

Procedures to Post, Remove & Edit Research Flags In CPRS

OBJECTIVES:

- a) Outline the process to post Category II flags in CPRS for research participants
- b) Provide additional protection to patients that are participating in research studies
- c) Inform the subjects' healthcare providers of their research participation

RESPONSIBILITIES:

- a) Principal Investigators (PI) and/or designees are responsible for posting a Category II Research Flag for subjects who are participating in research studies involving:
 - I. Investigational or FDA approved drugs
 - II. Investigational Devices
 - III. A clinical intervention (e.g. the study utilizes treatments, procedures, or assessment tools which are usually used in clinical care)
- b) The PI and/or designee are responsible for providing information relevant to the research study to other healthcare providers, which may affect or interact with their medical care.

PROCEDURES BEFORE POSTING RESEARCH FLAGS:

- a) Contact the Clinical Studies Center Director to request access to the Patient Flag Category II menu option.
- b) There are templates in CPRS for the "initial" posting, "continue" which is used for renewing the flag (every 6 months) and "completed", which is used when the subject completes study participation.
- c) To access these note templates, log into CPRS and select a test patient such as: Z8888. Go to the "notes tab", click on "templates" double-click on "Shared templates" and open the "Research Flag" folder.
- d) Select one of the following templates in the " **Research Flag**" folder as appropriate:



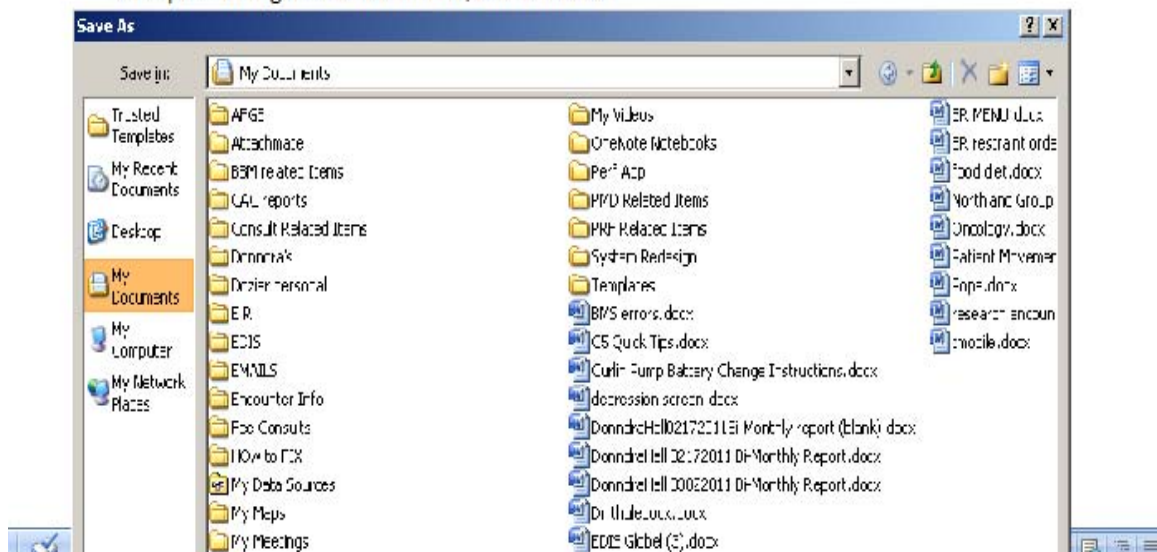
- e) Right click on the templates you will use for you study and “copy template text” into a blank word document. Edit the note template to reflect desired study information. **Create and save a text for each** the initial, continues and study completed notes for future use on your

This patient is currently participating in **The Curious Case of Posting a Research Flag** which is an investigational study.

Please contact the Principal Investigator if additional information is required.

Special Information: Questions, confusion, blurred vision (side effects)

Principal Investigator: Donndra Hall, CAC ext 2964



POSTING THE FLAG



- f) To start the process, sign into the "VISTA" Icon located on your computer desk top Using the same access and verify codes as used with CPRS
- g) Type: **^** FLAG for menu options (**^** = shift and 6 key)
- h) Type FA (FLAG ASSIGNMENT) at prompt (select item 1 or item 2)
- i) Type "SP" to select patient
- j) Enter the desired patient by typing the first letter of the last name and last 4 digits of the social security number. Then, hit enter. (Z8888, Z1234, Z7035)
- k) Type "AF" to assign flag
- l) At the "Select a flag for this assignment" type: Research. The computer will perform a search and Research Clinical Trial will appear, hit enter at the yes prompt.

Flag	Assigned	Review Date	Active	Local	Owner Site
1 PREGNANCY LACTATION	06/29/10	N/A	NO	YES	ATLANTA VAMC
2 MISSING PATIENT FLAG	06/29/10	N/A	NO	YES	ATLANTA VAMC

Enter ?? for more actions	
SP Select Patient	EF Edit Flag Assignment
DA Display Assignment Details	CO Change Assignment Ownership
AF Assign Flag	

Select Action:Quit/af Assign Flag

Select a flag for this assignment: Research

Searching for a National Flag

Searching for a Local Flag

RESEARCH CLINICAL TRIAL ACTIVE CLINICAL

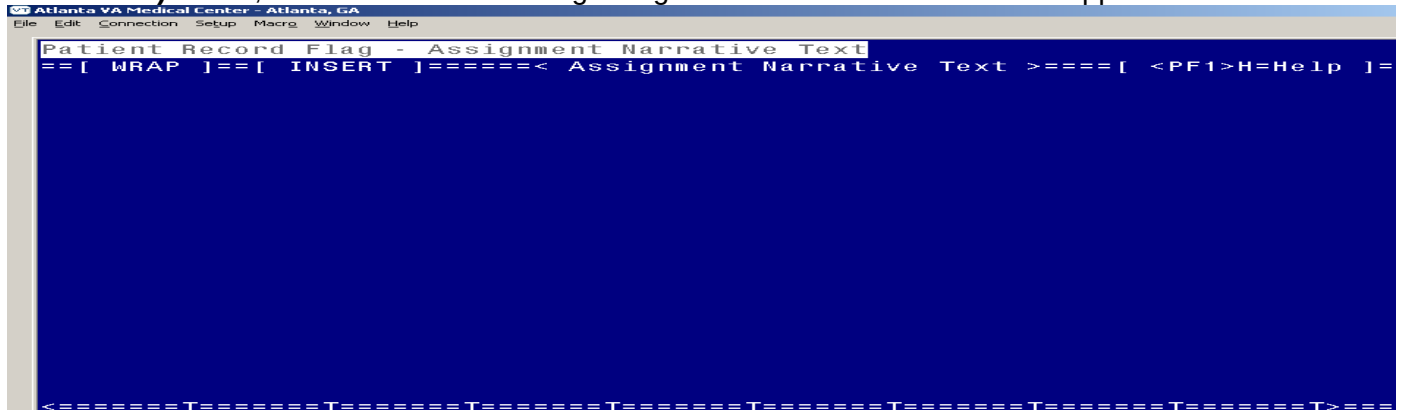
...OK? Yes// ☐

- m) Hit enter at prompt "Enter Owner Site: Atlanta VAMC//".

- n) At the prompt “Approved by”, type: “Bower, David”, who is the Chief of Staff.

