Smart Tools: SmartPhrases

Keep calm and work smart.
Examples of when smart phrases can be used with research

- Document who presented the research study to the study subject/family
- Document consent process
- Document study visits
- Document the procedures that were completed.
How can I create my own SmartPhrase? (while already in a patient’s chart)

- From the progress note field or other text field,
- after typing the phrase that you want to use as a SmartPhrase, highlight the phrase and
- select the plus sign.
How can I create my own SmartPhrase? (while already in a patient’s chart—cont’d)

➢ The SmartPhrase Editor window will open with the text you selected.
How can I create my own SmartPhrase?

- Make any necessary edits. (do not include PHI)

- Enter a name for your SmartPhrase in the SmartPhrase Name field.

- Click Accept. The SmartPhrase is now available for use.
How do I see a list of the SmartPhrases that I have created?

- Select the icon within the smart tool enabled text box and this will show the user a list of SmartPhrases that they have access to.
The user can also find all their personal SmartPhrases by selecting the Epic button > Tools > SmartTool Editor > My SmartPhrases.
How do I create my own SmartPhrase when NOT in a patient’s chart?

- To create a new phrase, follow this pathway:
  - Epic
  - Tools
  - SmartTool
  - Editors
  - My SmartPhrases
  - New
How do I create my own Smart Phrase when NOT in a patient’s chart? (cont.)

- This will bring you to the Smart Phrase Editor.
- Now you can create your phrase in the text box and enter your Smart Phrase Name.
- Then Accept.
Sharing SmartPhrases

- To share SmartPhrase with others, select Sharing.
- Names can be typed in the search box.
- If you want the additional person/people to be able to make changes to the saved SmartPhrase, click on the Can Edit? Check box.
Editing a SmartPhrase

- In the SmartPhrase list, select the phrase that you want to Edit
- Click on the Edit icon
Editing a SmartPhrase

Make any and all applicable changes to the text box as shown below.
Removing/Deleting a SmartPhrase

- If you have a SmartPhrase you don’t use (or someone added you as a user and you don’t want to use) and you want to remove from your list.
- Select the SmartPhrase you want to remove
- Select Remove
Removing/Deleting a SmartPhrase

- If you want to Delete the SmartPhrase (this will Delete for all users), Select Delete

- A pop up text box will confirm you want to Delete
Investigator Documentation
Who Requires Study Documentation?

- Proper study documentation is required by multiple agencies –
  - Department of Health and Human Services (DHHS)
  - Federal Drug Administration (FDA)
  - Institutional Review Board (IRB)
  - Local institutions
Accuracy of Data

- Both Patient care and Outcome of trial relies on accurate data recorded for:
  - Reliability
  - Quality
  - Integrity
  - Traceability
Authenticity of Data

- Document to indicate that information is actual research data
- Allows for verification of research data
- Shows protocol has been followed
- Provides important information to the clinical staff/care coordination
- Patient safety – both clinical and financial
Documentation of Interventions

- Document all study interventions:
  - Consent – specifically the consent process and that consent was obtained prior to any study interventions
  - Enrollment in study – indicate subject met all inclusion and none of the exclusion criteria
  - All visits, exams, research assessments, study recommendations, Adverse Events, medication changes or other health recommendations, study completion and return to clinical care, study blind maintained (if appropriate)
  - If during research visit – something is done for clinical care – need to clearly indicate this in the note
Keeping It Real...Time

- Document all activities when they occur
  - Proofread especially important when using copy/paste or SmartPhrases
  - Don’t abbreviate

- Don’t assume others know the study protocol or your procedures

- Be specific. Don’t use statements like – “all study related procedures completed” (Non-study clinical personnel have no idea what procedures are completed for the study)
Documenting Adverse Events

- Adverse Events
  - Record any clinical assessments
  - Relatedness to research intervention
  - Any treatments given
  - And study modifications made
Auditor should be able to see study course from the information documented in the chart.
What to Leave Out

Do not include:

- Study financial information (amount of patient stipend, amount sponsor is paying for visit, etc.)
- Non-study or non-health related personal or confidential information
- Audit reports or findings
Errors

- Common errors:
  - Consent documentation is incomplete or missing
  - Protocol details not documented or can’t be verified
**If it wasn’t documented – it didn’t happen!**
What to include in your consenting note

- The study name and IRB#
- The names of the individuals involved in the process of consent
- The period of time over which the consent was conducted
- Description of how consent was presented (in a private clinic room, by telephone, etc.)

- Brief discussion of: elements of consent; the project is research; risks, benefits and alternatives explained, coercion or undue influence were minimized, description of any additional protections for vulnerable populations, rights of research subjects were explained; listing of all documents provided; confirmation that all questions have been answered; subject/parent/LAR were able to comprehend information provided

- Subject/Parent/LAR agreed to participate, date and time of signature of consent, copy of consent was provided
What to do (visit note example)

*CF Child Consent*

IRB #: *** / Short Title: ***

@MRN@ / Screening #: ***

**Consent/Assent Verification**

Dr. *** and I discussed the possibility of participating in a clinical research trial for the above-referenced protocol with parents and the subject. The study was explained in detail including but not limited to the contents of the informed consent, purpose of the study, visits, and procedures involved, risks and benefits, alternative treatments, confidentiality and HIPAA requirements, the right to withdraw from the study at any time and treatments provided. The parent(s) were given adequate time to read the informed consent, and all questions were answered to the satisfaction of the parent(s). The Child Information Sheet was discussed at an appropriate age level with the subject. The subject was given adequate time to read the Child Information Sheet, and all questions were answered to the satisfaction of the subject. The parent(s) and subject verbalized understanding of the rights and responsibility of being a study participant, and both the parent(s) and subject wish for the subject to participate. The Parental Consent was signed, and a copy was given to the parent(s) as well as a copy of the “Rights of Research Subjects” and “What Do I Need To Know Before Being In A Research Study”. The subject was given a copy of the Child Information Sheet. A copy of the signed consent forms was sent to medical records for entry into the patient's electronic medical record. Study procedures were initiated after the consent form was signed. The processes, as stated above, are in compliance with GCP guidelines. Contact numbers provided to the subject, including the after-hours on-call number. The parent(s) and subject voiced understanding of all of the above discussed and will call with questions or problems.

The Informed Consent was signed by the parent on ***/***/*** at ***

(24 hour clock)
What not to do example

- Do not consent AFTER research procedures or data collection are initiated
- Do not allow unauthorized personnel to document consent
- Do not use expired or outdated consent documents
- Do not alter or write notes on original consent form
QUESTIONS?