



Walter Reed Army Institute of Research
Standard Operating Procedure



Appendix C	Allegation of Non-Compliance Process Checklist	SOP No. UWS-HP-606
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Date:

Protocol Title:

1. Allegation of Non-Compliance:

Complete Intake and Preliminary Review Form

2. Promptly notify:

IRB Administrative Director and IRB Chair (or designees)

Log receipt of report into HSPB Database

3. 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



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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.



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