1. PURPOSE:
The purpose of this SOP is to provide guidance to investigators and key study personnel in preparation before, during, and after monitoring of human subjects research projects by a monitor from the study sponsor, Clinical Research Organization (CRO) or the UH Office of Research Compliance and Education.

2. SCOPE:
All human subjects research protocols conducted and approved by the UH Institutional Review Board (IRB), Centralized IRBs, or studies conducted at any UH facility or affiliate facility. This SOP does not override the procedures, policies or processes required by the study sponsor, CRO or other agency.

3. RESPONSIBLE INDIVIDUALS:
Principal Investigators, Sub-Investigators and Co-Investigators, and Research, Regulatory, and Study Coordinators and staff listed on IRB approved research.

4. DEFINITIONS:
Case Report Forms (CRFs) a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

Contract Research Organization (CRO) a person or organization contracted by the sponsor to perform one or more of a sponsor’s trial-related duties and functions (e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports and preparation of materials to be submitted to the Food and Drug Administration.

Corrective and Preventive Action Plan (CAPA) actions taken to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.

Good Clinical Practice (GCP) is a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Institutional Review Board an independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, welfare, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials of protocols and amendments, and of the methods and material to be used in obtaining informed consent of trial subjects.
**Investigator** a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

**Investigational Product (IP)** a preventative (vaccine), a therapeutic (drug or biologic), device, diagnostic, palliative or placebo used in a clinical trial, including a product when used for an unapproved indication or when used to gain further information about the approved use.

**Monitor** is a designee of the sponsor, CRO, or UH Office of Research Compliance and Education who is assigned the task of monitoring the study to ensure the rights and well-being of human subjects are protected. That the reported trial data are accurate, complete, and verifiable from source documents and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

**GCP E6 5.1.8**

**Monitoring** the process of reviewing human subject research studies to ensure proper conduct of the study, as stated in the IRB approved protocol. It also involves the review of clinical research standard operating procedures, Good Clinical Practices and regulatory requirements.

**Monitoring Report** a written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor’s SOP(s).

**Protected Health Information (PHI)** is any information about health status, provision of health care or payment for health care that can be linked to a specific individual. Office of Civil Rights 45 CFR 160.103.

**Research** a systematic investigation including research development, testing, and evaluation to develop or contribute to generalizable knowledge.

**Source data** are all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

**Source documents** are original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions, certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).
**Sponsor** is a person who takes responsibility for and initiates a clinical investigation.

**Sub-Investigator (Co-Investigator)** any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions.

### 5. POLICY STATEMENT:
All Investigators, research, regulatory and key study personnel listed on the protocol should support the preparation and coordination of the monitoring visit as well as reconciliation of findings.

### 6. PROCEDURES:
- Upon notification of the monitor’s routine or closeout visit, inform the Principal Investigator, key study personnel and staff from applicable support services about the visit. e.g., investigational pharmacy, lab services, nutrition lab, etc.
- Reserve a private room or area with internet access for the monitor to review the study documents during the visit.
- Ensure that all records being copied or leaving the site do not have PHI.

#### Before the Monitoring Visit
- Once the monitoring date(s) is confirmed, send a calendar invitation to all study personnel, including any support services with the agenda and schedule of location for meeting.
- Make sure the PI has time set aside to meet with the monitor.
- Determine the specific documents that will be reviewed during the visit.
- Ensure all source documents and medical records are available for review.
- Review the [Clinical Trials Regulatory Files Checklist](#) (PDF) and verify that the regulatory file is up to date and that all required regulatory documents are completed, accurate, submitted, up to date and filed.
- Ensure all subject’s medical records, source documents, case report forms or electronic data entry are complete and accurate.
- If EMR access for the monitor is required, submit the request several weeks in advance of the monitoring visit. For Monitor access to the UHCare acute for external monitors of clinical research:
  1. Obtain a Network ID and UHCare Login by accessing the following link: [http://idportal.uhhospitals.org/identitymanagement/default.aspx](http://idportal.uhhospitals.org/identitymanagement/default.aspx).
    a. Only UH employees can request access for monitors
    b. The following information about the monitor is required to obtain access to UHCare:
       - First and Last Name
• Mother’s maiden name
• Favorite color
• Last 4 digits of SSN
• Place of birth
• End date when access will be removed
• Email address
• Name of company

c. Create a Patient List for the Monitor
d. On the Day of the Monitoring Visit
e. The monitor can use a computer (UH or non-UH asset) to access Myapps.UHhospitals.org and will use the provided Network ID and password and UHCare ID and password to login and access UHCare.

