Epic Tip Sheet

Children's of Alabama

Study Start-Up and Activation

PT Approver Initials: TP
Analyst Approver Initials: TP
Approved Date: 04/29/2025

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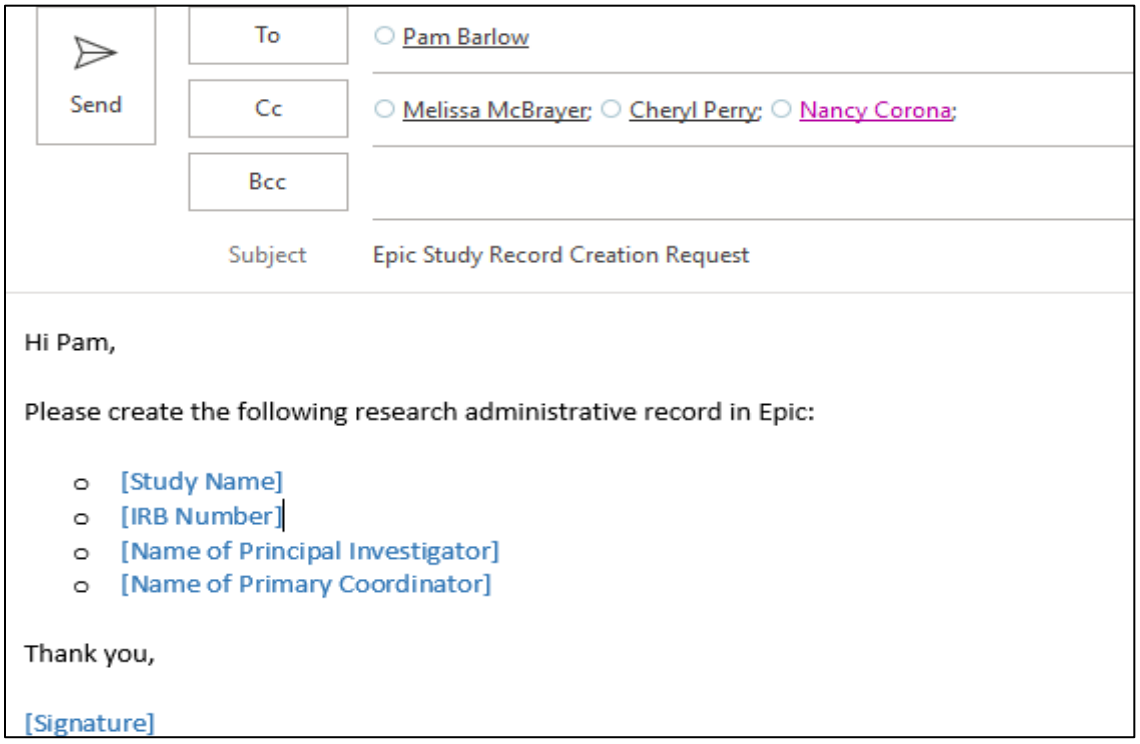
Research Study Record Creation

Once the UAB IRB Office has approved an IRB for a patient-oriented research study, you may request creation of the study record in Epic. Email the following information to Pam Barlow at the COA Research Administration Office and cc those indicated.

- **TO:** Pam.Barlow@childrensal.org
- **CC:** Nancy.Corona@childrensal.org; mmcbrayer@uabmc.edu; cherylperry@uabmc.edu
- **Subject:** Epic Study Record Creation Request
    - Include the following information in the body of the email.
        - Study Name
        - IRB Number (this will be the Epic study record number)
        - Name of Principal Investigator
        - Name of Primary Coordinator
- Supply the primary coordinator's name only. Once the research study record is created, the primary coordinator listed will add other coordinators and research contacts as needed.

Once the "skeleton" research study record is created in Epic. Pam will notify you by email.



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Confirm the Details

Before activating your study record, confirm the crucial details. Log into Epic. When prompted to select a department; choose COA Research Support.

- On the main toolbar, select **Study Maintenance**.
- In the **Study Select** window, search for your study by IRB number.
- Open the study record. Under **General Information**
  - Replace the placeholder name with what you will call the study (can be a shortened version).
  - Confirm the study code is the same as the IRB #.
  - Update the study type.
  - Update Study Division or Department.
- Under **Users and Providers** form, confirm the study coordinator and PI listed are appropriate. Add any additional users as appropriate. **Only the PI and study coordinators will receive automated messages (ADT, appointment change, etc.). Regulatory staff or additional users who do not need this context should be listed in the other fields.**

Update Additional Information

The information noted above is required. All items below are technically optional, but teams are strongly urged to consider each item for use as appropriate.

- **General Information**
  - NCT Number (if applicable)
  - Patient-Facing Area of Research (if used by your research area)
    - Items b and c were provided to the project team by your specific departments. If you feel something is missing, please submit a help desk ticket to request additional build.
  - Description (recommended). This can either be a brief description of the study, study contact information, or both.
  - IRB Approval Information (Recommended)
    - IRB number for the study in the format: IRB-XXXXXXXXX
    - IRB approval Date and Expiration Date
- **Users and Providers**
  - Fields must be maintained as staff turnover occurs to ensure accurate and ongoing access to the study records and billing.
- **Studies Activity Setup**
  - Links - Use to store any relevant study hyperlinks.
- **Report Groupers**
  - Provided to the project team by specific research areas. If you feel something is missing, please submit a help desk ticket to request additional build.

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  - Release of Information (ROI) Special Attention
    - Used to display a warning to ROI staff when they are performing a release of patient information linked to the Research study. Confirm with your regulatory team and/or PI prior to changing this field from "Always Okay to Release."
  - Special Billing Handling
    - Leave blank unless there are extremely special circumstances. Used to exclude the studies charges from Research Billing Review. It is very important
    - that this field is only used if there are no charges that will be billed to the study account and all charges will go to the patient's account. If inappropriately set, all charges that should be paid for by the research study will be billed to the patient.
- **Automated Actions**
  - Can be used to override default messaging configuration. Use this section to prevent messages related to ADT events, appointment changes, and research results from being sent to the study team.
  - Release Restrictions
    - A stronger section that functions like the above "ROI Special Attention" grouper. It specifically requires release staff to request Research records before including them in a release. Like above – confirm with your regulatory team and/or PI prior to setting a release restriction.

Activate the Record

!	**Note: After a study's billing status is made Active, it cannot be made Inactive again.**

A study record must be active before you can link patient records, encounters, and orders to the study, and is necessary for billing to route to the research guarantor account.

- Under **General Information**, change the study billing status from Inactive to Active.
- Update the study status. (Tip: Think through how recruiting is currently being carried out, if carried out at all, to motivate your selection. Is it recruiting, by invitation, etc.?)

Provide Research Study Charges to Research Billers

- **Excel File Billing "Calendar"/Fee Schedule**
  - If the research study has **COA Hospital** charges that should be billed to the study account, research study staff must provide the research billing staff at the Westerkamp Group with an excel file for that study at study start-up.

- These calendars should only list **COA Hospital** charges that are **Study-Related – Bill to Study** on a visit-by-visit basis.
- The name of the billing calendar must include the IRB number ("Study Code" in Epic), so the research billers know to which Epic study record the billing calendar belongs to facilitate research billing review.
- The template for creating the billing calendar is found on the home page of the UAB Pediatric Research Office: https://www.uab.edu/medicine/peds/images/PRO/IRB_Fee_Schedule_Template.xlsx
- An example of how the form should be filled out:

IRB-300002424	**XYZ Research Study**		
	Week 1	**Week 3**	**Week 5**
Charges [CPT Code]	**Visit 1**	**Visit 2**	**Visit 3**
CBC/PLT WITH AUTO DIFF [85025]	RSH	RSH	RSH
NECK SOFT TISSUE, CT [70490]		RSH	
X-RAY EXAM OF NECK [70360]	RSH		
Legend: RSH = Research (bill to study)			

- Pam Barlow of the COA Research Administration Office will have already provided the CPT code and research price(s) for the COA Hospital Charges at the time of budget development.
- Once completed, the excel billing calendar is sent by the primary research coordinator to the following research billers at the Westerkamp Group: Nick Harig nharig@wgrcm.com, Rhonda Gunn rgunn@wgrcm.com, Patrick Ryan pryan@wgrcm.com, and Barbara Lucia blucia@wgrcm.com.

Use the COA Research Pre-Registration Form

Prior to each encounter that will generate a research clinical billable, complete the COA Research Pre-registration form. The latest version is on the UAB Pediatric Research Office page (**www.uab.edu/peds/pro**) under Conducting Research at Children's of Alabama.

- The pre-registration form should list items that are COA Hospital Study-Related – Bill to Study for the encounter in the middle text box on the form.
- The bottom area of the form should be assessed for other charges such as UAB professional fees, research echos, etc. Contact the Pediatric Research Office staff with any questions on non-COA billables: Melissa McBrayer **mmcbrayer@uabmc.edu** or Cheryl Perry **cherylperry@uabmc.edu**.
- Once completed, the pre-registration form needs to be sent to the list of contacts on the bottom of the form.