



Veterans Walk for Health Study

FAX

To: **Angela Larkin** From:

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Re: **Adverse Event Report** CC:

Urgent For Review Please Comment Please Reply Please Recycle

● Comments: **Adverse Event Reporting:** Whenever something bad, no matter how minor, happens to a participant, it **MUST** be reported to your site PI and to the Ann Arbor coordinating center as an adverse event!!! Whose job is it to report an adverse event? Whoever learns about it first. One of the primary jobs of the site coordinator will be to make sure all adverse events are reported appropriately.

Adverse Event Reporting Procedure (from recruitment site to Ann Arbor coordinating center)

- 1) Make sure the participant is safe or obtain emergency services immediately
- 2) Fill out an adverse event reporting form (available from your site coordinator)
- 3) Submit the form to your site PI before the end of the day.
- 4) Fax the report to Ann Arbor: 734-845-3250 before the end of the day.

No participant identification information should be on the Adverse Event form when it is faxed to Ann Arbor, only site and study ID should identify the participant.

In Ann Arbor, all serious events will be classified according to three scales:

- severity
- expectedness
- relatedness to study interventions.

Unexpected, serious adverse events will be reported immediately to all 7 IRB's. This may result in immediate suspension of the study until the IRB gives approval to continue the study. **Even minor adverse events (harms to the patient) must be reported.**