



Walter Reed Army Institute of Research  
Division of Human Subjects Protection  
Standard Operating Procedure

SOP Title	<b>ROUTINE MONITORING FOR HUMAN SUBJECTS RESEARCH PROGRAM COMPLIANCE</b>	SOP No.	<b>UWZ-C-633</b>
		Version	<b>.01</b>
Effective Date	<b>APR 06 2011</b>	Page	1 of 11

**Signatures and Dates:**

Author:

QA Director:

WRAIR IRB  
Administrative  
Director:

For signatures, please see original in the  
Division of Human Subjects Protection

**Review/Approval for unchanged documents**

Date	Author	QA Review	Approving Authority



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1. **Purpose/Applicability:** This Standard Operating Procedure (SOP) sets forth a mechanism for routine monitoring of human subjects research conducted by the Walter Reed Army Institute of Research (WRAIR). This monitoring will serve as a tool to periodically assess whether human subjects research is being conducted in compliance with governing federal regulations, WRAIR policies, Institutional Review Board (IRB) approved protocol, and other applicable regulations. The results of the review provide an opportunity to identify and develop focused training programs for investigators, their research staff, Division of Human Subjects Protection (DHSP) staff and the IRB members, as well as, provide dialogue with Investigators and research staff.
2. **Responsibilities:** This SOP applies to the DHSP Director and Staff, the IRB Chair/Designee and IRB members, and the Institutional Official (IO).
  - a. The DHSP staff conducts monitoring on behalf of the IRB or IO, writes monitoring reports and keeps the DHSP Director informed of the monitoring activities. In addition, the DHSP staff, provides administrative support to the IRB in fulfilling their responsibilities under this SOP (hereafter, referred to as 'monitor(s)' for the purposes of this SOP).
  - b. The IRB Chair (or designee) and IRB members participating in the compliance monitoring visit assist the monitor(s) by reviewing the monitoring reports and making recommendations for quality improvement, as well as, identifying/addressing non-compliance, per the Non-Compliance SOP (UWZ-C-606).
  - c. The IO and the Office of Quality Activities (OQA) are informed if non-compliance is discovered during routine monitoring, per the Non-Compliance SOP (UWZ-C-606).
3. **Investigator Guidance:**

The Principal Investigator (PI)/WRAIR POC is expected to:

- a. Respond to all requests for information from the monitor(s) and IRB (if applicable), and
- b. Comply with any determinations made by the IRB and the IO regarding the research or appeal the determination per the Appeal of IRB Decision SOP (UWZ-C-612).



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**4. Background:**

Routine monitoring is conducted by DHSP monitor(s), as workload allows. At the request of the IRB Chair/IRB Administrative Director/IO, IRB members may also participate in the routine monitoring of human subjects research. Additionally, at the request of the U.S. Army Medical Research and Materiel Command (USAMRMC), Human Research Protections Office (HRPO), monitors from USAMRMC may also participate.

Routine monitoring should be a non-punitive review that gives the PI and research staff feedback on the human subjects protection conduct of their protocol and provide an opportunity for questions and answers. However, if non-compliance is found or suspected during the monitoring, this should be reported to the IRB Chair and a directed monitoring visit (UWZ-C-634) may ensue immediately.

The monitor(s) may review the IRB's records to determine accuracy and consistency with the investigator's research records and to verify that the investigator made no material changes to the protocol without IRB approval and Commander implementation authority. The findings of the routine review are shared with the PI, research staff and IRB. If the findings reveal non-compliance with the human subjects protections program, actions per Non-Compliance SOP will be initiated.

