GUIDELINE FOR DOCUMENTING RESEARCH INFORMATION IN THE ELECTRONIC HEALTH RECORD (EHR)

Research information is typically maintained separately from clinical information; however, there are studies where research information should be maintained in the electronic health record (EHR), or information is automatically included according to institutional procedures. The following are examples of situations where research information may or will be included.

1) CLINICAL CARE UNDER RESEARCH / TREATMENT - Subject's clinical treatment is provided through a research study.
   - Oncology treatment provided through research study
   - HIV or AIDS treatment provided through research study
   
   **What to document:** All/most information documented in EHR, including a scanned copy of the consent form in the ‘Media’ tab.

2) RESULTS OF RESEARCH TESTING
   - There may be times when the study team has no control over whether or not results from testing are included in the EHR, either tests that are conducted for research purposes or for clinical care as part of the research study. For example, imaging, echocardiograms, electrophysiology studies, etc.
   
   **NOTE:** URMC Labs offers a service to process laboratory samples collected for research purposes. As part of the request process, there is the option to prevent research labs from going into the EHR (including MyChart). For example, if the access to the research results could potentially unblind researchers, clinical care physicians, or subjects to their randomization assignment. URMC Labs intake process allows the Investigator the option for lab results to be “blinded” and therefore not recorded in the EHR. To learn more about this process, please contact URMC Clinical Laboratories or refer to the URMC Labs website under For Researchers.

3) SAFETY - In order to maintain the safety of the individual participating in the study.
   - Randomized controlled trial or a study where study drug(s) or device(s) are administered.
      
      **What to document:** “Flag the subject” - associate the subject with the research study in the EHR and scan a copy of the consent form into the ‘Media’ tab.
   
   - Greater than minimal risk study where the use of the EHR is required to ensure the safety and integrity of a clinical procedure is consistent with standard clinical practice when conducted for research purposes. Please note that the RSRB considers the clinical expertise of the individuals performing the procedure when approving the use of greater than minimal risk procedures in research. If a different process is used in research than what is used clinically, this could undermine the safety of the research procedure.
      
      **Example –** Endoscopy, use of moderate sedation
      
      **What to document:** “Flag the subject” - associate the subject with the research study in the EHR, scan a copy of the consent form into the ‘Media’ tab, and enter any information normally included in the EHR when the procedure is performed for clinical purposes.
   
   - Greater than minimal risk study that involves the conduct of a procedure or a procedure that includes administration of a medication, which may have a subsequent effect on the subject’s clinical care. If the subject has an adverse reaction or becomes ill for other reasons after the...
procedure, it would be important for the clinician treating the adverse event to know of the procedure and if any medications were administered.
- Example: Use of moderate sedation, interventional radiology

What to document: “Flag the subject” - associate the subject with the research study in the EHR, scan a copy of the consent form into the ‘Media’ tab, enter any information normally included in the EHR when the procedure is performed for clinical purposes.

4) OTHER

- Some other study specific reason - Individual situations, which do not fall under the circumstances above, when an Investigator feels it is important to document research information in the EHR may be proposed to the RSRB and will be considered on a case-by-case basis.

Please Note: When a subject is listed as “Enrolled” in a research study in the electronic health record, if the subject is seen for other health care services at URMC or affiliated facilities (e.g., emergency room visit), the study team may be notified.

IN ALL CASES, THE SUBJECT MUST BE INFORMED IN THE CONSENT FORM THAT INFORMATION ABOUT THEIR PARTICIPATION WILL BE INCLUDED IN THEIR ELECTRONIC HEALTH RECORD.

Refer to the Consent Templates for language that should be included in the consent based on the information that will be included in the subject’s EHR.

For Additional Information

For more about how to enter information into the electronic medical record, please refer the URMC CTSI website “eRecord for Researchers” under Education Materials.