**VA Minutes Supplement**

Additional Veterans Administration (VA) Requirements

**For an Unanticipated Problem Involving Risks to Subjects or Others the IRB’s determination as to whether:**

* The incident, experience, or outcome <is/is not> unexpected and related to the research or possibly related to participation in the research and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized (i.e., whether the incident, experience or outcome constituted an actual Unanticipated Problem Involving Risks to Subjects or Others) OR there is insufficient information to determine whether the incident is an Unanticipated Problem Involving Risks to Subjects or Others.
* A protocol modification <is/is not> warranted.
* A consent document modification <is/is not> warranted.
<If a consent document modification is warranted:>
* Previously enrolled subjects <must be/do not have to be> notified of the modification.
<If previously enrolled subjects must be notified:>
* Such notification must take place <when>.

Such notification must be documented by <how>.

**For Serious Non-Compliance or Continuing Non-Compliance, the IRB’s determination as to whether:**

* Serious Non-Compliance or Continuing Non-Compliance <did/did not> occur.
<If Serious Non-Compliance or Continuing Non-Compliance did occur:>

Remedial actions <are/are not> needed to resolve present and/or future compliance. <If remedial actions are needed, describe.>

**For external suspensions or terminations of research, the IRB’s determination as to whether:**

* The suspension or termination <was/was not> A result of a local adverse event(s), local non-compliance, or other local issue(s).

Local action <is/is not> required to ensure the safety, rights, or welfare of local research subjects, personnel, or others or the effective of the local HRPP.