB staff for holidays. Finally, if you are in this program, you have the choice to use a study telephone. This phone will be yours to use for the 6 months when you are talking with your peer advisor. We ask that you only use the phone to talk with your peer advisor. You will need to return the phone to UAB after you finish the study. If you would like to use a study phone, the phone will be provided to you during the in person data collection visit. You will return the phone to UAB at the second in person data collection visit.

After 6 months, all participants in both programs will be asked to participate in a second in person data collection visit and a telephone interview. During month 6, UAB study staff will call you by telephone to schedule the in person visit and the telephone interview. The same information and tests will be collected during the second in person data collection visit as we

collected in the first in person visit. We will measure your blood sugar levels, cholesterol levels, two blood pressure measurements, and your weight and height. We will make another list of your medications, doses, and frequency. You will also receive a health report card with your measurements. At the second telephone interview, we will ask you many of the same questions that we asked at the first interview. The in-person data collection visit and phone interview will each take 45-60 minutes.

Risks and Discomforts

The risks in this study are minimal. There is a potential for loss of confidentiality. You may experience discomfort or pain during the blood test and may experience temporary redness and soreness on your finger. It is possible that your numbers may be high or low when we test them. A doctor or nurse will be available by phone to help you address any concerns you may have.

If you are working with a peer advisor, it is possible that the peer advisor may not always know the right answer. The study investigators will be helping the peer advisors and meeting with them weekly. Peer advisors are trained by study investigators. So the chance of the peer advisor giving you the wrong information is very small. If any time you have concerns, you can contact Dr. Cherrington.

You will be assigned to a program by chance, which may prove to be less effective than the other study group or available information.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat diabetes better in the future. You will receive a "health report card" at the data collection visits that tells your blood sugar number, cholesterol number, blood pressure, and weight.

Alternatives

The alternative to this study is not to participate and continue your routine diabetes treatment.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of PCORI and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.

Some of your sessions with your peer advisors may be audio recorded. A study investigator will listen to these recordings to make sure that the peer advisor is conducting the sessions correctly. The recordings will be kept in a secure place, a locked cabinet in a locked office suite at UAB until they are listened to. The recordings will be erased after they are listened to.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with UAB.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You receive a portable DVD player and $20 for participating in this study. You will receive the DVD player at the first in person data collection visit. You will receive a $20 VISA card at the second in person data collection visit.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research, you may contact one of the studies investigators. For UAB, contact Dr. Andrea Cherrington. She will be glad to answer any of your questions. Dr. Cherrington's number is 205-996-2885.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant	Date
Signature of Person Obtaining Informed Consent	Date
Signature of Witness	Date

Reviewed by:

Signature of Principal Investigator Reviewing Consent Document	Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Living Well (Improving Medication Adherence in the Alabama Black Belt)-AIM 2

UAB IRB Protocol Number: X160301010
Principal Investigator: Andrea Cherrington, MD MPH
Sponsor: PCORI

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____

In-person Data Collection Form

Living Well Baseline Data Collection Packet

Table of Contents

Your role as a data collector is very critical to this study. The information that you gather will help us make important decisions. Therefore, we have to have confidence in the conclusions that we make. We get that confidence from knowing that the data was collected in a standard, reliable way.

The information that you collect will help us:

- Better understand the day-to-day experiences of individuals living with diabetes.
- Determining what effects the project has on the health and well-being of study participants.

During today's session you will collect (in this order):

- Informed Consent
- Blood pressure
- Hemoglobin A1c
- LDL Cholesterol
- Height & weight
- Medication names, doses, and frequencies
- Provide the participant with information on their first contact with their Peer Advisor and provide them with the report card.

This packet is a guide to help you gather the data in a standard and reliable way.

Remember to complete each page, fill out each blank, and check each item off on the list as you complete them.

Use this packet along with the Living Well Biometric Protocol, v. 2016-May24
It is very important that you do not rush and the data that is collected is accurate. Document if anything unusual happens or if it was necessary to make changes to any of the protocol in the "Notes" sections.