**5. Procedures:**

- a. The monitors may randomly select a protocol for review based on a variety of criteria including, but not limited to: review type, funding source, off-site research, event types, specific research categories, department, PI, currently approved and active for one year; or subjects currently enrolled in a protocol. Consultation with the IRB is encouraged, or the IRB may suggest protocols for monitoring visits.
- b. Once it is determined which protocol(s) is to be monitored, a monitor notifies the PI by phone and in writing of the upcoming routine review. The time frame of advance notice of a site review is a minimum of two weeks with added flexibility for the PI's availability. When a review is to be conducted at a distant site location (i.e., U.S. Army Medical Research Unit-Kenya, U.S. Army Medical Research Unit-Europe, Armed Forces Research Institute of Medical Sciences) travel preparation and time must be



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considered when establishing the review dates, and staffing through the overseas coordinator is essential.

- c. Prior to the monitoring visit, the monitors may study the initial review meeting minutes and all subsequent lifecycle actions taken by the IRB, IRB records, and the DHSP database to become familiar with the protocol(s) and to identify any issues to address during the monitoring process.
- d. The monitors conduct entrance and exit interviews with the PI and/or the PI's Department Chief/Division Director/Detachment Commander, as appropriate. At the PI's discretion, select research staff may also attend.
- e. The entrance interview precedes the review of the PI's research records/on-going study activities. The monitors may use this time to explain the goals of the visit. The PI/research staff may take this opportunity to explain what the protocol entails, and answer any questions arising from the review of the WRAIR IRB protocol records.
- f. The records, activities and items to be reviewed at the PI's site may consist of, but are not limited to, the following:
  - 1) Protocol Binder/Regulatory Documentation - noting whether the records retained meet Federal, International Conference on Harmonisation/Good Clinical Practices (as applicable), Institution and IRB guidelines;
  - 2) IRB Documentation - comparing the PI records with the IRB records. Review of IRB documentation affords the opportunity to determine whether the PI made material changes prior to WRAIR IRB approval & Commander Implementation authority;
  - 3) Consent Forms - when applicable, examining consent forms used to enroll the subjects to ensure that the subjects signed the appropriate consent form for their respective study and that the forms were properly signed and dated;
  - 4) Case Report Forms (CRF) - when applicable, determining if the subjects met the inclusion criteria and none of the exclusion criteria for their respective study, the PI/research staff recorded and documented



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items properly, and whether a record serves as both a CRF and a source document;

- 5) Source Documents/Medical Records- when applicable, reviewing medical records for clinical trials to verify the information in the CRFs, including storage and security and that a copy of the consent form has been provided to the volunteer(s);
- 6) Electronic and hard copy study data to verify consistency with CRF, source documents and approved protocol;
- 7) Sponsor monitoring reports and/or follow-up letters, if applicable;
- 8) Study Logs – when applicable, drug accountability logs, specimen storage logs, delegation of authority logs, signature/initial logs, enrollment logs, etc. will be reviewed; Observation of the consenting process and other study procedures; and
- 9) Direct contact with individual subjects.

For assistance/clarification during the review, the monitors may contact the PI directly or, if applicable, inquire with the PI's research staff.

- g. The monitors conduct the exit interview after the completion of the review of the PI's records/study activities and may ask for clarification regarding the protocol or research procedures at that time. The monitors provide the investigator and/or Division Director with a verbal summary of the findings and explain the remaining procedures for conclusion of the review. A hard copy of the query log (Appendix D) should also be provided. The PI will be afforded the opportunity to clarify findings or correct inaccuracies at this time.
- h. After the exit interview, the monitors prepare a Monitoring Report (Appendix B) outlining the findings of the review pertinent to the PI records, on-site observations, and interviews with the investigator and research personnel. All monitors are given an opportunity to review and edit the report prior to finalization. As a means of maintaining confidentiality, the monitors do not record subjects' protected health information in the review findings. The monitors are expected to complete their report promptly.



