Appendix B
Reportable Events – Serious Problems

Serious Problem Occurs in VA Research?  
No → See Appendix A

Serious Problem is Unanticipated
(Reflects a RISK that is New or Greater than previously known)

Yes → PI must report the Serious Problem to the IRB through the AVAMC Research Admin. Office within 5 business days of discovery using the RE Form

RE form is reviewed by the IRB member-reviewer who determines whether the serious problem is serious and unanticipated and related to the research within 5 business days of notification

Serious Problem was determined by the IRB member-reviewer to be unanticipated?

No → Anticipated Serious Problems probably or definitely related to the research are reported to the IRB at Continuing Review

Yes → If the problem includes the unauthorized use, disclosure, transmission, removal, theft, loss or destruction of PHI, III or other confidential information, please see policy “Research Information Incidents” for additional reporting requirements

Serious Anticipated Problems that are not related to research are not Reported to the IRB at Continuing Review

Serious Anticipated Problem was determined by the IRB member-reviewer to be related to the research?

Yes → Serious Anticipated Problem was determined by the IRB member-reviewer to be related to the research

No → No

Serious Unanticipated Problem was determined by the IRB member-reviewer to be related to the research?

Yes → Serious Unanticipated Problem was determined by the IRB member-reviewer to be related to the research

No → No

A simultaneous determination must be made by the IRB member-reviewer regarding the need for any action to prevent an immediate hazard to subjects. The convened IRB will determine if further actions are necessary. The IRB Chair or designee must report all problems that are determined by the IRB to be serious and unanticipated and related to ORO within 48 hrs, and in writing to the Facility Director within 5 business days with simultaneous copies to the ACOS-R and the R&D Committee. The Facility Director must report the event in writing to ORO RO within 5 business days after notification.

Serious UPs that are not related to research are not reported to the IRB at Continuing Review

Serious UPs related to research are reported in a summary at Continuing Review

*Shaded areas indicate reporting responsibilities of the IRB/Facility and not the responsibility of the study team.