**During the Monitoring Visit**

- Make sure that all requested materials are available upon the arrival of the monitor.
- Assign research team members to be available to assist the monitor as needed for the following:
  - Copy and fax requests (*records should not include PHI*)
  - Clarification of inquiries and corrections
  - Access to EMR
  - Travel to support service locations
  - Keep the Principal Investigator informed of the visit
- Verify that the PI participates in the monitoring visit
- Along with the monitor, sign the monitoring log

**After the Monitoring Visit**

- Return all study documents to the secured locations.
- Return or request a pickup for all hardcopy medical records to their locations.
- Monitoring findings.
  - Ensure that a follow up letter or monitoring report is received from the monitor.
  - Review the findings in the monitoring report with the PI and key study personnel and have the PI sign the letter. Develop any necessary process changes and document any corrective and preventative action (CAPA); *Refer to SOP QA 503-CAPA.*
  - Complete and send the requested corrections or responses to the monitor.
- Place a copy of the monitoring and corrections letter in the Regulatory Binder.

**Close out Visit**

- Confirm the date for the closeout visit with the monitor according to the confirmation letter and notify the PI, key study personnel, and if applicable, support services.
- Determine the specific documents that will be reviewed during the visit.
- Make sure that all requested materials are available upon the arrival of the monitor.
- Ensure all subject’s medical records, source documents, case report forms or electronic data entry are complete and accurate.
- Verify that the regulatory file is up to date and that all required regulatory documents are completed, accurate, submitted, up to date and filed. Consider using the Office of Research Compliance and Education Tool - Clinical Trials Regulatory Files Checklist (PDF).
- Verify and ensure that all CRFs have been submitted to the sponsor.
- Complete the verification of all data recorded on CRFs with source documentation.
- Assign research team members to be available to assist the monitor with the following:
  - Copy and fax requests (records should not include PHI)
  - Clarification of inquiries and corrections
  - Access to EMR
  - Travel to support service locations
  - Keep the Principal Investigator informed of the visit
- Verify that the PI participates in the monitoring visit.
- Along with the monitor, sign the monitoring log.
- Travel to support service locations
  - Keep the Principal Investigator informed of the visit.
- Verify that the PI participates in the monitoring visit.
- Along with the monitor, sign the monitoring log.
- Ensure all data queries are resolved.
  - Ensure the study drug/device is either prepared for return to sponsor/CRO or disposed of at the site per the agreement with sponsor.
  - Coordinate a monitoring visit with support services.
  - Ensure that the IP and device accountability are completed and documented appropriately.
  - File copies of study IP and device packing slips and shipment receipts as required.
  - Ensure Note-to-Files are completed to clarify any discrepancies or errors with study procedures and personnel.
  - Request all hardcopy medical records and or if needed, ensure access to electronic medical record are arranged.
- During the Close Out Visit
  - Ensure the monitor has access to all documents required to complete the close out visit.
  - Ensure research staff are available to provide clarification on any study-related issues.
  - During the visit, the PI and key study staff should be available to discuss any issues related to review of the regulatory files, source data verification, IP reconciliation, and data retention and storage.
- Follow-up after the study Close Out visit.
Ensure or obtain confirmation that all study-related costs and expenses, including patient care charges, have been charged to the study. Refer to Policy R-34 Award Close Out.

If applicable, ensure that all IP(s) have been destroyed or returned to the sponsor per agreement and documented appropriately.

Store and secure all study records per institution, FDA and or sponsor requirements. Refer to SOP 405: Records, Retention, Archive and Storage.

Close the study with the IRB when required.