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- i. The DHSP Director and IRB Chair will review the draft Monitoring Report prior to sending it to the PI.
- j. Any edits requested by the DHSP Director and/or IRB Chair are incorporated, and a draft version of the Monitoring Report is then provided to the PI to allow clarification/correction to the report prior to being finalized.
- k. Once the Monitoring Report is complete, DHSP sends it to the PI. The Monitoring Report is addressed to the IO. The results may or may not require a response from the PI. The monitors determine the date for any response on a case-by-case basis. Additionally, the routine Monitoring Report is provided to the DHSP Director, IRB Chair and Director, OQA. The IRB Chair may provide the report to the full IRB, as deemed necessary. Substantive rebuttals may be referred by the IRB Chair to the full IRB for resolution.
- l. When a PI's response to the monitoring report is required, the response is reviewed by the monitors to ensure all requested items have been addressed.
- m. When non-compliance is identified, a brief summary is reported to the IRB Chair. The IRB Chair also reviews the complete report and PI's response. A determination is made as to whether further information (via a directed monitoring visit) is needed, or to forward the report and response for additional review or acknowledgement by the fully convened IRB. If appropriate, the DHSP schedules a review of the PI's response with the full IRB at the next available convened meeting. The IRB Chair or DHSP Director notifies the PI of this action.
- n. In the DHSP database, the HSPS enters that the protocol(s) was "Routinely Monitored by DHSP" and/or "IRB" (Appendix C).
- o. For any findings requiring review by the full IRB, the IRB members vote for one of the following actions:
  - 1) Approved - No further action is required. The DHSP sends a notice to the PI describing the outcome of the IRB review.



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- 2) Revision/additional information requested- The IRB may give the Chair the authority to approve the revisions/additional information or require review of the revisions/additional information at a convened meeting. If the IRB request necessitates further review, the DHSP acts accordingly and processes any additional findings/information for review based on the IRB determination at the convened meeting (either given to the Chair or assigned to a convened IRB meeting for review). If the IRB request necessitates a response from the PI, the IRB Chair or monitors inform the PI of the request.

When the PI responds to the IRB's request in writing, the DHSP processes the response based on the IRB determination (either given to the Chair or assigned to a convened IRB meeting for review). If the Chair is the IRB's designated reviewer, he/she may decide to forward the response to the entire IRB for additional review, request additional information, or approve.

- 3) Suspension or termination of the research: (See SOP UWZ-C-606, Non compliance Procedures). The IRB Chair or monitors communicate the outcome of the IRB review to the PI. The outcome is provided to the PI in writing. Appeals are managed as per the Appeal of IRB Decisions SOP (UWZ-C-612).
- 4) When the IRB receives reports of non-compliance findings from reviews, the IRB determines whether to report the findings to the study Sponsor, Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the IO, other participating IRBs, WRAIR management, and/or the USAMRMC ORP, as appropriate.
- p. Copies of all correspondence and reports are kept in a central file within the DHSP for all routine monitoring visits conducted by DHSP.
- q. Copies of query sheets & worksheets (Appendices A, C, & D) may be destroyed after final response to the Monitoring Report.



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**6. Explanation of Abbreviations and Terms:**

CRF	Case Report Form
DHSP	Division of Human Subjects Protection; the administrative support of the WRAIR IRB.
FDA	Food and Drug Administration
HRPO	Human Research Protections Office
HSPS	Human Subjects Protection Scientist
Human Subjects Research	Research involving humans as research subjects, or involving biological specimens, data, specimens from repositories or anatomical substances of human origin. This includes the administration of questionnaires or surveys, as well as research done in an educational setting.
IO	Institutional Official
IRB	Institutional Review Board
IRB Chair	Includes designee (if recusal)
Monitors	DHSP staff and/or IRB members that are responsible for conducting routine monitoring visits
Non-Compliance	Non-compliance is defined as departure from the protocol and can be further defined as either minor (unintentional departure), serious (intentional or unintentional, but effecting the welfare of subjects) and/or continuing (numerous departures).
OHRP	Office of Human Research Protection
OQA	Office of Quality Activities
PI	Principal Investigator or WRAIR POC



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POC

Point of Contact

Routine Monitoring

An established program that serves to periodically assess whether human research protocols are being conducted in compliance with human subjects regulations, WRAIR policies, and the IRB approved protocol.

