Epic FYI Flags for Research Subjects

All patients on a clinical research study that includes clinical services are required to have an FYI placed on their electronic medical record in Epic.\(^1\) For the purposes of the FYI, “clinical services” is defined as any procedure, test, or exam performed by an OHSU licensed practitioner including, but not limited to, blood draws, imaging procedures, clinical lab tests, non-invasive examinations, and dental work, regardless of whether the clinical services are considered standard of care.

If you are unsure if your study requires an FYI, please contact the CRBO by emailing crbo@ohsu.edu

Creating SmartPhrase:

Upon IRB approval, prior to enrolling your first patient, you will need to contact the Clinical Research Billing Compliance Office via their email at crbo@ohsu.edu to set up the SmartPhrase for your study. You will need to provide:

- The eIRB #
- The research industrial account #
- Primary contact information
- The contact information for any additional research staff in your department who needs edit rights to the SmartPhrase.

All active (enrolling) studies will have a billing analysis performed by a Clinical Research Billing Analyst. The analysis will determine which type of FYI should be assigned to subjects.

You will receive an FYI notification letter from the CRBO. (See example at end of document.) This will serve as your confirmation that a SmartPhrase has been created for the study. The SmartPhrase will be named with the IRB #, e.g. “.4416”

The study-specific SmartPhrase provided to you should always be used when entering an FYI on a research patient. This will cut down on your time and limit errors. The content of the FYI is specific to each study as shown in the following example for IRB #4416:

Placing FYIs

There are two types of research FYI’s: 1) Research; and 2) Research-NCD. The type of FYI is primarily a billing indicator used by OHSU coders and billers.

- NCD stands for National Coverage Determination (For further information on this, please visit CMS.gov)

The FYI notification letter describing the type of flag to use on your study and the rationale behind it will be provided to you once the billing analysis is performed. This letter will include:

- FYI type
- SmartPhrase Name
- SmartPhrase Content

The FYI should be entered within 3 business days of a patient signing consent on a study. This would also be the appropriate time to send your consent form to be scanned into Epic. For FYI purposes, the consent date and enrollment date are the same.

When a patient completes all protocol-driven clinical services, including those required during follow up:

- The discontinuation date should be entered
- The FYI deactivated

This should be done within 3 business days of the discontinuation date.

An example: Your study has follow up visits that require an annual physical exam. Even though this only occurs annually, and would likely be considered standard of care, this exam would be considered protocol-driven and patients participating in this study would need to have their FYI flag left active until all the follow up physical exams are completed.
Adding, Editing & Deactivating FYI Flags in Epic

Adding a new FYI Flag (reflects Epic Summer 2009 changes):

1) Select a patient using the Patient Care menu option, and select ‘Chart’.

2) Select ‘More Activities’ at the bottom left of the screen and then select ‘FYI’. This will take you to the FYI form and will add a tab to the form navigator on the left.
3) Select the ‘New Flag’ button on the form. If it is grayed-out, it means you do not have the appropriate shared security to enter a patient FYI Flag and you need to contact the Epic Help Desk at 4-2222 to obtain access.

![Image of Epic system interface]

4) Click on the magnifying glass in the ‘Flag type’ box and you will be given the choice of “Research” or “Research-NCD”. Select the flag type that was provided to you for that particular study on the letter from the CRBO.

![Image of Epic system interface with magnifying glass on ‘Flag type’ box]
5) Enter the SmartPhrase number (IRB number preceded by a dot), e.g. ‘.4416’ and press Enter to insert the text into the window.

6) Move the cursor to the ‘Enrollment Date’ field and replace asterisks with the correct date. **The date should be entered as MM/DD/YYYY.** (A shortcut to move to the field and delete asterisks is F2.) **NOTE:** For FYI purposes, the consent date and enrollment date are the same.
7) Click on ‘Accept’ after entering the date.

8) The FYI has now been saved.

** The only information you will need to enter when you put the FYI flag on a patient’s record is the enrollment (consent) date.**

**Editing an FYI Flag:**

An FYI flag should be edited to either change an enrollment date or to enter a discontinuation date.