Supplies:

At the end of the day, note any supply items that are running low.
Complete the Supply Request Checklist and fax to UAB: 205.975.6753 or call UAB.

At any point during the data collection a question arises, STOP and CALL the study manager at 205-617-7512

Data Collector NAME:	
Date of Data Collection:	

Client PID:	
Client Name:	

Client Contact Information

(Update as needed)

Telephone Numbers:

Mailing Address:

Directions / Notes:

☐ Data Collection in the Home / Residence	☐ Data Collection in the Community Venue *Venue Name / Location:*_____

Data Collection Time

Start Time	:	AM or PM	**End Time**	:	AM or PM

Greet client and ask where would be a good location to set up for data collection.

The data collection area will need:

- ☐ 1 electrical plugs
- ☐ Area to set-up table and chair. ***Client must be able to rest his or her arm on the table***.
- ☐ Quiet area with privacy
- ☐ Not in direct sunlight

Supplies - Beginning of each day, make sure you have all of these items.

General Equipment:

- ☐ Informed Consent forms
- ☐ Data Collection Packet
- ☐ Extra Medication Lists
- ☐ Extra batteries: Double A and Triple A
- ☐ Biohazard and trash bags

Blood Pressure Measurement Supplies:

- ☐ Watch / clock
- ☐ Tape measure, eyebrow pencil
- ☐ Blood pressure monitor
- ☐ Blood pressure cuffs (regular, large, extra-large)

HBA1c and LDL-Cholesterol Measurement Supplies:

- ☐ A1c NOW Test kits (doublecheck that you have enough tests for that day)
- ☐ Cardiochek PA machine, Capillary tube, and test strips
- ☐ Lancet, alcohol wipes, bandaids, gloves, gauze, waste container

Height and Weight Measurement Supplies:

- ☐ Scale
- ☐ Stadiometer
- ☐ Step stool

Program Materials:

- ☐ DVD players and Signature log
- ☐ Client Specific Study Packet (General Health Program / Living Well Program)

Step 1: Blood Pressure

- ☐ Gather materials – BP cuff, BP monitor, tape measure, eyebrow pencil, alcohol wipe
- ☐ Check the BP monitor's battery life and change batteries or plug-in to a wall socket if available
- ☐ Squeeze all air from the BP cuffs
- ☐ Select arm (right arm, unless there is a reason to avoid measurement in this arm)
- ☐ Arm is bare to the shoulder

Client position

- ☐ Standing, facing away from you, arm bent at the elbow at a 90-degree angle (Hand on stomach)

Measure the arm

- ☐ Measure from the top of the shoulder (acromion / bony prominence of the shoulder girdle) to the tip of the elbow (olecranon process)
- ☐ Mark the midpoint on the back of the arm. At the mark, measure the circumference of the arm

Arm Circumference ☐☐ . ☐ cm

- ☐ Select correct cuff size.

Arm Circumference	Bladder Size	Cuff selected
24 – 35.5 cm	Regular / Medium	☐
36 – 42 cm	Large	☐
> 42 cm	Extra large	☐

- ☐ Client is seated comfortably in a chair with a back; both feet flat on the floor
- ☐ Arm is supported & resting comfortably on the table at a 90-degree angle with the palm facing up
- ☐ Room is quiet with no distractions

Apply cuff

- ☐ Find and mark the brachial artery with the eyebrow pencil
- ☐ Place cuff around the upper arm, approximately at heart level
- ☐ Wrap cuff snugly on the arm, inner bladder of cuff over the area of the brachial artery (insert first joint of two fingers under the cuff)
- ☐ Arm is resting on table with palm facing up and connect cuff to the monitor

Arm Used: ☐ Left Arm ☐ Right Arm

5 minute rest time begun ☐☐ : ☐☐ AM or PM

BP Measurement 1	BP Measurement 2
Time 1 ☐☐ : ☐☐ AM or PM	Time 2 ☐☐ : ☐☐ AM or PM
BP 1 ☐☐☐ / ☐☐☐ Pulse 1 ☐☐☐	BP 2 ☐☐☐ / ☐☐☐ Pulse 2 ☐☐☐

