Office of Research Integrity
901 N. Lake Destiny Rd., Suite 400
Maitland, FL 32751
407-200-1615

ACCOUNT NOTIFICATION AND RECONCILIATION PROCESS

I. ACCOUNT NOTIFICATION OVERVIEW

The account notification process is used to communicate items/services related and performed as part of a clinical trial. This notification requires communication between the research study department and the department(s) assigned to billing the items/services.

A. *Notification is required for the following situations in the life of the study:*

1. When initiating a new research study; prior to patient enrollment.
2. Upon patient enrollment and/or screen failure.
3. Prior to protocol required inpatient stays and subsequent visits, when aware. For example, baseline and follow up visits regardless of whether visit assessment is all routine care, all research or a combination of both.
4. When a patient is removed from or completes a study.
5. When the study is complete or terminated.

B. *Please note the below regarding the Account Notification process:*

1. When consenting/enrolling an inpatient, do not wait until the day of discharge to send a notification. Late/Absent notifications may lead to sponsor covered items being billed to patient or insurance.

2. When a physician performs a procedure/service or interprets/reads diagnostic exams, there is a professional fee attached to this service. It is important to email FHMG and FRI when a physician representing Florida Hospital performs a service related to research.

3. Please remember to also communicate pertinent billing information to any independent physician/ancillary practices. To ensure the billing is performed according to the protocol, budget and Billing Grid/Coverage Analysis (CA).

II. ACCOUNT NOTIFICATION FORM

To ensure information is provided to billing consistently across all research departments, a form was created to help facilitate communication.

A. *This form was designed to communicate the following:*

1. Contact Personnel (Department Information section):
   - Department Name
   - Contact Person
   - Contact Number

2. Initiation of a new study (Study Information section):
   - Contact Personnel information
   - Protocol long title (Study Name)
   - Mnemonic (short name/IRBNet#/PI)
   - Name of Research Department
   - Point of contact for the study
   - Institutional Review Board (IRB) #
   - Principal Investigator
   - National Clinical Trial (NCT) #
   - IDE Number

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3. Patient enrollment (Patient Information section):
   - Contact Personnel information
   - New Study Information
   - Patient Name
   - Study ID
   - Date of Birth
   - Consent Date
   - Date of service
   - Treating Physician
   - Account Number (I.e. Hospital/Athena)
   - MRN (Hospital)

4. For all subsequent visits or inpatient discharge, notification form must include the following information:
   - Contact Personnel information
   - New Study Information
   - Patient Name
   - Study ID
   - Date of Birth
   - Consent Date
   - Date of service
   - Treating Physician
   - Account Number (I.e. Hospital/Athena)
   - MRN (Hospital)
   - Indicate the study visit type (Visit 1, 2-week F/U, 6=month visit, etc.)
   - Items billed to Research and/or Routine care items (Charge Delineation)

5. For patient end or disenrollment of a study, notification form must include the following information listed below:
   - Contact Personnel information
   - New Study Information
   - Patient Name
   - Study ID
   - Date of Birth
   - Consent Date
   - Date of service
   - Treating Physician
   - Account Number (I.e. Hospital/Athena)
   - MRN (Hospital)
   - Indicate which scenario applies in Visit type
   - Items billed to Research and/or Routine care items

B. *Please note the below regarding the Account Notification process:*

1. Each time you communicate new information, please make sure all pertinent sections are also filled out on the form.

2. At the bottom of the form there is a notes section that can be used to communicate any other information pertinent to communication.

3. If a patient is a **"Screen Failure"**, notify all entities included in the initial notification as soon as possible. Referencing the coverage analysis indicate any charges the patient received prior to failure and whether they should be billed to sponsor or insurance.

4. If more space is needed than field provided to communicate charge delineation, indicate information on separate piece of paper and attach to email. **If you have access to RS42 in Suncare/Sunport, follow the below steps:**

   - Print RS42 screen
   - Referencing the coverage analysis, circle charges that are billable to research and place an "R" next to the corresponding charge line.

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- Next circle charges that are Routine Care and billable to insurance and place an "RC" next to the corresponding charge line.
- Reply to original "Account Notification" email and attach updated account notification form checking the "Research and Routine Care Services" checkbox.
- Attach RS42 page with the charge delineation detail.

AdventHealth Orlando

RESEARCH SERVICES
ACCOUNT NOTIFICATION FORM

DEPARTMENT INFORMATION	
Department Name	
Contact Person	*Fill out once as this information will be the same throughout communication.*
Contact Number	

STUDY INFORMATION	
Study Name	
Principal Investigator	*Fill out once as this information will also be the same throughout communication. If you need to provide an update, then simply explain update in body of email. Only fill out information that pertains to current study. For example, if it is not a device study, then the IDE# would be left blank.*
Mnemonic Name	
IRBNet Number	
NCT number	
IDE#	

PATIENT INFORMATION	
Patient Name	*Treating physician is important because depending on the visit, treating MD may differ from the principal investigator. The Study ID is another way the patient can be identified.* *All services related to this visit should be identified in appropriate field (Billed to Research or Routine Care) OR information regarding this information should be attached.* *Check One Box – At least one should be checked. More than one can apply if patient is completing study.* *TIP: Keep an electronic or paper copy of this form with contact, study and certain patient information auto filled so that updating the billing teams on the patient's next visit would only need the visit type, service provided and check box indicating billing instructions. (See attached example)*
Date of Birth	
Study ID	
Date of Consent	
Date of Service	
Treating Physician	
MRN #	
FH/Athena Account #	
Visit Type	
Items Billed to Research	
Routine Care items	
Check one: *Check ALL that apply*	New Research Study ☐ Screen Failure ☐ Account Hold☐ Routine Care Only ☐ Research Reimbursed Services ☐ Release Bill ☐ Off Study ☐ Research and Routine Care Services ☐ Study Complete ☐
Notes	*Use this space to write any addition information not captured in form.*

