

AIM-HI Research Visit Protocol:

Baseline Visit ONLY:

- a. Study Coordinator consents patient **FIRST**
 - If consent is yes, randomize and pull off last 2 pages of the consent form
 - SC will pull the next **BIG ENVELOPE (outside of envelope numbered consecutively in order they should be pulled, i.e. 1, 2, 3, ... 30)**
 - Inside each big envelope are 12 Study ID labels for identifying study documents.
 - Place 1 ID label on each of the last 2 pages of the consent form
 - If patient decides not to participate, thank him/her and pay \$15. That is the end of the visit. Do not complete any other steps below

Patient-Study Coordinator visits (BASELINE, 4 MONTH, and 10 MONTH)

1. Obtain BMI and BP – record results on *Patient Data Collection Form*
2. Draw blood sample using the supplies provided by the AAFP NRN
 - a. Fill out *Liposcience Requisition Form*
3. Patient completes *Patient Health Survey* and eats a snack
 - a. Health survey not completed at 2 and 7 mo.
4. 3 minute step test – record results on *Patient Data Collection Form*
 - a. 3-minute step test not completed at 2 and 7 month
5. Pay patient \$15 or provide gift card
6. Schedule next appointment, if possible
7. A folder is provided (located in the BIG ENVELOPE) to store patient's additional research visit paperwork packets and a copy of his/her consent form. File in safe place.
8. Prepare blood for shipping - Follow "How to Prepare and Ship" instructions exactly
 - a. Place 1 ID label on collection tube (labels for collection tubes are specially marked)
 - b. Centrifuge sample
 - c. Refrigerate sample within 4 hours and store until ready to ship
 - d. Put *Liposcience Requisition Form* in front pocket of the specimen bag
 - e. Put collection tube inside the zip pocket of the specimen bag
9. ****Place yellow copy of the consent form signature page (baseline only), Consent demographics questions (baseline only), Patient Data Collection Form, and Patient Health Survey in prepaid Fed Ex shipping envelope to AAFP NRN.**
10. Record visit information on *Appointment Report (faxed weekly by the NRN)*

Patient-Study Coordinator Visits (FEEDBACK PATIENTS ONLY-2 MONTH and 7 MONTH)

1. Complete Steps 1 and 2 above
2. Pay patient \$15 (compensation) and schedule next appointment if possible
3. Prepare blood for shipping
4. ****Place Patient Data Collection Form in prepaid FedEx shipping envelope to AAFP NRN.**

**AIM-HI Shipping

- Ship ALL patient data to the NRN once per week in the prepaid Fed Ex shipping envelopes.
- Blood should be shipped *on scheduled shipping day of week*. **DO NOT SHIP on a Friday or on the eve of a Holiday**. You should ship after the week's last scheduled research visit.
- If the last visit of the week is on Friday, ship the week's samples on Thursday and ship the Friday patient's sample on Monday.

Fax updated *Appointment Report* to 913-906-6074 once per week (on same day of week). Payment for visit will be generated when the NRN receives all paperwork from practice and lab results from Liposcience.