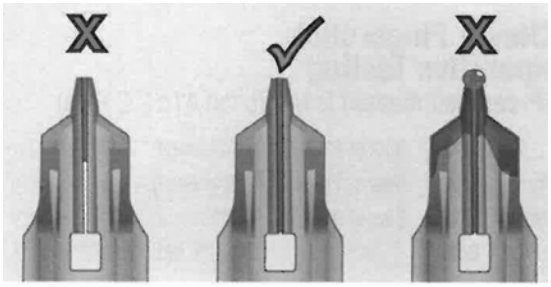
notes:

Remember! 1-minute rest is needed between measurement 1 and 2.

Step 2: Hemoglobin A1c and LDL Cholesterol Measurement

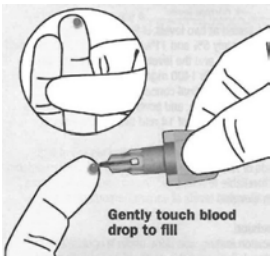
☐ Gather materials - gloves, lancet, gauze, alcohol wipe, band-aid, A1c NOW kit (3 items: machine, cartridge, & dilution kit) and cholesterol (Cardiochek PA machine, test strips, capillary tubes and plunger, test strips.

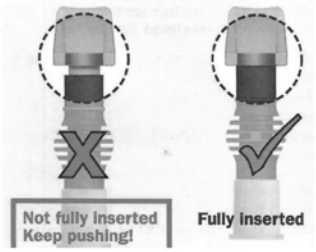
Before pricking finger, note time: ☐☐:☐☐ AM or PM

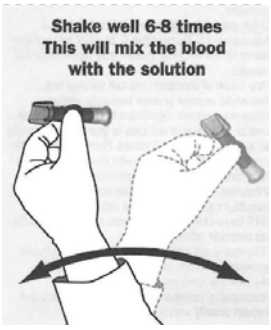


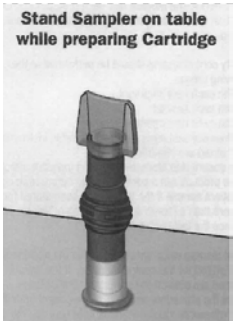
Collect Sample for A1c

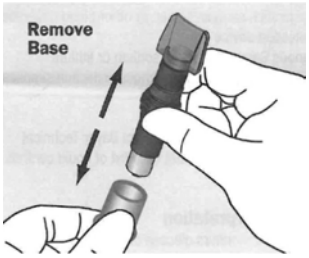
☐ Open dilution kit
☐ With alcohol wipe, clean finger, & allow alcohol to dry
☐ Use lancet, dispose into sharps bag
☐ Wipe away first drop of blood with gauze
☐ Use 2nd drop for the test. Collect blood sample by gently touching blood drop with collector to fill.
☐ Fully insert blood collector into Sampler Body. Shake well 6-8 times. Stand sampler on table.











Prepare Cartridge

☐ Open Test Cartridge packet. ***IMPORTANT: Use the cartridge within 2 minutes.***
☐ "Click" cartridge into place. Monitor and Test Cartridge codes must match.
☐ When display says "SMPL", the monitor is ready.
☐ Ensure monitor is on a level surface.
☐ Remove base from the blood collector.
☐ Push down blood collector on the cartridge completely to dispense sample. Remove quickly.
☐ **Do not handle the monitor again until test is complete**.

Recording the results

☐ results will display in 5 minutes.
☐ 3 items will be displayed: "QCOK" (QC test results), "00.0" (test results), "00TL" (# of test left)

Refer to the anthropromorphic protocol, page 11 for any error codes.

A1c ☐☐.☐	*notes:*

Remember:

- Machines should not be direct sunlight or near cold or heat sources
- Do not open the A1c NOW test kit materials until you are ready to begin that portion of the test
- Once test begins, do not move the machine until the test is complete

Step 3: LDL-Cholesterol Measurement

☐ After A1c test is being analyzed, collect sample for cholesterol machine.