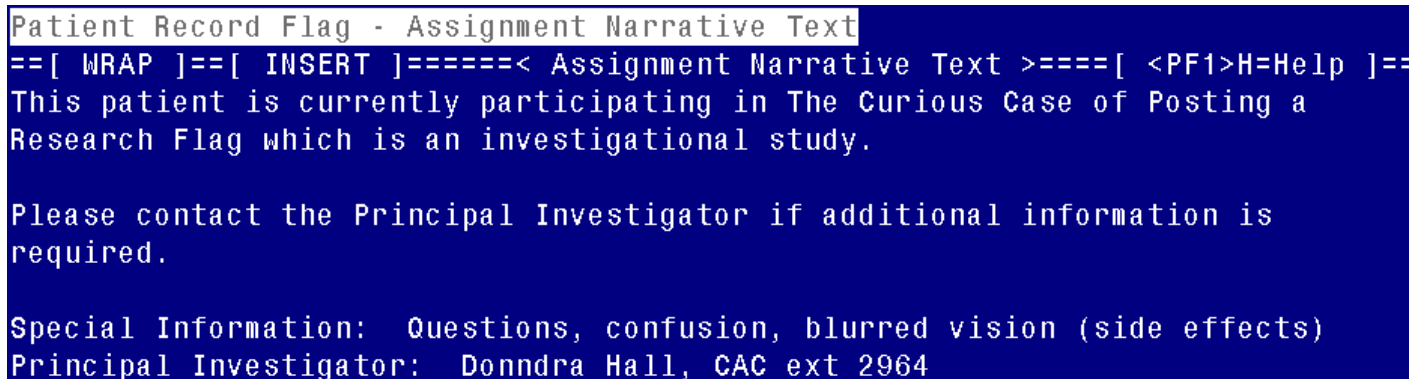
```
Enter Owner Site: ATLANTA VAMC//      GA VAMC 508
Approved By: bower,david BOWER,DAVID JAMES      DJB      STAFF PHYSICIAN
111      STAFF PHYSICIAN
```

- o) Then, the “Patient Record Flag-Assignment Narrative Text” box will appear



```
Patient Record Flag - Assignment Narrative Text
==[ WRAP ]==[ INSERT ]=====< Assignment Narrative Text >====[ <PF1>H=Help ]=
<=====T=====T=====T=====T=====T=====T=====T=====T=====T>====
```

- p) Go to “edit” on the tool bar, then paste the note text previously saved for the study as appropriate (e.g. study drug initial, device study initial, etc.) in the narrative text box.
- q) When done, press num lock and E (num lock + E saves the text) to exit narrative field.



```
Patient Record Flag - Assignment Narrative Text
==[ WRAP ]==[ INSERT ]=====< Assignment Narrative Text >====[ <PF1>H=Help ]=
This patient is currently participating in The Curious Case of Posting a
Research Flag which is an investigational study.
Please contact the Principal Investigator if additional information is
required.
Special Information: Questions, confusion, blurred vision (side effects)
Principal Investigator: Donndra Hall, CAC ext 2964
```

- r) Hit enter at prompt “Enter Review Date”, then hit enter again to exit.

Enter Review Date: (2/23/2011 - 8/22/2011): 8/22/2011// (AUG 22, 2011)

s) The "REVIEW OF ASSIGN FLAG DATA INPUT BEFORE FILING" screen will display. You will be asked if you would like to review this new record flag assignment. Enter "no" if you do not wish to review

t) Hit return/enter to "file this new record flag assignment" Please see the screen shots below

```
REVIEW OF ASSIGN FLAG DATA INPUT BEFORE FILING
-----
Patient Name: ZZGRANT,TEST
Flag Name: RESEARCH CLINICAL TRIAL
Flag Type: CLINICAL
Flag Category: II (LOCAL)
Assignment Status: ACTIVE
Initial Assignment: 2/23/2011@14:27:57
Last Review Date: N/A
Next Review Date: 8/22/2011
Owner Site: ATLANTA VAMC
Originating Site: ATLANTA VAMC
Assignment Action: NEW ASSIGNMENT
Action Date: 2/23/2011@14:30:15
Entered By: HALL,DONNDRA D
Approved By: BOWER,DAVID JAMES

Record Flag Assignment Narrative:
-----
This patient is currently participating in The
Enter RETURN to continue or '^' to exit: █

Record Flag Assignment Narrative:
-----
Research Flag which is an investigational study.

Please contact the Principal Investigator if additional information is
required.

Special Information: Questions, confusion, blurred vision (side effects)
Principal Investigator: Donndra Hall, CAC ext 2964

Action Comments:
-----
New record flag assignment.

Do you want to review again? NO//
Would you like to file this new record flag assignment? YES//
Filing the patient's new record flag assignment...
Assignment was filed successfully.
Enter RETURN to continue or '^' to exit: █
```