USAMRMC

United States Army Medical Research and Materiel Command serves as the Command Headquarters for the WRAIR.

USAMRMC ORP HRPO

U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protections Office

WRAIR

Walter Reed Army Institute of Research

WRAIR IRB

WRAIR Institutional Review Board; the ethical review committee for research involving human subjects as per the cited regulations and policies at WRAIR, its detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (investigator, medical monitor, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is through WRAIR.



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**7. References:**

Reference Number or Authors	Document Title
AR-40-68	<i>Clinical Quality Management</i> , 26 February 2004.
AR-70-25	<i>Use of Volunteers as Subjects of Research</i> , 25 January 1990
Command Policy 2004-11	Standard Operating Procedures (SOP) for Food and Drug Administration (FDA) Regulated Activities within the Command, 1 September 2004.
WRAIR IRB Charter, Version 6	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter, Version 6, dated 30 July 2008.
WRAIR HRPP, Version 1.2	Walter Reed Army Institute of Research (WRAIR) Human Research Protections Program (HRPP), Version 1.2, dated 30 July 2008
ICH-GCP-E6	<i>Guideline for Good Clinical Practice</i> .
OHRP Guidelines	<i>Guidelines for Formulating Written HURC Policies and Procedures</i> , 11 July 2002. <a href="http://ohrp.osophs.dhhs.gov/HURC/HURC_guidebook.htm">http://ohrp.osophs.dhhs.gov/HURC/HURC_guidebook.htm</a>
Titles 21, 32 and 45	<i>Code of Federal Regulations</i>
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers, 2006.
SOP UWZ-C-606	Non-Compliance Procedures Standard Operating Procedure
SOP UWZ-C-612	Appeal of IRB Decisions Standard Operating Procedure
MRMC Policy	Non-Compliance
SOP UWZ-C-634	Directed Monitoring of Human Subjects Research



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**8. Forms and Appendices:**

Form or Appendix Number	Title
UWZ-C-633-A Appendix A	IRB Monitoring Worksheet
UWZ-C-633-B Appendix B	Monitoring Report Format
UWZ-C-633-C Appendix C	Worksheet for Documenting Monitoring events in DHSP Database
UWZ-C-633-D Appendix D	Sample Query Form

**9. Document Revision History:**

Version Number	Brief Description of Changes	Effective Date
.00	New	15 October 2008
.01	Biennial Review; updated for consistency with current policies/procedures	<i>APR 06 2011</i>

Appendix A	<b>IRB Routine Monitoring Worksheet</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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**WRAIR protocol #:**

**Date(s) Monitoring Conducted:**

**Monitor(s) (names):**

**Title of Project(s):**

**Principal Investigator (name):**

**IRB(s) of Record (name):**

**Other Collaborating IRB(s):**

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**Routine Monitor Summary**

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**At the Exit Interview an oral summary of the review and a hard copy of the Query and Clarification Forms were provided to the PI**

**Monitoring Report submitted to:**

- Director, Division of Human Subjects Protections**
- Director, Office of Quality Activities**
- Chair, WRAIR IRB**
- WRAIR Commander**
- Principal Investigator**
- Others (specify): (Ex. Department Chief/Division Director/Detachment Commander)**

**Monitors' Recommended Response:**

- None**
- Exposed valid deficiencies require written response from the PI to the DHSP**
- Exposed valid deficiencies require written response from the PI to the IRB**
- Exposed valid deficiencies may require IRB reporting to the FDA, OHRP, the study sponsor, convened IRB, or others**

**Status of Monitoring:**

- Closed Date: \_\_\_\_\_**
- Remains open pending follow up**  
**Specify:**

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**Monitoring Team Comments:**

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**Signature of Monitor**

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**Date**

*\*Note: Add signature lines for all participating monitor(s) and Institutional Review Board members, as applicable.*

Appendix A	<b>IRB Routine Monitoring Worksheet</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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**Part A – WRAIR IRB Regulatory File (Background Information)**

