University of Hawai’i

Human Studies Program

Monitoring Visit Report

**WKSH 353 - Biomedical Research**

**Monitoring Site Visit Checklist and Report**

**Study Details**

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **PI Name:** |  |
| **Department:** |  |
| **Research Site:** |  |
| **Sponsor:** |  |
| **UH HHS Number:** |  |
| **Visit/ Review Date** |  |

**Study Personnel Present During Visit Name(s) and Title(s)**

**Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Monitor Team Names:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Type of Visit:**

**[ ]  Routine/ Scheduled**

**[ ]  Unscheduled/ For Cause**

The FDA and the HHS have regulations that contain provisions for data monitoring and auditing of protocols involving human subjects.

**Provisions for Data Monitoring**
Federal regulations give the IRB responsibility for ensuring that research protocols include an ongoing monitoring program to protect research subjects. Specifically, HHS regulation 45 CFR 46.111(a)(6) and FDA regulation 21 CFR 56.111(a)(6) state that IRBs must approve research only when "the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."

**Audit Systems**
HHS regulation 45 CFR 46.109(e) and FDA regulation 21 CFR 56.109(f) state: "An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research." Institutions that hold an approved OHRP federalwide assurance are required to ensure that they have procedures that "include formal mechanisms for monitoring compliance with human subject protection requirements."

**Documents Reviewed:**

1.

2.

3.

4.

5.

6.

**Subject Status:**

**Date of First Subject Enrolled**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date of Most Recent Subject Enrolled**\_\_\_\_\_\_\_\_\_\_\_\_

**Total # Subjects Enrolled**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Total # Subjects Planned**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**# Subjects Screened**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Total # Subjects Completed**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**#Subjects Active**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **# Subjects Prematurely Withdrawn**\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**#Unanticipated AEs**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**#Protocol Deviations**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FACILITIES / STAFF** | **YES** | **NO** | **N/A** | **Action Items/Issues/Comments** |
| Changes in staff?  |  |  |  |  |
| If yes, was the study documentation updated?  |  |  |  |  |
| Has investigator accepted new studies since last year?  |  |  |  |  |
| Is investigator properly supervising other personnel?  |  |  |  |  |
| Is investigator devoting enough time for the study?  |  |  |  |  |
| Investigator accessible during visit?  |  |  |  |  |
| Has facility/work area changed since last visit?  |  |  |  |  |
| If yes, was study documentation updated?  |  |  |  |  |
| If yes, were the new facilities/equipment inspected?  |  |  |  |  |
| Are treatment facilities adequate?  |  |  |  |  |
| Other:  |  |  |  |  |
| **SERIOUS ADVERSE EVENTS (SAEs)**  | **YES** | **NO** | **N/A** | **ACTION ITEMS** |
| Any SAEs since last visit?  |  |  |  |  |
| If yes, were required forms completed and submitted?  |  |  |  |  |
| Outstanding data or forms for this or previous events?  |  |  |  |  |
| Were any unreported SAEs discovered?  |  |  |  |  |
| IRB informed, if required?  |  |  |  |  |
| **SUBJECT VERIFICATION** | **YES** | **NO** | **N/A** | **ACTION ITEMS****See “Other” in this section.** |
| Protocol requirements being followed:  |  |  |  |  |
| Consent form(s) signed before enrollment?  |  |  |  |  |
| Subsequent, applicable consent form(s) signed?  |  |  |  |  |
| Subject eligibility confirmed?  |  |  |  |  |
| Subject enrollment log up-to-date?  |  |  |  |  |
| Recruitment on schedule?  |  |  |  |  |
| Did subjects have required lab work, etc?  |  |  |  |  |
| Were any significant laboratory abnormalities discovered?  |  |  |  |  |
| Is follow-up current and properly recorded?  |  |  |  |  |
| Are dropouts/withdrawn subjects documented?  |  |  |  |  |
| Have adverse events been adequately documented?  |  |  |  |  |
| Have there been protocol deviations since last visit?  |  |  |  |  |
| Other:  |  |  |  |  |
| **Investigational Product Accountability**  | **YES** | **NO** | **N/A** | **ACTION ITEMS****No Investigational Product is part of this research.** |
| Are product storage facilities adequate, secure?  |  |  |  |  |
| Did the location of product storage change since the last visit?  |  |  |  |  |
| Product forms complete and up to date?  |  |  |  |  |
| Product inventory checked and counted?  |  |  |  |  |
| Is the site product accountability log complete and up to date?  |  |  |  |  |
|

