Status **Active** PolicyStat ID **11773336**

Origination	01/2010
Last Approved	05/2022
Effective	05/2022
Last Revised	05/2022
Next Review	05/2025

Owner	Amy Flaherty: Risk Management Director
Area	Administration
Applicability	Erie County Medical Center
References	ADM-041

Clinical Research Study Monitor Procedure

POLICY STATEMENT:

All clinical research proposals must be submitted in writing to the Office of the Medical Director as per the Clinical Research policy. This application includes, but is not limited to, 'Appendix A' application, complete study protocol, study manuals for pharmacy and laboratory, IRB approval, and any study budget or consent pieces.

In addition to application requirements, researchers are required to contact the Office of the Medical Director with any changes or amendments to this application, including any additional staff having access to records (sponsor monitors included). The procedure for appropriate notification and allowing such access is as follows:

Prior to Monitor Visit

Prior to a monitor visit, the researcher or other study staff will notify the Clinical Research Facilitator in writing a minimum of ten (10) business days before the proposed visit. Once this notification has been received, the following departments will be notified of the research project approval:

- Medical Records
- Human Resources
- IT

When a monitor schedules a visit the following information will be communicated via email or hard copy to the Clinical Research Facilitator:

- Name of the sponsor or CRO

- Name of the monitor
- Date(s) of the visit
- Names of the subject records being reviewed at visit.

With this submitted data, the Clinical Research Facilitator will work with study team to complete appropriate paperwork and access forms in order to be prepared for the day of visit. All fields should be completed and signed aside from the signature of the party in question.

On Day of Visit

On the day of the visit the following will occur:

- Completed paperwork for both a badge and EMR (Meditech) access will be obtained from the Research Facilitator and signed by either the Director of Risk Management or the Chief Medical Officer and the Monitor.
- The Study Coordinator will escort the monitor to the Hospital Police window on the Ground Floor for a temporary badge, and to IT for temporary access to the electronic medical record.
- The monitor will be escorted to medical record department and assisted with chart review and EMR navigation by a member of the study team.

Reference:

Joint Commission RI.01.03.05

NYS HIPAA

Clinical Research policy

ECMCC has developed these policies and procedures in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team in making clinical decisions about patient care. These policies and procedures should not be construed as dictating exclusive courses of treatment and/or procedures. No health care team member should view these documents and their bibliographic references as a final authority on patient care. Variations from these policies and procedures may be warranted in actual practice based upon individual patient characteristics and clinical judgment in unique care circumstances.

Approval Signatures

Step Description	Approver	Date
	Sam Cloud: MD • ER	05/2022
	Amy Flaherty: Risk Management Director	05/2022

Applicability

Erie County Medical Center