ADIRONDACK HEALTH

TITLE:	Rules for Monitors and Auditors from Outside This Institution	POLICY #: SOP-14
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 3
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 3/3/16	REVIEWED/REVISED:	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) _____ Chandler Ralph (CEO/President) _____		

(This is the only SOP which can be given to outside individuals without written permission from the IRB)

1. Pharmaceutical and device companies frequently have monitors and/or auditors (called monitors herein for simplicity) review the data from clinical trials by comparing those data to the subject's medical records, including electronic medical records (EMR). The consent form that the subject signed before enrolling in a clinical trial, gives permission for this type of review. However, certain constraints will be placed on outside monitors in order to control what information leaves the building and in what format. In addition, monitors will have to abide by the rules set by the IRB when on-site so that it is known who is in the building, for how long and what functions they are performing. The IRB's goals are to protect our subjects in clinical trials, to protect their personal health information and to facilitate monitoring visits to be as productive and uncomplicated as possible.

2. Monitoring visits will be scheduled by the monitor with the Principal Investigator or her/his staff (PI) at least three weeks in advance. The PI will notify Medical Records by email with the date and time and which subjects' records are needed. Medical Records will save the email in a file, paper or electronic, so that confirmation can be made by an IRB audit, if necessary. If only the PI's office records are needed, no notice to Medical Records is required. In that case, the PI must keep a log of the monitor's visits on a form supplied by the IRB.

3. Investigators must save confirmation letters from monitors in their office study files for IRB review, as needed.

4. Monitoring hours are between 8:30 and 4:30 daily unless other arrangements are made and approved in advance with the Medical Records department and/or the PI. Medical Records will keep a log of the monitor's visit with date, time and signature on a form supplied by the IRB.

5. Monitors missing appointments with Medical Records will be re-scheduled at the convenience of the Medical Records department.

6. If the Pharmacy department is involved with the clinical trial and the monitor wishes to see drug inventory, etc., a separate appointment must be made with the

Pharmacy by the PI. Hospital personnel must remain with monitor while the monitor is in the Pharmacy. The monitor will be supplied with the study drug inventory, accountability logs, temperature monitoring logs, and return or destruction logs for their study only. The Pharmacy may keep any style of log supplied by the sponsor of the study as long as it complies with the record keeping specified in Good Clinical Practices or they may use their own, if approved by the sponsor. The monitor may take the originals of the drug logs as long as they leave a copy for the Pharmacy records. The monitor may take copies of any temperature logs; the originals must stay in the Pharmacy records. Pharmacy records are medical records, so all the rules that apply to medical records, apply to Pharmacy records. The Pharmacy will keep a log of the monitor's visit date and time and signature on the form supplied by the IRB.

7. If the Laboratory department is involved with the clinical trial and the monitor wishes to see lab supplies being used for the study, they may do so with an appointment made by the PI. Monitors may check supply, expiration dates, and storage conditions of the sponsor-supplied kits under the supervision of hospital personnel.

8. Our medical records can only be accessed from the institution, so monitoring from outside the institution is not possible. Monitors will be given read-only access to the EMR and may not share their password with anyone else at any time.

9. Paper medical records, EMRs or PI's office records may not be printed out, copied or downloaded in **any** way to an electronic device such as a laptop, phone or thumb drive. Except for some Pharmacy records-see #6 above.

10. Monitors may NEVER:
    a. write anything in a medical record,
    b. highlight anything in a medical record or
    c. dismantle a medical record.

11. Monitors should be given access to regulatory binders for their study, only. Pages from their regulatory binder may be copied by the monitor, as needed, to assure the sponsor that the binder is up-to-date and complete.

12. Any information regarding safety violations of the protocol, GCP violations or other significant findings from a monitoring visit must be sent to the IRB within two weeks of learning about them from the monitor. This will usually take place in a follow-up letter from the monitor or from the visit-closing conversation between the PI and the monitor. In either event, the Chair of the IRB should be notified by email to Valerie Oliver. Significant findings will be reported to the rest of the IRB at the next meeting. At that time, a determination may be made to put the project on hold, to close it down or to continue without changes.

13. Investigators must save follow-up letters in their office study files for review by the IRB, as needed.

14. Inspections by Regulatory Agencies, including the FDA have slightly different rules.
    a. Check photo identification and badge number for each inspector
    b. Have each inspector sign the Monitor/Auditor visit log
    c. They will probably wish to start off with a conversation with an administrative officer
    d. Settle them in a conference room; make sure there are no documents, notes on the chalk board, etc. other than study documents in that room
    e. Confirm exactly which documents they wish to review
    f. Confirm the names and positions of the hospital personnel required
    g. Copy whichever documents they request, if the document is a medical record, redact any and all patient identifiers; subject initials and study numbers may be added by either the inspector or hospital personnel
    h. Keep a list of the documents they take from the institution
    i. A hospital employee must escort inspectors if they wish to go elsewhere, other than the conference room, in the institution
    j. Keep a list of where they went and with whom they spoke
    k. At the end of the visit, they may wish to speak with an officer once again; someone should take notes at that meeting containing exactly who was at the meeting and what was discussed in as much detail as possible
    l. The inspector will tell the officer when a follow up letter should be expected

15. Always be courteous and respectful; inspectors have a job to do too and much can be learned from their findings.

REFERENCES:

CFR (Code of Federal Regulations):