RECORD FLAG ASSIGNMENT		Feb 23, 2011@14:35:20		Page: 1 of	
Patient: ZZGRANT,TEST (000006035)			DOB: 04/19/64		
ICN: 1012707158V840906			CMOR: ATLANTA VAMC		
Flag	Assigned	Review Date	Active	Local	Owner Site
1 PREGNANCY LACTATION	06/29/10	N/A	NO	YES	ATLANTA VAMC
2 MISSING PATIENT FLAG	06/29/10	N/A	NO	YES	ATLANTA VAMC
3 RESEARCH CLINICAL TR	02/23/11	08/22/11	YES	YES	ATLANTA VAMC

Enter ?? for more actions

SP Select Patient	EF Edit Flag Assignment
DA Display Assignment Details	CO Change Assignment Ownership
AF Assign Flag	

Select Action:Quit//

- u) Hit return/enter to "quit" and get out of the flag menu
- v) Go to CPRS and select desired patient. The flag should pop up on the screen. Close it and proceed to make a "New Note" in CPRS.
- w) Select the "Notes Tab", click on "New Note", then "New Visit", and enter the "Visit Location" (e.g. "Research Study") in the box.

Location for Current Activities

Select the appointment or visit that should be associated with the note or orders .

Encounter Location
ATL RESEARCH-STUDY Feb 23,11 14:42

Clinic Appointments | Hospital Admissions | **New Visit**

Visit Location
ATL RESEARCH-STUDY

ATL RESEARCH-ONCOLOGY TRTMNT
ATL RESEARCH-ONCOLOGY-A
ATL RESEARCH-PRE-DIAB SCREEN
ATL RESEARCH-SIBA
ATL RESEARCH-STUDY
ATL RESEARCH-TBI GH
ATL RESIDENTIAL CARE

NOW

☒ Historical Visit: a visit that occurred at some time in the past or at some other location (possibly non-VA) but is not used for workload credit.

Check the "Historical Visit" Box

- x) Enter date and time and **click on the “Historical Visit Box”** then “ok”
- y) Under the progress note title, enter: “Patient Record Flag Category II-Research Clinical Trial”.

Progress Note Properties

Progress Note Title: PATIENT RECORD FLAG CATEGORY II - RESEARCH CLINICAL TRIAL

Date/Time of Note: Feb 23, 2011@14:42

Author: Hall,Donndra D - CLINICAL APPLICATIONS CO

Which Patient Record Flag Action should this Note be linked to?

Flag	Date	Action	Note
RESEARCH CLINICAL T...	FEB 23, 2011@14:27:57	NEW ASSIGNMENT	

- z) **Highlight the flag shown at the bottom** part (as shown in above picture) of the box and click “OK”.

aa) The note screen will appear, select the flag action, complete the template and sign your note.

Template: PATIENT RECORD FLAG CATEGORY II - RESEARCH CLINICAL TRIAL

Research Clinical Flag **** FOR RESEARCH PURPOSE ****

☐ Initial Flag ...

☐ Continuing Study ...