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**1. Prior to the monitoring visit the reviewers may study the following to become familiar with the protocol and to identify any specific points to address during the review:**

- |  |
|--|
| <p><b>a. WRAIR IRB records (noting versions) to include:</b></p> <ul style="list-style-type: none"> <li>- Current approved protocol</li> <li>- Current approved informed consent document( to include assents and back translations and v</li> <li>- Prior approved informed consents noting reason for revision</li> <li>- Investigator Brochure (if applicable)</li> <li>- Adverse Event or Unanticipated Problems reports</li> <li>- Amendments</li> <li>- Deviation reports</li> <li>- Continuing review application(s)/approval(s)</li> <li>- Host country approvals (to include continuing review approvals)</li> <li>- Collaborating IRB approvals (to include continuing review approvals)</li> <li>- Correspondence between the IRB and Investigator</li> </ul> |
| <b>b. WRAIR IRB database specific to the protocol(s)</b>   |
| <b>c. WRAIR IRB Meeting Minutes specific to the protocol(s)</b>  |
| <b>d. Any Previous Monitoring Reports</b>  |

**Monitor Comments or Concerns:**

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**Part B – Investigator Regulatory File**

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2. Does the investigator have a comprehensive and secured file containing the following records:

	Yes	No	NA
a. IRB approved protocol (version____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Investigator's Brochure (version____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. IRB approved amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Current IRB stamped/approved copy of the informed consent (version____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Translated consent forms and verification certificates			
f. Recruitment flyers/Study Advertising (version____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Study Logs			
1. Study Team Signature/Initial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Screening			
3. PI Delegation of authority			
4. Product (drug/biologic/device) accountability			
5. Deviation			
6. Training (SSPs, etc)			
7. AE/UAPs			
8. Specimen Storage/Shipping Log			
9. Subject Enrollment			
10. Other _____			
h. All Safety reports for investigational new product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Adverse Event reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Other relevant safety information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Records of continuing reviews	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. IRB review and approval letters, and Command implementation approval, as applicable ( i.e. protocol, informed consent, amendments, continuing review, adverse events, unanticipated problems, deviations)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. All correspondence between the IRB and Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n. Sponsor Monitoring Reports/Follow-Up Letters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. Financial Disclosure Forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. FDA form 1572	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. Secure and appropriate storage of Regulatory files	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. DSMB/SMC/IDMC reports/summaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s. Training files (CVs, CITI, licenses, BLS, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
t. Normal clinical/research laboratory ranges (Lab certs: CLIA/CLIP/CAP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
u. Other regulatory review approvals (IBC, RSC, RAC, OBA, PPB, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

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**Part C – Subject Documentation Review**

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**3. Did the investigator implement the protocol as approved by the IRB according to the following criteria? (See “NOTE” below)**

	<b>Yes</b>	<b>No</b>	<b>NA</b>
<b>a. The current IRB-approved version of the consent form was used.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>b. The consent form(s) were signed and dated by the subject (initial and subsequent informed consent).</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>c. IRB-approved inclusion and exclusion criteria for subject accrual were met.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>d. The date of the first intervention(s) is consistent with the date that the consent form was signed and after the WRAIR Commander’s Authority to Implement.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>e. All research related procedures performed were described in the IRB-approved protocol.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>f. Subjects received only the approved dose range(s) of the study drugs</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>g. All serious adverse events or unanticipated problems were promptly reported to the IRB</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>h. All protocol modifications were implemented only after IRB approval and WRAIR Command implementation approval, except when in the immediate medical interest of the subject.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>i. The number of evaluable subjects accrued was within the IRB approved limit (briefed, screened vs. enrolled, replacements appropriate).</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>j. The procedures for ensuring privacy and monitoring the confidentiality of data and specimens were implemented as approved by the IRB.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>k. Secure and appropriate storage of subject research documents, specimens/data</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>l. Documentation that Subject received a copy of the consent form</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>m. There are distribution log for payments.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**NOTE: Generally, the number of subject records (may include original data, case report forms (for FDA regulated studies), medical records, and electronic/hard copy study database) will be 10% of the total number of records. At a minimum, review 4-6 individual subject records. Four to six records may be sufficient if no major problems are identified. If major problems are identified it would be sensible to review additional records and even possibly all subject records. The number of individual subject records to be monitored may vary.**

