

Veterans Walk for Health  
Adverse Events Checklist

Participant Enrollment ID: \_\_\_\_\_

|                                  |  |   |   |
|----------------------------------|--|---|---|
| Cardiovascular Events            | Heart attack<br>Angina<br>Syncope  | Arrhythmia<br>Stroke /TIA<br>other _____                                  | Requires suspension until MD clearance. Inform site PI and Ann Arbor coordinating center. |
| New Concerning Symptoms          | Short of breath<br>Diaphoresis<br>Chest pain<br>Other _____  | Light headed/dizzy<br>Orthopnea<br>Lower ext. edema                       | <i>either</i><br>Systolic BP > 160 at visit<br><i>or</i><br>Diastolic BP > 95 at visit    |
| Other Significant Adverse Events | Motor Vehicle Accident<br>Bacterial Infection on Antibiotics<br>Problems with low or high blood sugar<br>Other _____ | Serious Musculoskeletal Injury<br>Problems with medication<br>Dehydration | Contact with PCP recommended. Participant can resume walking when feels ready.            |
| Minor Adverse Events             | Minor Musculoskeletal injury<br>Lacerations, scrapes or blisters<br>Sore muscles<br>Other _____                      | Problems from pedometer<br>Problems from accelerometer                    | No suspension required.   |

Describe the adverse event in detail:

Event Date: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Is the Event Serious? YES NO

(Death; a life threatening experience; hospitalization or prolongation of hospitalization; persistent or significant disability or incapacity; congenital anomaly and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.)

Is the Event Unexpected? YES NO

(Any adverse event and/or reaction, the specificity or severity of which is not consistent with the informed consent. Further, it is not consistent with the risk information described in the general investigational plan or proposal.)

Is the Event Related? NO UNLIKELY POSSIBLY PROBABLY YES

[The result of: (a) the interventions and interactions used in the research; (b) the collection of identifiable private information in the research.]

Was the participant on a walk when the event occurred? YES NO

If the event was cardiac (ex. chest pain, shortness of breath) did the event occur within 6 hours after a walk? YES NO

Has the participant been seen by a physician for this problem? \_\_\_\_\_

Site PI Informed? YES NO

Ann Arbor informed? YES NO (Who? \_\_\_\_\_)

Staff initials \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Participant suspended? YES NO

If yes, date suspended: \_\_\_\_\_

Med. Clr. to resume? YES NO

If yes, Date resumed: \_\_\_\_\_