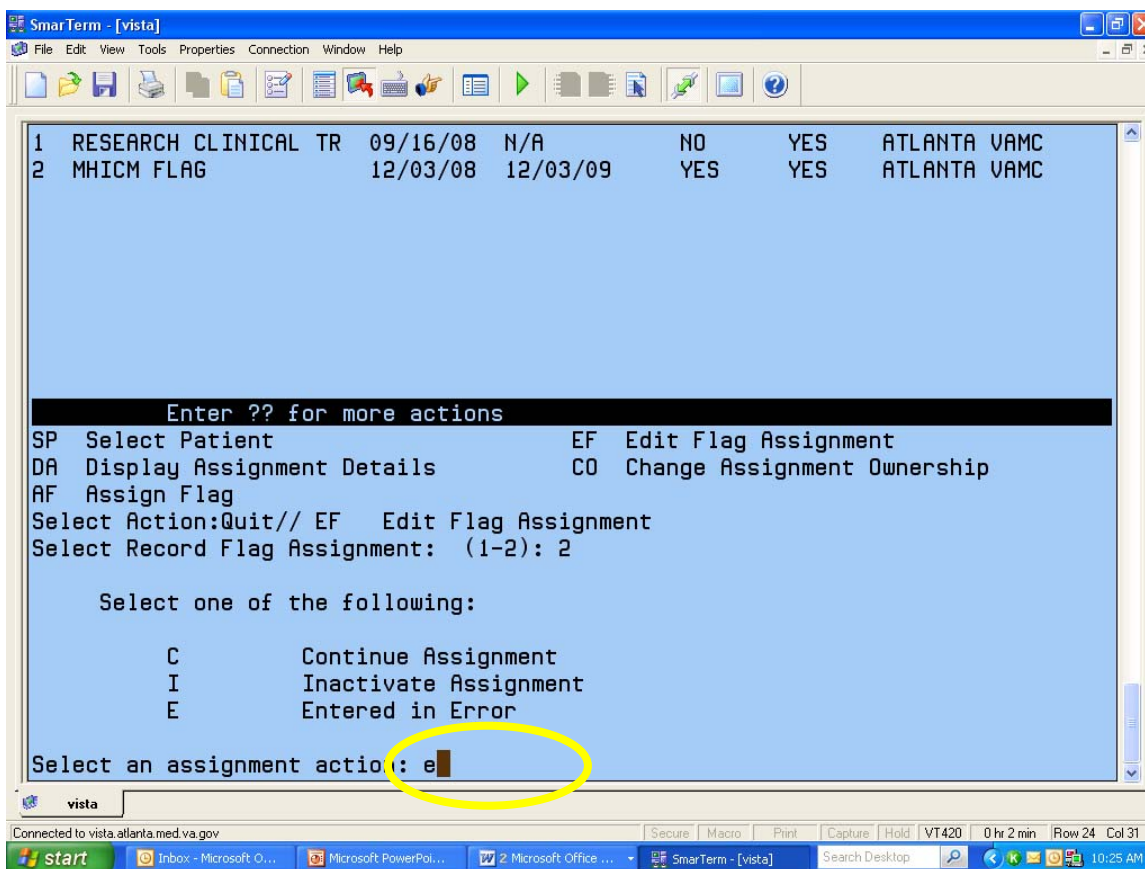
☐ Study completed ...

All None * Indicates a Required Field Preview OK Cancel

bb) The flag status will be automatically reviewed every 6 months.

Procedures to Remove and/or Edit the Research Flag

- a) Sign into **Vista**
- b) Enter **^FLAG** for menu options.
- c) Enter **FA** (Flag Assignment) at prompt.
- d) Enter **SP** to select patient.
- e) Enter the first letter of the patient's last name and last 4 digits of the patient's social security number.
- f) Enter **EF** (Edit Flag Assignment)
- g) On the screen, select the number for the "Research Clinical TR" flag you would need to edit (the patient may have more than one flag).