**If applicable, use Query and Clarification Form (Appendix D) for noting specific problems.**

**Total Number of Subject Charts: \_\_\_\_\_ Total Number of Subject Charts Reviewed: \_\_\_\_\_**

**Comments or Concerns:**

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**Part D- Observations**

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**4. Observation of the consent process:**

- Direct observation of the consenting of subjects
- Individual interview with study subject
- Interview with Principal Investigator or Research personnel

	YES	NO
<b>a. Was the environment in which the consent process took place conducive to rational and thoughtful decision making on the part of the subject?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>b. Was the length of time devoted to the consent process sufficient?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>c. Was the subject given an adequate explanation of the research using appropriate simplified language?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>d. Was the subject given adequate opportunity to ask questions?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>e. Did the subject demonstrate an acceptable understanding of the research before signing the consent form?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>f. Is the individual performing the informed consent appropriate for the process?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>g. Is the consent form available in the local language?</b> Comment:	<input type="checkbox"/>	<input type="checkbox"/>

**If the optimal direct observation of the consent process is not possible a direct subject interview (with appropriate consent) would be the next option. Otherwise request that the investigator and/or research personnel describe how the above processes were conducted. How does this compare to the approved protocol and the basic tenants of human subject protections?**

Appendix A	<b>IRB Routine Monitoring Worksheet</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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**Observation of study procedures:**

**Observation of staff's training/ability to carry out the study safely:**

	<b>YES</b>	<b>NO</b>
<b>a. Did the subject meet all the inclusion and exclusion criteria?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>b. Were the correct activities done for or by the subject at each visit?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>c. Did the subject come in for each visit during the appropriate time period?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>
<b>d. Was the subject given the appropriate drug and the appropriate amount at each visit?</b> Observation:	<input type="checkbox"/>	<input type="checkbox"/>

**5. Are there appropriate resources such as equipment, maintenance of equipment?**

**Describe the availability and appropriateness of the space utilized to conduct study activities.**

**Comments or Concerns:**

Appendix A	<b>IRB Routine Monitoring Worksheet</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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**Part E- Interviews with the Investigator and Research Personnel**

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6. Did the investigator and/ or research personnel identify any of the following:

	YES	NO
a. Did the investigator encounter any problems in recruitment, subject retention, or other area? If so, what was the nature of the problem and how was it addressed?	<input type="checkbox"/>	<input type="checkbox"/>
b. Did any subject suffer a serious, unanticipated adverse event? If so, what was the nature of the event and how was the subject treated?	<input type="checkbox"/>	<input type="checkbox"/>
c. Do the investigator and/or research staff report any difficulties with the IRB review process, staff, etc.? If so, what are the problems and proposed solutions?	<input type="checkbox"/>	<input type="checkbox"/>

The interview is a time when problems identified during the records review can be discussed and any necessary clarifications obtained. It is also an ideal time to educate the investigator and his/her staff.

Comments or Concerns:

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**Part F- Preparation of the Report and Follow Up**

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6. After the monitoring visit is completed and all findings are analyzed and determined to be valid, construct a written report. Include recommendations for how deficiencies can be best corrected with appropriate citations of the federal regulations and institutional policies. ( See attached report format)
7. If significant/major deviations from the approved protocol or non-compliance is found, a brief summary should be sent to the Director, DHSP and the IRB Chair. A determination will be made by the fully convened IRB regarding serious or continuing non-compliance. If evidence of serious and/or continuing noncompliance is found (please refer to the Non-Compliance Procedures SOP UWZ-C-606) this must be reported promptly to Institutional official and the OHRP, if applicable. If the research involves use of an FDA-regulated product noncompliance must also be report to the FDA.
8. If IRB review of this monitoring activity is required, submit the written report and, if required, the PI response report.

