TriHealth Hatton Research Institute

Documenting the Consent Process

Why Create a Note to Document the Consent Process?

It is required by the TriHealth IRB.

- TRI 701 ver. 2.0: Informed Consent Requirements and Documentation of Informed Consent states:

  The Investigator is responsible for ensuring a progress note documenting the informed consent process is placed in the subject's medical record. An entry must also be placed in the progress note when the human subject is actually entered into the study and when the human subject's participation is terminated. ***Note:*** *Consent and entry notes can be combined when both occur at the same visit.*

It gives research staff an opportunity to explain that required elements were included:

- Opportunity to ask questions, all questions answered
- State that consent was given voluntarily
- State that no study-related tests or procedures were done prior to IC
  - Especially important if study procedures done on same date as IC signed
- Also gives an opportunity to explain anything out of the ordinary
  - Example: A note in EPIC states subject needs an interpreter, but your assessment is that they are fluent in English and can understand the IC document and discussion in English

Also, it can be a tool to communicate with other members of the subject's care team

- Other treating MDs
- Emergency Departments

How Should a Consent Note be Entered?

The note should be placed in EPIC. This can be done by having a paper note scanned into EPIC or by entering a progress note directly into EPIC. **Entering a note directly into EPIC is preferred** as it can be entered in real time, is time stamped, and may be more accessible for review by other clinicians. The date and time of the note should correspond with the date and time that the informed consent document was signed. An example of recommended text for a consent note in EPIC is:

> **This patient was evaluated for the (insert name of study) Research Study and was found to meet all inclusion and no exclusion criteria based on the information known at the time by (insert your name). The informed consent was explained to the patient by (insert your name). Time was allowed for verbalizing any questions or concerns by the patient and all questions were answered to the patient's satisfaction. The patient verbally consented, signed the informed consent, and a copy was given to the patient. All study related procedures took place after the patient signed the informed consent.**

A SmartPhrase in EPIC has been created with this text (.HATTONCONSENT). To request access to use this SmartPhrase, please contact Amy Sulken at Amy_Sulken@trihealth.com.

AS 2-12-19