If a change needs to be made in the PI name or contact info, please request a change in the SmartPhrase so all patients going forward will have the correct FYI text entered. Contact the Clinical Research Billing Compliance Office at crbo@ohsu.edu for such changes.

*Please note, a change to the SmartPhrase will not change FYIs already attached to patient’s charts. To change this information you must edit each flag individually using the updated SmartPhrase from the CRBO. Please follow the steps for editing the text of the SmartPhrase.*
1) Follow steps 1 & 2 above to bring up the patient’s record and select the FYI link in the Patient Header.

2) Make sure the FYI you want to edit is highlighted (there may be more than one FYI listed), and click on the ‘Edit’ button.

3) Enter the change and click on the ‘Accept’ button. It will be grayed-out until you have made a change. **PLEASE DO NOT CHANGE ANY TEXT IN THE FYI OTHER THAN THE ENROLLMENT OR DISCONTINUATION DATE.** All other text is set up through the SmartPhrase and should be changed in the SmartPhrase if necessary. Contact the Clinical Research Billing Compliance Office via crbo@ohsu.edu if a SmartPhrase change needs to be made.

4) If you entered a discontinuation date, skip Step 5 below and proceed to the next section on how to deactivate the flag.
To exit FYI window, select another tab in the navigator or close the patient record by clicking the x-box at the top.

**Deactivating an FYI Flag:**

When a patient will no longer be receiving any protocol-driven clinical services, in addition to entering the discontinuation date in the FYI, the FYI must be deactivated. This should be done at the same time as the discontinuation date is entered.

1) After entering a discontinuation date in the FYI text and clicking on ‘Accept’ (Step 3 above), click on ‘Deactivate’.
2) The FYI will no longer be displayed in the FYI window, although the blue FYI will remain in the Patient Header until you close the patient record.

3) To exit FYI window, select another tab in the navigator or close the patient record by clicking the x-box at the top.
**Additional Information:**

1) If you want to see all FYI flags on a patient, including the deactivated flags, go to the FYI window and click on the box ‘Show inactive flags’. From there you can also re-activate the flag if you need to.
1) If you enter an FYI in error, you cannot delete it. Delete all the text and type, ‘ENTERED IN ERROR’ and click ‘Accept’.

2) Then deactivate the FYI by clicking on ‘Deactivate’.
SmartPhrase Access for Other Staff

Passing along access to other study staff:

When a SmartPhrase is created for a study, access will be granted to all study staff that were listed when obtaining the SmartPhrase. An exception may be when common names bring up multiple matches in Epic. When that occurs or when new staff are added, someone who has SmartPhrase access for that study will need to “pass along” access for that person.

1) Select the menu option of ‘Tools’ and then select ‘My SmartPhrases’.

![Image](image1.png)

2) A list of all the SmartPhrases you have access to will come up. Highlight the phrase that you want to share and click on ‘Share’.

![Image](image2.png)

3) Click on ‘Users’ field and enter name of staff member who needs access. Enter last name, first name in the following format: hawkins,melanie. If there is more than one user with that name, a list will come up. You can also look up the name by clicking on the magnifying class.
4) When done, click ‘Accept’ then ‘Close’.

If you have any questions regarding whether your study should have a SmartPhrase, or about the FYIs in general, please contact the Clinical Research Billing Compliance Office at crbo@ohsu.edu
FYI NOTIFICATION

NOTE: There are two types of FYI’s for clinical trials: 1) Research; and 2) Research-NCD. These are billing determinations. This study is non-therapeutic. Therefore, it is NOT considered a Medicare qualifying clinical trial for billing purposes. However, this does not prevent billing for routine and necessary services that are not related to the study.

All patients on this study should be assigned the “Research” FYI flag type in Epic.

This information is provided to allow you to correctly assign FYI flags within Epic for clinical trial patients. Please make sure all information contained in the SmartPhrase below is correct before using. If not, notify the Clinical Research Billing Compliance Office by emailing crbo@ohsu.edu

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For detailed information regarding this study, please refer to the patient’s informed consent in scanned documents. Go to the Media tab and filter on Consent Research Study.

PROVIDED TO: Primary Contact Name
DATE: 1/1/20xx