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III. ACCOUNT NOTIFICATION EMAIL

Once the Account Notification form is filled out, it should be sent to all appropriate groups who bill charges for each patient. Communication should identify research funded (Sponsor Reimbursed) services as well as routine care (Billable to Insurance) items related to each study as documented in the coverage analysis. Please see below email addresses and ensure that the correct email is sent to any/all groups that your communication applies to:

1. **For FH Facility Services (PFS Hospital Account)** - FH.PFS.Research.Studies@flhosp.org
2. **For FH & FHMG Physician Services** (Professional Fees) – FHMG.Clinical.Trials@flhosp.org
3. **For FRI Billing** (Radiology Account for X-ray, CT, MRI or PET scans) – FH.FRI.Billing@Flhosp.org
4. **For Infusion Center Services (Blood draw...etc.)** – FH.Infusion.Center.Charge.Auditing@flhosp.org
5. **For Independent Physician and Ancillary Services –** Please email contact person associated with each site.

Each research department shall make their own determination of the intradepartmental names to also include (i.e. manager/director, financial rep, etc.…).

Helpful Hint: *"CC" yourself in this initial email. This will prevent you from having to retype needed information in the 2nd phase. You will only need to reply all to this email and provide reconciliation information.*

A. *Email Subject Lines:*

To increase efficiency and consistency, please add the following subject lines to each email where applicable. This will help the Billing Department quickly identify the reason for your communication and will help you keep track of the information you send. **Please note when determining items/services that are billable or research funded, always refer to the coverage analysis.**

1. **INITIATING STUDY:** Use this subject line to communicate the start of each new study.
   - ***"New Research Study":*** This is sent when a new research study is approved. All billing departments representing services that will be performed according to the protocol need to be informed. This is due to a flagging label created by billing to attach to future enrolled patient accounts for facility (Hospital) services and also hold all patient accounts on the professional (Physician) services side.
2. **PATIENT ENROLLED:** Use this subject line to communicate the enrollment of a patient.
   - ***"Research Account Hold":*** If patient is enrolled in a study during an inpatient stay, notify appropriate parties to place the account on hold. If aware of specific services, please also indicate which charges will be Research (Covered by sponsor) and/or which charges are Routine Care (Billable to insurance).
   - ***"All Research-Create Account":*** Patient currently enrolled and next outpatient service date is a sponsor reimbursed services with no charges being billed to insurance. Upon services performed, Research Department will verify all services to ensure charges listed are still research reimbursed only. If any charges are not sponsor reimbursed, billing teams must be notified.

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- ***"All Routine Care-Create Account"**:* Patient currently enrolled and next outpatient service date is billable to insurance. Upon services performed, Research Department will verify all services to ensure charges listed are still routine care only. If any charges are sponsor reimbursed, billing teams must be notified.

3. **NEW PATIENT ACTIVITY:** Use this subject line to communicate Inpatient and Subsequent follow up services and visits. This will update the billing teams on held accounts and give them direction on how to bill accordingly. NOTE: If the patient is Inpatient, communication must be completed within 3 days of discharge or completion of scheduled assessments.

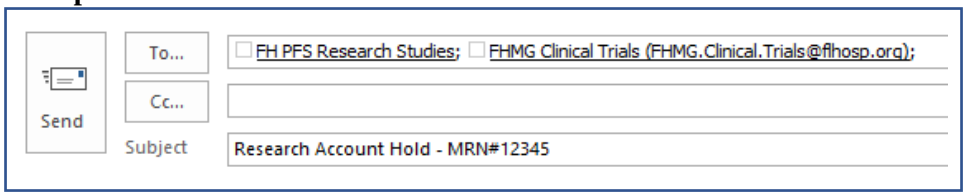
- ***"Research Reimbursed Services":*** Patient enrollment previously communicated and now identifying item/services that need to be invoiced back to research dept (Sponsor Reimbursed) and removed from the billable account.

- ***"Routine Care Only"**:* Services performed are part of the study but are routine care and billable to Patient's insurance.

- ***"Research & Routine Care Services"**:* Services performed contain both Sponsor reimbursed (Invoiceable to Department) and Routine care (Billable to insurance) services. Please indicate what items/services fit each category.

NOTE: Please add patient MRN# after subject line statement to quickly identify research patient during reconciliation process.

Example...



4. **PATIENT SCREEN FAILURE/WITHDRAWN/COMPLETED STUDY:** Use this subject line to communicate when a patient is no longer being followed in a study.

- ***"Release Bill":*** *Patient not enrolled due to screen failure, withdrawn or completed research study.*

5. **STUDY END:** Use this subject line to communicate the end of a study.

- ***"End of Study":*** *Study has now ended and will have no further enrollments or patient visits.*

If you have any questions or need any clarification regarding this document, please contact the Office of Research Integrity via phone at 407-200-1615 or email at FH.ORI@flhosp.org.