7. REFERENCES

- Food and Drug Administration
- International Conference and Harmonisation (ICH) and Good Clinical Practice (GCP)
- National Institute of Allergy and Infectious Disease
- HIPAA Privacy Rule, Office of Civil Rights (OCR)
- UHCMC IRB Policy, Monitoring
- Standard Operating Procedures for Good Clinical Practice at the Investigative Site. ISBN 1-931107-55-6

8. FORMS OR ATTACHMENTS

Appendix A- Monitoring Visit Checklist
Appendix B- Monitoring Closure Visit Checklist
Clinical Trials Regulatory Files Checklist

APPROVALS

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– June 1, 2017
# Close-Out Visit Checklist

**Protocol:**

**Principal Investigator:**

**Date:**

**Action Items:**

<table>
<thead>
<tr>
<th>Action Items</th>
<th>Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification of the close-out visit to the Principal Investigator, key study personnel, staff and support services i.e. investigational pharmacy, lab services, nutrition lab, etc.</td>
<td>☐</td>
</tr>
<tr>
<td>Reserve a private room or area with internet access for the monitor to review the study documents.</td>
<td>☐</td>
</tr>
<tr>
<td>Send a close-out visit calendar invitation to all study personnel, including any support services with the agenda and location for the visit</td>
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</tr>
<tr>
<td>Schedule the Principal Investigator to meet with the monitor.</td>
<td>☐</td>
</tr>
<tr>
<td>Request EMR access for Monitor, if applicable.</td>
<td>☐</td>
</tr>
<tr>
<td>Verify that all subject’s medical records, source documents, case report forms or electronic data entry are complete and accurate.</td>
<td>☐</td>
</tr>
<tr>
<td>Contact your RFS of close-out visit so that they can assess all patient claims have been dropped and paid</td>
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</tr>
<tr>
<td>Verify that the study drug/device is either prepared for return to sponsor/CRO or disposed of at the site per the agreement with sponsor and verification that the IP and device accountability logs are complete. Copies of study IP and device packing slips and shipment receipts are filed as required.</td>
<td>☐</td>
</tr>
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<td>Verify that the study regulatory file is up to date and that all required regulatory documents are completed, accurate, submitted, up to date and filed including Note-to-Files clarifying any discrepancies or errors with study procedures and personnel.</td>
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<td>Assign research team members to assist the monitor with copy and fax requests, clarification of inquiries and corrections, EMR access and travel to support service locations, as applicable.</td>
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<tr>
<td>Subject’s medical records, source documents, Case report forms and regulatory files made available for the monitoring visit.</td>
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<td>At the conclusion of the visit, sign the monitoring log</td>
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<tr>
<td>Return all study documents, including medical records to their secured locations.</td>
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<td>Ensure that a final letter or monitoring report is received from the monitor regarding any findings and review the findings in the monitoring report with the PI and key study personnel.</td>
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<td>Complete and send the requested corrections or responses to the monitor and ensure that the PI has signed the letter.</td>
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<td>Place a copy of the monitoring and corrections letter in the Regulatory Binder.</td>
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<td>Ensure or obtain confirmation that all study-related costs and expenses have been charged to the study</td>
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<td>Store and secure all study records per institution, FDA and or sponsor requirements.</td>
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<tr>
<td>Close the study with the IRB when required</td>
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**Signature of individual completing the form:** _______________________________ **Date:** ______________

**Principal Investigator Signature:** _______________________________ **Date:** ______________

Closeout Visit Checklist 08.2016
# Monitoring Visit Checklist

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<td>Assign research team members to assist the monitor with copy and fax requests, clarification of inquiries and corrections, EMR access and travel to support service locations, as applicable.</td>
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<td>Prior to study visit, hold pre-visit meeting with research team to confirm that everyone knows their roles and responsibilities</td>
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<td>Subject’s medical records, source documents, case report forms and regulatory files made available for the monitoring visit.</td>
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<td>At the conclusion of the visit, sign the monitoring log</td>
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<td>Develop any necessary process changes and document any corrective and preventative action (CAPA).</td>
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<td>Complete and send the requested corrections or responses to the monitor (by the deadline date, if specified) and ensure that the PI has signed the letter.</td>
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<td>Place a copy of the monitoring and corrections letter in the Regulatory Binder.</td>
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Signature of individual completing the form: ________________________ Date: ________________________

Principal Investigator Signature: ________________________ Date: ________________________

Monitoring Visit Checklist 08.2016