



## Veterans Walk for Health Study Documentation

### Subject Data Collection

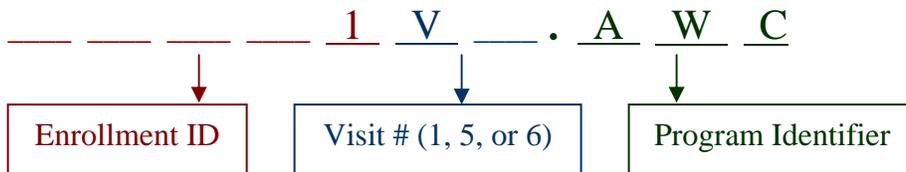
- Black ink only.
- No white out – never obliterate a mistake. Draw a single line through the error, and initial and date each correction.
- Leading zeros must be included.
- All questions must be answered (unless instructed to skip.)
  - NAp - not applicable
  - UNK – unknown
  - ND – not done
- No patient identifiers should be included on documents sent to Ann Arbor (study Ids only.) Black permanent marker can be used to remove identifiers from documents printed from CPRS.
- Fax the following documents to Ann Arbor as soon as they are completed.
  - Adverse Event Forms
  - Drop Out / Termination Forms
- Fax the following documents to Ann Arbor on a weekly basis.
  - Sportbrain Device Logs (any pages with updates)
- Ship the following documents to Ann Arbor on a monthly basis. Please complete a log of everything you will be sending per shipment. These should be sent express mail (something that can be tracked) and will include;
  - Original Surveys
  - Copy of Visit Documentation Forms (if printed from CPRS template, must be de-identified and labeled with study ID only)
  - Original Calendar Pages (for participants who have completed the study)
  - Original Actical Wearing Logs
  - Protocol Deviation Forms
- Data Entry
  - Screening/Enrollment Data: For each patient that you enter onto the crosswalk you will need to enter data into a survey at the Survey Monkey Website. As soon as a patient has been randomized, or as soon as it is determined that the patient will not be randomized to the study, please complete this survey online.  
<http://www.surveymonkey.com/s.asp?u=612101381938>
  - Baseline Survey Data: Please complete the data entry for each baseline survey completed before sending the original to Ann Arbor.  
<http://www.surveymonkey.com/s.asp?u=441811392011>

- V5 Survey Data: Please complete the data entry for each V5 survey completed before sending the original to Ann Arbor. Please beware that the responses in question #13 are not in the same sequence in the Survey Monkey Survey as they are on the paper survey that the participants complete.

<http://www.surveymonkey.com/s.asp?u=430151864055>

- Actual Data Files

- These data are critical for analyzing the results of the study, so they must be stored and labeled carefully.
- The files will be named using the following standard



- The files need to be saved both to a computer and to a disk. The files should be sent to Ann Arbor by email as the data is uploaded. The copies at the site are to be stored until the end of the study. At this time a complete set of the files should be sent to Ann Arbor, and any data at the site erased.

- Maintained Only at the Site (not shipped to Ann Arbor)

- Informed Consent Document
- Medical Clearance Form(s)
- Correspondence Documents
- Screening for Eligibility Worksheet

### Online Tools

- BMI Calculator <http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm>

### Study Binder

- All data points on study forms are supported by source documents
- Source documents are ideally found in the subject's medical record and are generated in the course of routine medical care.
- The subject file, maintained by the Study Team, will contain the source documents or clearly indicate where the source documents can be found.
- Source entries are timely (written at the time of the event or identified as late entry).
- Entries are signed and dated by the author.
- Every subject contact is documented.
- Retain all documents related to the study.
- Obtain written authorization from Ann Arbor prior to destroying any study documents.

- Maintain all study records in a secure environment that protects the subject's privacy and protects the documents from destruction.