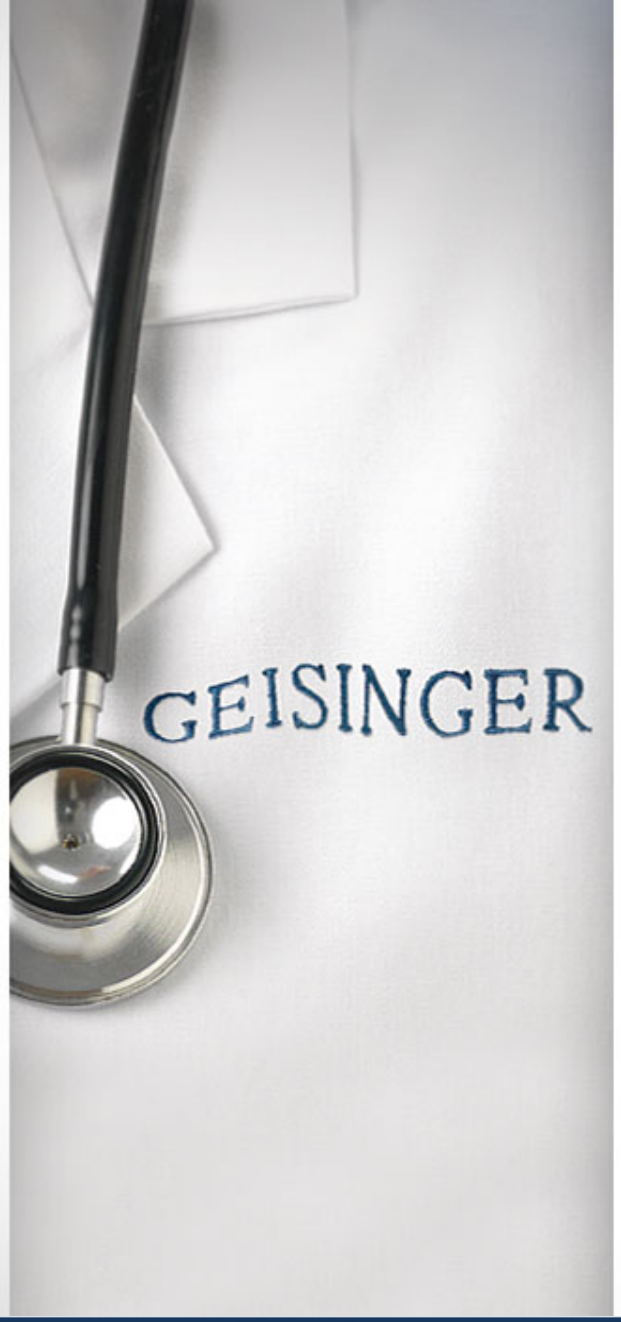

Obtaining and Documenting Assent

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Objectives

- Describe the reported incident
- Understand the process for enrollment of minors in research
- Describe how to document consent/assent within Epic

Description of the Incidents

- Outdated assent/consents
- Assent form missing and not scanned into EHR
- Assent not dated by the patient
- Additional documentation needed for assent process
- Update on implementation of action plan

Resources

- Geisinger HRPP Manual – Section 12
- Geisinger Research Policy 09.103.008 – Research Involving Children – Additional Protections
- Geisinger Guidance – Children and Consenting Minors and Assent

Documentation and Electronic Medical Record

- How to document?
- What should be added to the record?
- Where should it be documented?
- Should a copy of the consent form be scanned into the record?

Documentation of Consent

(45 CFR 46.117)

- Always use most current and approved consent form
  - iRIS Consent Documents (recommended)
- Must be signed and dated by the subject
- Copy must be given to person signing form
- Must be given adequate time to read before signing

Documentation of Consent

- Identify the patient and study
- Consent document discussed with patient
- Sufficient time for patient to review the consent document
- Provide opportunity for the patient to ask questions
- All questions answered to the satisfaction of the patient
- Confirmation that the patient desires to enter the study
- Document that the patient signed an IRB-approved consent form and include:
  - Version date
  - Date signed
  - Time signed noting “prior to any study procedures”
- Consent form can be referenced in the following locations:
  - Original in patient’s research study file
  - Signed consent scanned into the patients medical record in Epic
  - A copy of the signed consent form was given to the patient

Sample Documentation of Consent

PATIENT is a 30 year old female who is being seen today for possible entry into the BLANK study (Include the study title).

Informed Consent

The consent document for the BLANK study was thoroughly discussed with the patient. PATIENT read the consent document and had the opportunity to ask questions regarding the study. All questions were answered to the satisfaction of the patient.

PATIENT desires to enter the study and signed the IRB-approved consent form, version 9/12/15 on 2/8/2016 @ 0905 prior to any study procedures. The consent form can be referenced in the following locations:

- The original signed consent form is located in the patient's research study file.
- The signed consent form will be scanned into the patient's medical record in Epic.
- A copy of the signed consent form was given to the patient.

Sample Documentation of Signed Assent

PATIENT is a 12 year old female who is being seen today for possible entry into the BLANK study (Include the study title).

Informed Consent/Assent

The consent document for the BLANK study was thoroughly discussed with the patient and PARENT or LEGAL GUARDIAN. PATIENT and PARENT or LEGAL GUARDIAN read the consent document and had the opportunity to ask questions regarding the study. All questions were answered to the satisfaction of the patient and PARENT or LEGAL GUARDIAN.

PARENT or LEGAL GUARDIAN and PATIENT desire to enter the study. PARENT or LEGAL GUARDIAN signed Parental Permission/Consent form, version 9/10/15 on 2/8/16 @ 0905 and patient signed the IRB-approved Assent form, version 9/12/15 on 2/8/2016 @ 0905 prior to any study procedures. The consent form can be referenced in the following locations:

- The original signed consent form is located in the patient's research study file.
- The signed consent form will be scanned into the patient's medical record in Epic.
- A copy of the signed consent form was given to the patient.

Questions?