Appendix B	<b>Monitoring Report Format</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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[DATE]

**(U) Monitoring and Review of the Human Subjects Protection [Protocol# Title]** On [date] the Walter Reed Army Institute of Research (WRAIR) Division of Human Subjects Protection (DHSP) and/or [IRB] conducted a **routine monitoring visit.**

The primary purpose of the monitoring was to [add appropriate info here, i.e. to review study records for compliance with human subjects protection requirements, and to identify opportunities to provide additional support to [name] in the conduct of human subjects research].

NAME  
Director, OQA  
Contact Information

Appendix B	<b>Monitoring Report Format</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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MCMR-UWZ-C

[date]

MEMORANDUM FOR Commander, Walter Reed Army Institute of Research, 503 Robert Grant Avenue, Silver Spring, MD 20910

SUBJECT: [type] Monitoring Visit and Review of [name] Human Subjects Protection Program, [date of event]

**1. References.** [modify as appropriate]

- a. Belmont Report: Ethical Principles and Guidelines For Research Involving Human Subjects. Federal Register Document 79-12065
- b. 10 USC 980 Limitations on Use of Humans as Experimental Subjects
- c. International Conference on Harmonization (ICH): Guideline for Good Clinical Practices
- d. 32 CFR 219, Department of Defense (DoD) Protection of Human Subjects
- e. 45 CFR 46, Department of Human Health Services (HHS), Protection of Human Subjects, inclusive of Subparts A, B, C and D.
- f. DoD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
- g. Army Regulation (AR) 70-25, Use of Volunteers as Subjects of Research
- h. USAMRMC Command Policy 2008-10, USAMRMC Quality Policy
- i. WRAIR Human Research Protections Program, Version 1.2, dated 30 July 2008

Appendix B	<b>Monitoring Report Format</b>	SOP No. Version	<b>UWZ-C-633</b> <b>.01</b>
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**2. Team Membership.** The monitoring was conducted by the following representatives from the WRAIR Division of Human Subjects Protections (DHSP):

- a.
- b.
- c.

WRAIR Institutional Review Board (if applicable):

- a.
- b.

U.S. Army Medical Research and Materiel Command (if applicable)

- a.
- b.

**3. Purpose/Plan.** The purpose of the [type] visit was to:

- a.
- b. [add as appropriate to the specific monitoring]
- c.
- d.

**4. Findings**

- a. [add specific monitoring findings]

**5. Areas in which continuing human subjects protection and regulatory compliance training are needed:**

- a. [add any specific to this monitoring event]

**6. Items that require further action/clarification:**

- a. From DHSP or IRB to [site]
  
- b. From [site] to DHSP or IRB

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**7. Recommendations:**

Additional Attachments:

Appendix A: Review of records, databases and additional discussions

Appendix B: Documents provided to [site] during this visit:

Appendix C: Pertinent Documents prior to this report:

Appendix C	<b>Worksheet for DHSP Database Entry of Monitoring Activity</b>	SOP No. UWZ-C-633	Version .01
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**Information to be recorded in the DHSP Database:**

- **Date of Review Request**
- **Monitoring Type and Reason for the Monitoring**
- **Names of Monitor(s)**
- **Documentation of Communication to PI regarding notification of pending monitoring visit (to include means of communication, who communicated the information, location of the visit and any other pertinent discussion about the pending monitoring visit)**
- **Date(s) monitoring visit conducted, entering "Monitored by DHSP" and/or "WRAIR IRB"**
- **Brief Results of the monitoring visit and requirements for all parties involved (i.e. report to be reviewed by the convened IRB)**
- **Outcome (i.e. corrective action report by PI; PI required specific training to help him/her achieve desired level of compliance; noncompliance reporting to FDA, OHRP; additional monitoring by the IRB)**
- **Location of hard copy of the documents relating to the monitoring**
- **Any other pertinent information**