Collect Sample for Cholesterol Test

- ☐ With alcohol wipe, clean finger, & allow alcohol to dry
- ☐ Use lancet, dispose into sharps bag
- ☐ Wipe away first drop of blood with gauze
- ☐ Use 3rd drop for the test. Collect blood sample by gently touching blood drop with capillary tube to fill to the black line on the tube.
- ☐ Deposit the sample on the test strip of the Cardiochek PA machine.
- ☐ **Do not handle the monitor again until test is complete**.

Recording the results

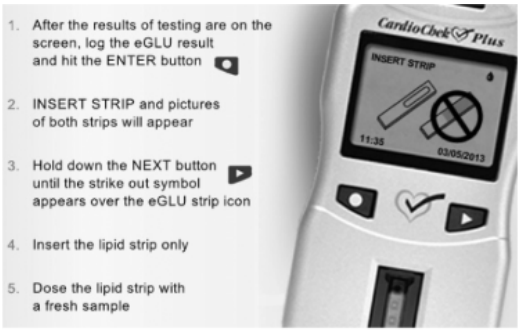
- ☐ Results will display in approximately 2 minutes.

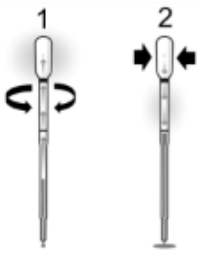
LDL ☐☐☐	*notes:*

Remember:

- Machines should not be direct sunlight or near cold or heat sources
- Prepare the Cardiochek PA machine (insert test strips in the machine, lay out capillary tube and plunger) before A1c test is started.
- Once test begins, do not move the machine until the test is complete

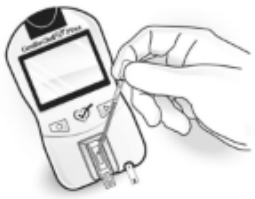
Insert MEMo Chip with finger notch (top) side up, lot number code facing down.





1) Collection:
Place your thumb and finger just ***under*** the bulb

2) Deposit:
Place your thumb and finger ***on*** the bulb.
Cover the air holes and *gently* expel the sample

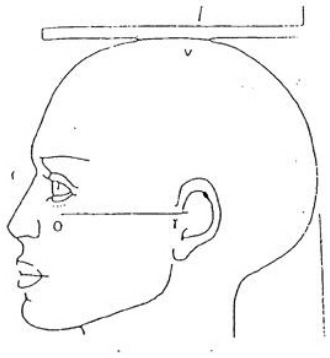


Deposit the entire sample
Do not touch the testing surface

Touch the tip of the capillary tube to the drop of blood
Fill completely to the black line with no air bubbles

Step 4: Height and Weight Measurement

- ☐ Gather materials - scale, stadiometer, step stool
- ☐ Check scale battery and replace if needed, calibrate on yourself



Height measurement

ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE: Orbitale-tragion horizontal line

Set up

- ☐ Scale and stadiometer is placed on level, uncarpeted floor
- ☐ Stadiometer – assemble by matching shapes on each segment
- ☐ Stadiometer's horizontal bar is correctly placed on the vertical rod.

Body Position

- ☐ Standing straight, not slouching, at the center of the foot plate
- ☐ Heels together, back against height rod
- ☐ Back, buttocks, heels touching height rod

Head Position

- ☐ Head is positioned correctly (Does not need to be touching the height rod)
- ☐ Client is looking straight ahead, ear and top of cheek bone should be level with the ground ***Ask client to raise or lower chin as needed***
- ☐ Horizontal bar is lowered firmly onto the top of the head - may need to alter hair styling to make contact with the top of the scalp

Measurement

- ☐ Ask client to breathe in deeply → **"Take a deep breath"**
- ☐ Just before client exhales, note the reading on the stadiometer → **"Breathe out"**
- ☐ **MEASURE IN CENTIMETERS**
- ☐ Repeat measuremet. ***If the measurement is different by .04 cm, repeat both measurements.***

Height 1 ☐☐☐.☐ **CM**	**Height 2** ☐☐☐.☐ **CM**
notes:	
☐ *not needed.* **Height 3** ☐☐☐.☐ **CM**	☐ *not needed.* **Height 4** ☐☐☐.☐ **CM**

Alternative Position - Client unable to place heels, buttocks, and back on the vertical height rod.

