SUBJECT: VA Ann Arbor Healthcare System (VAAAHS) Requirements for Study Monitor Visits

1. PURPOSE:

The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. This guidance outlines the local requirements for notifying IRB staff and reporting a study monitor visit.

2. DEFINITIONS:

Study Monitor: The study monitor is the person from the study sponsor who visits study sites to evaluate local study procedures and provide feedback.

3. Notifying IRB Staff of Upcoming Study Monitor Visit:

a) Upon becoming aware of a planned study monitor visit from the study sponsor, the local study team should inform the IRB coordinators of the visit. The study team should provide details of the study monitor visit including: the name(s) of the monitor(s), sponsor and date(s) of the visit. In addition, please provide Principal Investigator and Title of Protocol. This information may be sent by email to the IRB Administrator at catherine.kaczmarek@va.gov.

4. Reporting Results of Monitor Visit to IRB:

a) Following a visit by a study monitor, the study staff are responsible for providing a report or briefing of the visit from the study sponsor to IRB. Study staff should email this report to the IRB Coordinators for their records.

5. CONTACTS:

IRB Coordinators:

Cathy Kaczmarek, IRB Coordinator at 734-845-3439
Sheena Hatcher, IRB Coordinator at 734-845-5901
Terry Robinson, IRB Coordinator at 734-845-3440

6. FOLLOW-UP RESPONSIBILITY: VA IRB Coordinators