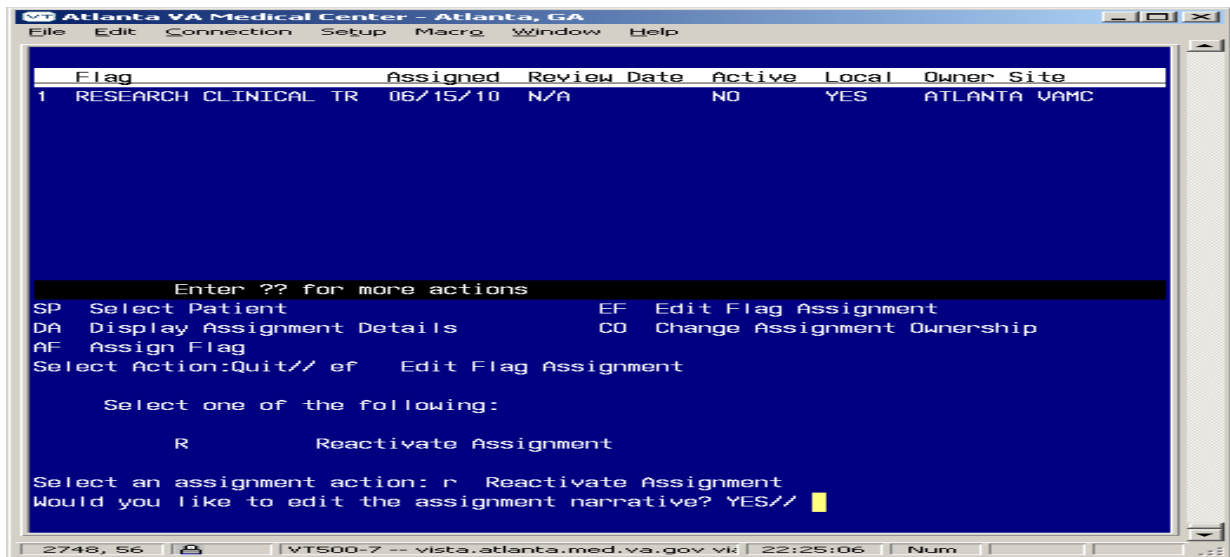


- h) Select: "Continue Assignment" if renewing that flag, "Inactive Assignment" if discontinuing the flag" or "Entered in Error" if entered by mistake.

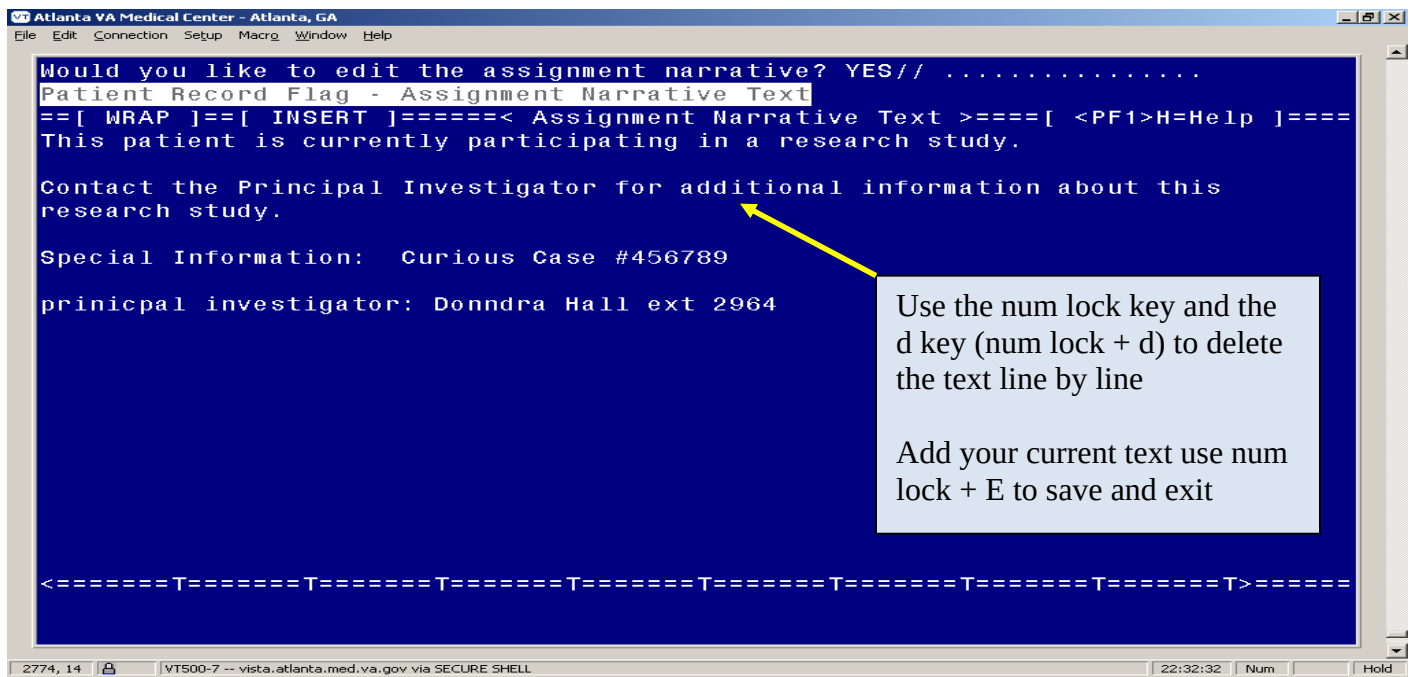
- i) **If you wish to continue the flag:** You will need to hit **num lock + D** to **delete** current text and paste/copy the text you desire for “Drug Study Continues, “Investigational Device Continues” or “Clinical Intervention Continues” as appropriate or edit text as appropriate in the narrative text screen. Press “num lock + e” to save text changes and exit the narrative text box. **This is 2-step process and requires a note in CPRS as in the initial flag posting.**
- j) **If you wish to inactivate the flag:** You will need to **hit num lock + D** to **delete** current text and paste/copy the text you desire into the “Study Completed” narrative text screen. Press “num lock + e” to save text changes and exit the narrative text box. **This is 2-step process and requires a note in CPRS as in the initial flag posting.**
- k) **If you select Enter in error:** You will need to **hit num lock + D** to **delete** current text. Edit the flag assignment narrative to reflect the correction action taken. Press “num lock + e” to **save** text changes **and exit** the narrative text box. This is a **one step process and does not require a note in CPRS.**

