Appendix A
Reportable Events – Serious Adverse Events

If SAE is an Anticipated DEATH and is Possibly, Probably, or Definitely Related to the research (or unknown), report to the IRB through the VA Research Administration Office within 5 business days using the RE form. OTHERWISE, report all local SAEs to the IRB at Continuing Review.

If SAE is an Unanticipated DEATH and the relationship to the research is Unknown, Unrelated or Related, report to the IRB through the VA Research Administration Office within 5 business days using the RE form.

Serious Adverse Event occurs in VA research?

Yes

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

No

Yes

PI must report SAE to the IRB through AVAMC Research Admin. Office within 5 business days of discovery using the RE form.

RE Form is reviewed by the IRB member-reviewer who categorizes the event as serious, unanticipated and related to the research within 5 business days of notification.

SAE was determined by the IRB member-reviewer to be unanticipated to the research?

No

Yes

SAE was determined by the IRB member-reviewer to be related to the research?

No

Yes

Report all local SAEs to the IRB at Continuing Review

Report all local SAEs to the IRB at Continuing Review

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 the IRB determination of serious, unanticipated and related events 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. The IRB determination and any required action(s) will be posted in eIRB.

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

VHA Handbook 1058.01 EU IRB Polices & Procedures (1/13/12)

VHA Handbook 1200.05

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