**Date:**

**Protocol Title:**

1. **Allegation of Non-Compliance:**

**[ ] Complete Intake and Preliminary Review Form**

1. **Promptly notify:**

**[ ] IRB Administrative Director and IRB Chair (or designees)**

**[ ] Log receipt of report into HSPB Database**

1. **Provide Initial Report to:**

**[ ] IRB Administrative Director (Director, HSPB)**

**[ ] IRB Chair**

**[ ] Institutional Official**

**[ ] If immediate suspension of enrollment necessary, add the N/C intake report to Agenda of next IRB Meeting**

**4. [ ] IO/ IRB Chair/ IRB Ad Dir Decision on Investigation Process**

**5. [ ] Notification of Respondent(s) regarding allegation of non-compliance**

**6. [ ] Execution of Investigation Process**

**7. [ ] Management of Investigation Process**

**8. Allegations Substantiated**

**[ ] Identify specific regulation(s), policy or procedure(s) that were not followed**

**[ ] Report to full committee for determination of non-compliance, serious non-compliance and/or continuing non-compliance.** The report will contain, at a minimum, a detailed description of the allegations, investigation findings, and recommendations to the IRB.

 **[ ] Corrective Action Plan Developed**

 **[ ] IRB Determination and Corrective Actions to IO for final review**

**Reporting Requirements:**

 **[ ] Report Serious or Continuing Non-Compliance to :**

**[ ] USAMRDC ORP HRPO**

 **[ ] AHRPO**

 **[ ] USDR&E by AHRPO**

**[ ] As applicable to the funding and type of research:**

 **[ ] HHS**

 **[ ] US FDA ( if OTSG is Sponsor USAMRDC will notify US FDA)**

 **[ ] Collaborating Institutions**

 **[ ] Sponsor**

 **[ ] Funding Agency**

**9. Allegation NOT Substantiated**

**[ ] Written communication to PI of unsubstantiated findings of allegation of non-compliance**

**10. Follow Up Procedures:**

**[ ] Document that all corrective actions have been completed in a satisfactory manner and timeframe. Provide the IO and IRB with this documentation. The IO and/or the IRB may impose additional requirements/sanctions.**

**[ ] Retain documents in separate file specific to non-compliance.**

**[ ] Add any Determinations and outcomes of Non-Compliance to the Annual report Log to go to AHRPO.**