Posting A Flag For A Patient That Previously Participated In Another Research Study And Now Has An “Inactivate Assignment”:

- a) To assign a research flag for a different study, you need log into VISTA
- b) Type: ^FLAG for menu options
- c) At option “Record Flag Assignment”, select (FA) at the prompt
- d) Type “SP” to select patient
- e) Enter the desired patient by typing the first letter of the last name and last 4 digits of the social security number. Then, hit enter.
- f) Select: “**EF/ Edit Flag Assignment**” as the assignment action.
- g) Select: R Reactivate Assignment



- l) Hit enter to “would you like to edit the narrative assignment narrative? YES//” (as shown above)
- m) For approved by, enter David Bower (Chief of Staff)
- n) The “Narrative Text” box with the **text previously** entered will appear on the screen



Approved By: bower,david BOWER,DAVID JAMES DJB STAFF PHYSICIAN
111 STAFF PHYSICIAN

Enter the reason for editing this assignment:

Patient Record Flag - Edit Reason Text

==[WRAP]==[INSERT]===== < Edit Reason Text >===== [<PF1>H=Help]=
The patient is partaking in yet another study

Num lock + F to save and exit

Enter Review Date: (2/24/2011 - 8/23/2011): 8/23/2011// (AUG 23, 2011)

REVIEW OF EDIT FLAG ASSIGNMENT DATA INPUT BEFORE FILING

Patient Name: ZZBROWN,TEST
Flag Name: RESEARCH CLINICAL TRIAL
Flag Type: CLINICAL
Flag Category: II (LOCAL)
Assignment Status: ACTIVE
Initial Assignment: 6/15/2010@13:56:32
Last Review Date: 8/16/2010
Next Review Date: 8/23/2011
Owner Site: ATLANTA VAMC
Originating Site: ATLANTA VAMC
Assignment Action: REACTIVATE
Action Date: 2/23/2011@12:00:40
Entered By: HALL,DONNDRA D
Approved By: BOWER,DAVID JAMES

Record Flag Assignment Narrative:

This patient is currently participating in a research study.
Enter RETURN to continue or 'X' to exit: ■

REVIEW OF EDIT FLAG ASSIGNMENT DATA INPUT BEFORE FILING

Record Flag Assignment Narrative:

Contact the Principal Investigator for additional information about this research study.

Special Information: Curious Case #456789

principal investigator: Donndra Hall ext 2964

Action Comments:

The patient is partaking in yet another study

Do you want to review again? NO//

Would you like to file the assignment changes? YES//

- o) You will be asked, "Do you want to review changes?" Select yes or no as appropriate.
- p) You will be asked "Would you like to file the assignment?" Select yes. Only select no if you wish to change the information you entered.
- q) Exit VISTA

Second Step (Not Needed For Flags "Entered In Error")

- a) Sign into CPRS
- b) Select patient name (Flag will NOT display if removed or inactivated). It will display if you choose to reactivate it.
- c) Go to the "Notes" tab, click on "New Note", "New Visit", click on the historical box, enter the date and time and click "OK".
- d) Type in "Patient Record Flag" for note title, highlight the note as shown below and click "OK".