- Position client so that only the buttock & possibly the shoulders are in contact with the vertical rod
- It is important that these clients are standing straight and tall, legs together as much as possible with the buttock in contact with the vertical height rod.

Alternative Position - Clients with severe spine curvature

- Curvature of spine should touch the rod with the heels and buttocks
- If this is not possible, turn pt to the side, so the side of arm & shoulder is in contact with vertical rod

Remember to note any changes to the standard positions on the form above.

Weight measurement

Set up

- ☐ Scale is placed on uncarpeted floor / compressed carpet
- ☐ Scale is set on "lbs" not "kg"
- ☐ Client is not wear shoes or heavy jewelry or heavy clothing
- ☐ Ask client to use bathroom before measurement → ***"The measurement we are about to take is more accurate if you use the bathroom before we measure you."***

Measurement

- ☐ Ask client to step on the scale, feet positioned evenly on scale
- ☐ Client is still while weight is being determined, display will flash and then show the weight.
- ☐ Have client step off step off scale,
- ☐ ***Repeat 1-time, if different, repeat both measurements.***

Weight 1 ☐☐☐.☐ **lb**	**Weight 2** ☐☐☐.☐ **lb**
notes: ☐ weight greater than 400 lbs ☐ client needed support / help *(specify)*	
☐ *not needed.* **Weight 3** ☐☐☐.☐ **lb**	☐ *not needed.* **Weight 4** ☐☐☐.☐ **lb**

Notes to data collector:

- Make certain that the scale is on "LB"
- Weigh yourself while setting up to ensure that the scale is accurate
- Do not press the on/off button on the scale before measuring. Just step onto the scale.
- If the client needs support during the weighing, provide the minimum support that is safe and note on the form above.

Step 4: Medication List

- ☐ Double check that all medicines are listed
- ☐ Aspirin dose is noted
- ☐ Insulin is checked "yes" or "no"
- ☐ all doses and frequencies are listed
- ☐ ***For all medications – ask if it is taken as written on the bottle, if not, note on the form***

Brought Medications	☐ Yes ☐ Yes-from list	☐ No - schedule date/time for phone call:
Takes a daily aspirin	☐ No	☐ Yes - note the mg per day: _____mg

Insulin Name	Mix (__/__)	Unit (s)	# times per day	Total dose *(data entry only)*	Notes

Insulin = state the full name

Mix = state the mix values (i.e. 70/30)

 # Times per Day = state the number of times you take insulin in a day

Dose/total dose = (FOR DATA ENTRY ONLY) Use the # per day to determine the dose or doses of insulin the participant takes. Use this to calculate the total dose per day. (For example: # per day: 2, dose: 12 (am) & 25 (pm) → dose total: 37

Note any additional comments or concerns you might have about insulin:

Medication Name	*Combination* *Yes / No*	Freq 1 # pills taken	Freq 2 # times / day	Dose	Total dose *(data entry only)*	Notes
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					

- **Medication name** = Write the full name
- **Combination** = If yes, remember to write the dose for both medications
  (Ex. Glucovance contains glyburide and metformin HCl → be sure to state the two doses i.e. 15/500)
- **Freq 1** = State the number pills taken for the medicine (ex. 2 pills in the AM, 3 pills in the PM)
- **Freq 2** = State the number of times the pills are each day (ex. 2 times a day)
- **Dose** = the dose of the pill. ***Remember to write dose of both meds if a combination (ex: 15/500)***
- Total Dose = (FOR DATA ENTRY ONLY) use freq 1 and freq 2 to calculate (Ex. 1.5 mg = 1 pill, frequency = 2 pills are taken 3 times a day, dose = 3 mg & total dose: 9 mg)

