Cures Act Implications for Clinical Research

Contributing Authors: UNCH ORSC, SOM CRSO

Please note: Guidance and regulations are subject to change

What is "The 21st Century Cures Act" and how does it relate to research?

Key Items to Note:

Information blocking regulations are part of the 21st Century Cures Act that was passed by Congress in 2016. Patients are the center focus along with timely, ease of access to their health record information.

Effective with the UNC Epic upgrade on **04/11/21**, all notes were set to *Share with Patient* as the default to align with the Cures Act. Here is the Tip Sheet that has been released with more details.

All research personnel who document within Epic should be aware of clinical and research workflow considerations to ensure familiarity with patient information sharing and transparency impacted by these regulations.
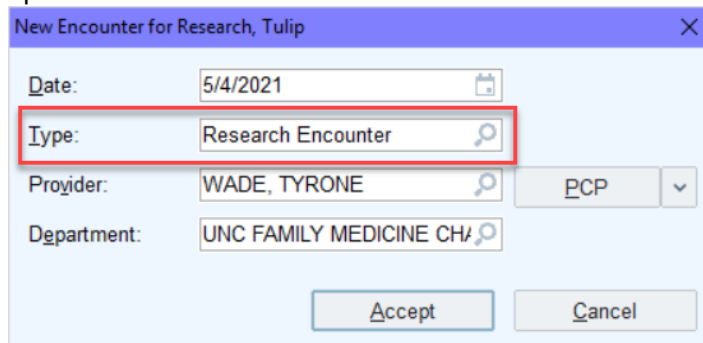
Specific to research:

Notes pertaining to research studies <u>are exempt</u> from information sharing and transparency regulations as determined by leadership at UNC Health. Epic currently has 3 areas set to block sharing of confidential research information:

1. Note type (e.g. Research Encounter)
2. Provider (Author) type (e.g. Research Coordinator, Physician)
3. Department type (e.g. CTRC).

Details about each of these settings follows.

1. **Note Type (e.g. Research Encounters)**
   a. **Research Encounters** are specific Encounter types available to select for documenting in Epic.

   b. All notes pertaining to research should be documented within a **Research or Telephone Encounter** when possible.
   c. *LINKING A VISIT* to research **does not** make a note a "Research Encounter"
   d. Notes written in a Research or Telephone Encounter are <u>NOT</u> shared (regardless of provider type, including physicians).
      i. The Share w/ Patient button is selected by default, but the system will show the warning sign icon that the note is blocked.
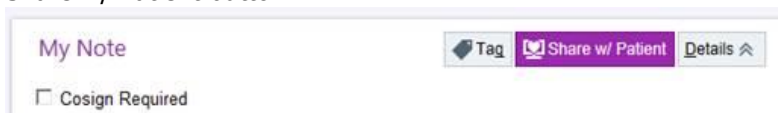

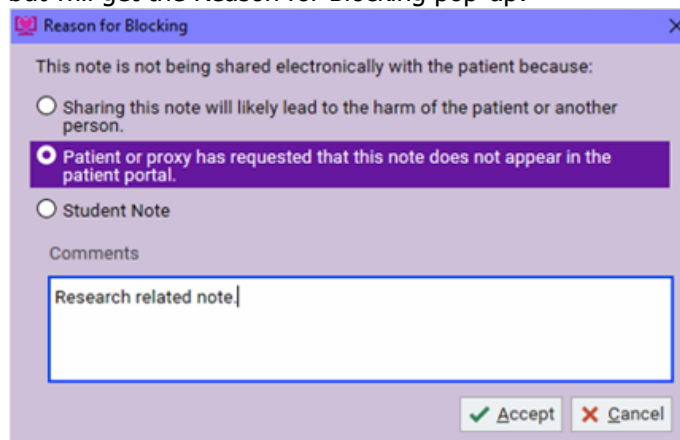2. **Provider or Author Type (e.g. Research Coordinator)**
   a. All notes written by a **Research Coordinator** are <u>NOT</u> shared (regardless of encounter type, including inpatient admissions).
      i. When looking at Notes in Chart Review >> Notes tab, the Author Type is the provider type.

   b. The Share w/ Patient button is selected by default, but if not in a Research Encounter, the system will NOT show the warning sign icon that the note is blocked. However, the note will still be blocked because of the Research Coordinator provider type, so no need to unclick the Share w/ Patient button.

   c. Notes that are co-signed by a Physician or other licensed provider from within a **Research or Telephone Encounter** will <u>NOT</u> be shared.
   d. Notes written or co-signed by a **Physician or other licensed provider** in any format outside of a Research or Telephone Encounter may be shared. If the information noted is specific only to the research study, the provider should click to block sharing of that information.
   e. *DUAL Epic Provider types*
      i. In certain instances, research staff may have dual provider types accessible within Epic. When documenting for research, ensure a **Researcher or Telephone Encounter** is utilized when possible.
      ii. When not possible, if a note is written in any other encounter besides **Research or Telephone Encounter** (i.e., Office Visit, Inpatient setting), these notes <u>will be shared</u> with the patient by default. Staff can choose to unclick the Share w/ Patient button, but will get the Reason for Blocking pop-up:

3. **Department Type (e.g. CTRC)**

    a. Epic has been programmed or set to limit sharing of information from certain institutional departments. The Clinical and Translational Research Center (CTRC) is one specific department that is collectively blocked from sharing information.

    b. When documenting within other hospital departments or clinic settings, please be aware information blocking may not be defaulted in these areas. Research notes written by provider types other than **Research Coordinator** provider type <u>will be shared</u> with the patient unless you unclick the Share w/ Patient button. A Reason for Blocking pop-up will be triggered.

    c. For more information regarding the information blocking limitations for specific departments, please contact ISD at 984-974-4357.