Vista CPRS in use by: Hall,Donndra D (live.atlanta.med.va.gov)

File Edit View Action Options Tools Help

ZZBROWN,TEST RCL G1 Feb 24,11 09:00 Primary Care Team Unassisted
 000-00-7035 Apr 27,1970 (40) Provider: HALL,DONNDRA D

Last 100 Signed Notes

PATIENT RECORD FLAG CATEGORY II - RESEARCH
 Vst: 02/24/11 ATL RESEARCH-STUDY

New Note in Progress

Feb 24,11 PATIENT RECORD FLAG CATEGORY II - RESEARCH

All signed notes

Template: PATIENT RECORD FLAG CATEGORY II - RESEARCH CLINICAL TRIAL

Research Clinical Flag **** FOR RESEARCH PURPOSE **** ...

☐ This flag was entered in error.

☐ Initial Flag ...

☐ Continue Initial Flag

☐ Study Study Title:

Research Coordinator:

This patient is currently participating in a research study involving a

Special Information:

Principal Investigator:

Contact the Principal Investigator if additional information is required about this research study.

e) Complete and sign the note and exit CPRS.

Common Error Message:

```

Searching for a National Flag

Searching for a Local Flag
RESEARCH CLINICAL TRIAL    ACTIVE    CLINICAL
...OK? Yes//    (Yes)

Unable to proceed with flag assignment...
Record flag is already assigned to patient

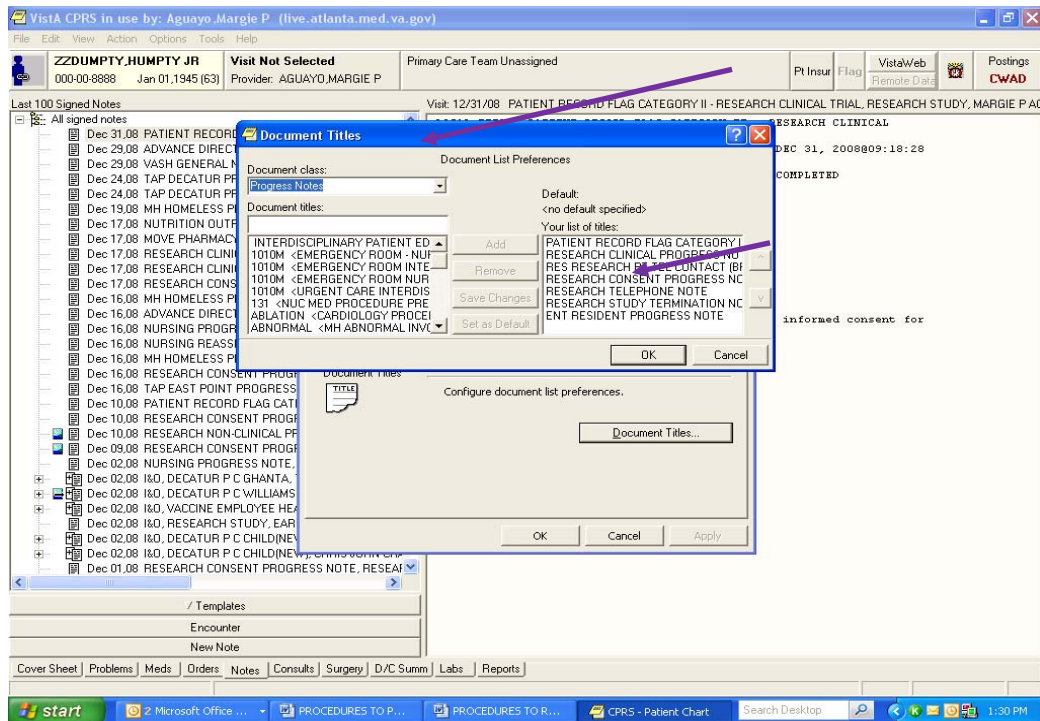
Enter RETURN to continue or '^' to exit: █

```

You must follow the instructions for *Posting A Flag For A Patient That Previously Participated In Another Research Study And Now Has An "Inactivate Assignment"*:

Procedures to set the “patient record flag category ii- research clinical trial” note as a preferred note title:

- Go to CPRS
- Click on “Tools”, then “Options”.
- In the Options box, select the notes tab and then the “Document Titles” box will pop up.
- The document class will be “Progress Notes”. Type the “PATIENT RECORD FLAG CATEGORY II-RESEARCH CLINICAL TRIAL” to select the note in the “Document Title” section, and then click ok



To finalize, click “OK” in the “Option” box.