University of Hawai’i

Human Studies Program

Monitoring Visit Report

**WKSH 352**

**Regulatory Requirements Checklist**

The following areas, as they pertain to regulatory requirements, are subject to review:

1. Roles and responsibilities of Investigators and key personnel.
2. Any research management documentation, e.g., delegation logs, accountability logs, screening and enrollment logs.
3. IRB Documentation, i.e., submission forms, approval letters, IRB correspondence, etc.
4. Consent/Assent Forms.
5. Participant Research Records. A random sample to determine if:
	1. The participants met the inclusion/exclusion criteria for the study.
	2. Study-related procedures are performed according to the protocol.
	3. Study-related procedures are scheduled and performed per the study time line.
	4. Data are recorded in a manner as described in the IRB-approved protocol and consent Form.
	5. Unanticipated problems/ adverse events have been reported according to institutional policy. Protocol deviations and violations have been reported to the IRB, as appropriate.
	6. Compensation provided to participants as described in the protocol.
	7. Participant ID numbers are assigned according to the protocol.
6. Facilities.
	1. Research data stored securely as described in the IRB approved protocol.
	2. Materials containing Participant’s PII information stored securely and separately from research data as described in the IRB approved protocol, e.g., signed consent forms.
	3. Location/setting where research is being conducted is as described in the IRB approved protocol.