Note any additional comments or concerns you might have about medication list

Medication Name	*Combination* *Yes / No*	Freq 1 # pills taken	Freq 2 # times / day	Dose	Total dose *(data entry only)*	Notes
	☐ Yes ☐ No					
	☐ Yes ☐ No					
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	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					
	☐ Yes ☐ No					

- **Medication name** = Write the full name
- **Combination** = If yes, remember to write the dose for both medications
  (Ex. Glucovance contains glyburide and metformin HCl → be sure to state the two doses i.e. 15/500)
- **Freq 1** = State the number pills taken for the medicine (ex. 2 pills in the AM, 3 pills in the PM)
- **Freq 2** = State the number of times the pills are each day (ex. 2 times a day)
- **Dose** = the dose of the pill. ***Remember to write dose of both meds if a combination (ex: 15/500)***
- Total Dose = (FOR DATA ENTRY ONLY) use freq 1 and freq 2 to calculate (Ex. 1.5 mg = 1 pill, frequency = 2 pills are taken 3 times a day, dose = 3 mg & total dose: 9 mg)

Note any additional comments or concerns you might have about medication list

☐ Additional pages needed (_____) pages attached.

Report Card

- ☐ Complete report card and present to the client.
- ☐ Living Well personnel should provide the results of the biometric measurements and explain what the numbers mean. **Their role is not to provide medical advice. If participants have questions beyond the explanation of the values and the risks that may be associated with elevated values, participants should be instructed to talk to their health care providers.**
- ☐ Review the script on page 29-30 of the Biometric Protocol.

Next Steps

- ☐ Peer Advisor will call you in 1-2 weeks.
- ☐ *Obtain preferences for times that peer should call.*

Best Times to Call

☐ **Morning**	☐ **Mon**	☐ **Thurs**	☐ **Sat**
☐ **Afternoons**	☐ **Tues**	☐ **Fri**	☐ **Sun**
☐ **Evenings**	☐ **Weds**		

If the participant is in the Living Well program:

- ☐ *Give participant Program packet.*
  - ☐ Please keep the DVD in a safe place. You will be able to keep the DVD at the end of the study, but it is very important for you to have for the study.
  - ☐ Also, please place the DVD player and program materials in a safe place. You will need these materials when your peer advisor calls you.
- ☐ *Offer study phone to the participant*
  - ☐ Study phone are available for you to use for the length of the research study. Please only use this phone with your calls with your peer advisor. Please do not use the phone for personal calls. This phone will need to be returned to UAB at the end of the research study. Would you like to use a study phone?
  - ☐ Yes, client will like to use a research study phone.
  - ☐ No, client declines the use of a research study phone.
- ☐ *Thank the client; another data collection will take place in 6 months. Show client where the phone numbers are to reach community coordinators and Birmingham staff.*

If the participant is in the General Health Program:

- ☐ *Give participant Program packet.*
- ☐ *Thank the client; another data collection will take place in 6 months. Show client where the phone numbers are to reach community coordinators and Birmingham staff.*

DVD Set Up

- ☐ Have client practice and set-up the DVD from the beginning.
- ☐ While cleaning-up and packing, have the client watch DVD 1.

Health Report Card

Report Card

There are some things you can do to reduce the health risk of diabetes.

These numbers can give you an idea of how you are doing.

Living Well with Diabetes

A1C *(Average Sugar Control over the last 3 months)*

☐ Great control	Less than 7
☐ Ok, not perfect	7.0 ⟷ 7.9
☐ Cause for concern	8.0 ⟷ 8.9
☐ Bigger cause for concern	> 9.0

Blood Pressure

☐ Normal	Less than 120/80
☐ Our Goal	Less than 140/90
☐ High-*talk to doctor*	140/90 or higher

Cholesterol *(LDL cholesterol or your "bad cholesterol")*

☐ Okay	Less than 100
☐ High-*talk to doctor*	100 or higher

Weight

- ☐ **Normal** *(excellent)*
- ☐ **Overweight** *(may be concerning)*
- ☐ **Obese** *(take action)*

You may want to talk to your doctor about...