University of Hawai'i

Office of Research Compliance

**WKSH 351**

**Site Visit Questionnaire**

In preparation for the Post Approval Monitoring (PAM) audit, please answer the following questions. Please be as detailed as possible.

1. How many participants are currently enrolled in the study? What is the IRB approved target enrollment number?
2. Are all key personnel working on the study listed on the IRB-approved application in the HSP eProtocol system? If there are key personnel not listed in eProtocol, please provide their names and specify their role in the study.
3. Have any participants withdrawn/dropped from the study? If so, why?
4. Have any adverse events occurred? Have these events been reported to the IRB? If so, please provide details about these adverse events.
5. Have participants provided their consent based on the most recent IRB approved stamped version of the consent form? If the answer is “no,” please describe discrepancies.
6. Have all the consent forms been signed and dated by both the participants and the person designated to obtain consent? If the answer is “no,” please describe discrepancies.
7. Have all study measures and procedures been approved by the IRB before implementation? If the answer is “no,” please describe discrepancies.
8. Are all study records stored as indicated in the approved protocol? If the answer is “no,” please describe discrepancies.
9. Have all the advertisements and methods of recruitment for the study been approved by the IRB before implementation? If the answer is “no,” please describe discrepancies.
10. Are participant identification numbers generated as described in the protocol? If the answer is “no,” please describe discrepancies.
11. Have all enrolled participants met eligibility criteria? Is there documentation of eligibility? If the answer is “no,” please describe discrepancies.
12. Have there been any protocol deviations? Have these deviations been reported to the IRB? If the answer is “no,” please describe discrepancies.
13. Have there been any unanticipated problems with protocol implementation? Have these problems been reported to the IRB? If there have been any unanticipated problems, please describe them.
14. Are raw data files organized, complete, and legible?
15. Is there any additional information the PAM Team should be aware of as part of this audit?

Please provide the documentation requested below through UH Dropbox at least one week prior to the scheduled audit. The instructions and a link to a secure UH Dropbox will be sent to you upon confirmation of the audit date.

Individual documents should be organized in folders labeled with names as described in the left column below before uploading to the UH Dropbox.

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| --- | --- |
| **FOLDER NAME** | **CONTENTS** |
| Current Protocol\_Protocol # | Copy of all study documentation, including as applicable:   * IRB approved protocol * IRB approved consent forms * Recruitment materials * Training documentation * Screening/enrollment logs * Subject visit schedule logs * Documentation of participant compensation * Participant eligibility criteria * Delegation Log (listing all key personnel) |
| Signed Consent Forms\_Protocol # | All signed consent forms for each participant |
| Data Collection\_Protocol # | All data collection forms and study instruments |
| Other Documents\_Protocol # | Any other study-related documents, including documentation related to:   * Protocol violations * Protocol deviations * Adverse events * Unanticipated problems * Participant complaints |