|  |
| --- |
| Are the patient product accountability log(s) accurate and complete?  |

 |  |  |  |  |
| Study supplies adequate?  |  |  |  |  |
| **REVIEW OF SITE REGULATORY BINDER**  | **YES** | **NO** | **N/A** | **ACTION ITEMS** |
|

|  |
| --- |
| Protocol – IRB approved  |

 |  |  |  |  |
| Signed protocol signature page  |  |  |  |  |
| Current investigator brochure or packet inserts  |  |  |  |  |
| IRB-approved amendments signed & dated  |  |  |  |  |
| IRB-approved consent(s)  |  |  |  |  |
| IRB letters of approval  |  |  |  |  |
| IRB Annual Report  |  |  |  |  |
| IRB Annual Re-approval letter(s)  |  |  |  |  |
| Safety Updates/Reports submitted to IRB  |  |  |  |  |
| IRB Approved Patient Advertisement/Recruitment Tools  |  |  |  |  |
| IRB correspondence – Annual, SAEs  |  |  |  |  |
| IRB composition  |  |  |  |  |
| Signed and completed FDA 1572  |  |  |  |  |
| Signed and completed revised FDA 1572  |  |  |  |  |
| CVs for PI and sub-investigators  |  |  |  |  |
| CVs for Key site research personnel, e.g. Lab Director  |  |  |  |  |
| Medical Licenses for all Investigator(s) and sub-investigator(s)  |  |  |  |  |
| Financial disclosure forms for investigators  |  |  |  |  |
| Shipping records for investigational products and accountability records  |  |  |  |  |
| Agreements/contracts -executed |  |  |  |  |
| Agreements/contracts amendments - executed  |  |  |  |  |
| Lab certifications (licenses and accreditation)  |  |  |  |  |
| Lab normal ranges  |  |  |  |  |
| Screening & Enrollment Log  |  |  |  |  |
| Signature Participant Log/Delegation of Responsibility Log  |  |  |  |  |
| Study Monitor Visit Log current  |  |  |  |  |
| Telephone Logs current  |  |  |  |  |
| All pertinent correspondence  |  |  |  |  |
| **INVESTIGATOR/MONITORING MEETING**  | **YES** | **NO** | **N/A** | **ACTION ITEMS** |
| Reviewed all significant findings?  |  |  |  |  |
| Reviewed any unresolved issues and corrected items from previous visits?  |  |  |  |  |
| Discussed results of visits and action items with investigator and staff?  |  |  |  |  |
| Findings provided to the site in writing?  |  |  |  |  |
| Appointment made for next visit?  |  |  |  |  |
| **Overall Review of Study Status**  | **YES** | **NO** | **N/A** | **ACTION ITEMS** |
| Is maintenance of records complete? Is site in compliance with protocol and IRB?  |  |  |  |  |
| Are subjects accruing within timelines?  |  |  |  |  |
| Is additional clinical/technical training required?  |  |  |  |  |

\*Subject Verification and CRF Review

If all subjects cannot be reviewed, select a statistically valid number of subjects for complete review. List selected CRFs by subject’s identification code below. List inconsistencies in table and discuss in the appropriate comment section.

SUMMARY OF FINDINGS:

|  |  |  |
| --- | --- | --- |
| Finding | Action Item | Resolved |
|  |  | Yes | No |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **SUMMARY:** |

Recommendations of Monitor

[ ]  No action needed – study conduct is compliant with regulations, protocol and IRB requirements

[ ]  No action required, but visit site again in \_\_\_\_\_ weeks to ensure corrections have been made

[ ]  Action required: Investigator is noncompliant, schedule review meeting

[ ]  Action required: Terminate study at site

Monitor Signature and Date: \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Recommendations of Principal Investigator and/or President and CEO

[ ]  I agree with the recommendations of the monitor

[ ]  I do not agree with the recommendations of the monitor

Reason:

Principal Investigator Signature and Date: \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Cc: PI (with original CRFs)

All documents were reviewed with the following findings: