Lifespan
Delivering health with care.

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Office of Research Administration

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We're Back!

The Clinical Trials Office underwent a staffing change several months ago, and we have been busy hiring and training our newest team member. Please join us in welcoming our new Senior Research Administrator, Melissa-Lauren Hooks. Please note the changes to the Department/Division assignments on pages 2 and 3.

"NB" (Non-billable) vs. "S" (Sponsor) or "RC" (Routine Care)

In completing the coverage analysis for your study, please use this guide in determining the correct designation for a test or procedure.

NB: Non-billable items are those that could not be directly billed to a study subject or their insurance. Examples include: informed consent, vital signs, questionnaires, concomitant medications, and chart reviews. The hospital cost for these items is included in study staff time and effort.

S: Sponsor items are those that the Sponsor is paying that could be billed to a study subject or their insurance. Examples include: scans, labs, ekgs, and physical exams.

*****IMPORTANT NOTE: If any of these items are to be performed by study staff and charged as time and effort, they are still listed as "S" in the coverage analysis. The comments section should be used to clarify that the cost will be incurred as time and effort. This also applies to labs – if a CBC is going to a central lab, it is marked as an "S," and the comments section should be noted that a central lab is being used.**

RC: Routine-cost items are those that are study-related, but part of the subject's standard of care treatment (they would be having the test or procedure regardless of their participation in the study,) and that could be billed to a study subject or their insurance. Examples include: scans, labs, ekgs, and physical exams.

If you have any questions about these designations, please contact the CTO for clarification.

Who do I contact for my Clinical Trial?

For the departments listed below, contact **Gina Johnson**:

Cancer Center

Emergency Medicine

Endocrinology

Diagnostic Imaging

General Internal Medicine

Men's Health

Neurology

Ophthalmology

Orthopedics

Radiation Oncology

Renal

Rheumatology

Urology

Women's Health

LifeChart: Linking Patients to a Study Timeline, Encounters, and Orders

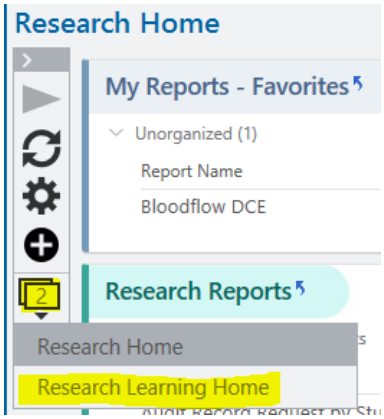
Research billing review can be time-consuming and often frustrating when charges are not correctly assigned to a study or insurance and corrections have to be made. One of the features of LifeChart is to make this process easier by linking research encounters and orders to the study, and linking study participants to the study timeline. *(Note: many older studies opened before Lifechart went live do not have a study timeline, for these studies the timeline instructions will not be applicable.)*

For studies with a timeline built in the LifeChart system, please be sure to link all study patients to the timeline. This will enable Lifechart to identify tests and procedures that occur during research timepoints and properly assign them to either the study or the patient's insurance.

Linking the patient's encounters and orders will also ensure more accurate information is reflected on the patient's bill when the Study Coordinator and CTO review the charges.

Detailed instructions on linking encounters, orders, and the timeline are available on LifeChart's Research Learning Homepage.

From your Research Home Page, click the down arrow as shown below, then choose Research Learning Home:



Who do I contact for my Clinical Trial?

For the departments listed below, contact **Melissa-Lauren Hooks:**

Behavioral Medicine

Bradley Hospital

Cardiology

Cardiothoracic Surgery

Dermatology

Gastroenterology

Infectious Diseases

Neurosurgery

Pathology

Pediatrics

Plastic Surgery

Pulmonary

Psychiatry

Rehabilitative Medicine

Surgery

Business Proposal Form Reminders

Please remember to submit all of the necessary documents to the CTO as one package, with all necessary signatures obtained. This will make the review process easier for the Department and the CTO. Some helpful tips are listed below:

- ***Business proposal form*** signed by the PI, Department Administrator (if applicable), and Division/Department Chair/Chief.
- Signed ***Lifespan Conflict of Interest*** *form*, or email confirmation from Peggy McGill for ALL "Investigators," as defined in the Lifespan Conflict of Interest policy. The Department Chair will have to co-sign if the Investigator chooses "Yes" for any of the COI questions.
  They must also have completed the mandatory training.
- ***Coverage analysis*** signed by the PI - with necessary comments included, and the NCT and committee numbers listed. If an NCT number is not yet available or not applicable, please indicate on the form. *Please include comments to explain who is performing tasks, where labs are being processed, etc. This will help to eliminate questions when the CTO is reviewing the document.*
- All ***quotes for Lifespan services*** being utilized (examples:
  MRI, CT, labs, ECHOs, EKGs, imaging reads.)
- ***Letters of Cooperation*** from service providers who will be invoicing for their services, including a price quote (examples: dermatology or psychiatric exams, CRC services.)
- ***Internal budget***, complete with estimation of all costs that the Institution will incur in performance of the study.
- ***QCT form***, signed.
- ***Pharmacy Worksheet*** if you are using the services of the Lifespan pharmacy.

Note: Business forms can be submitted to the CTO electronically. Verified electronic signatures are also acceptable (no name stamps.) **Department Chair approval may be submitted in the form of an email rather than signature, however please be sure that the study name and PI are listed in the email, along with a statement as follows:**

This e-mail serves as my approval as the Chief of _____ for the study noted below. I have reviewed the proposal and it is approved for scientific relevance and quality.

Application Title:
Sponsor:
PI: