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Lifespan

Office of Research Administration

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Welcome!

Welcome to the inaugural issue of the Office of Research Administration's (ORA) Clinical Trials Quarterly newsletter. This newsletter is designed to deliver helpful information, news, and tips for success for those researchers who conduct industry-sponsored clinical trials throughout the Lifespan system.

In October 2014, the Clinical Trials Office (CTO) was established by the Lifespan Office of Research Administration (ORA), recognizing the need for ORA to provide more specialized, centralized and timely services for our Investigators who conduct clinical trials.

In the past, ORA's Research Administrators handled all grants and contracts for their Investigators, but with the advent of the CTO, two Administrators handle *only* industry-sponsored clinical trials. Under the management of Deb Temple, RN, Research Administrator Kim-Marie Lawrence and Clinical Trials Compliance Administrator Gina Johnson are responsible for all Administrative tasks relating to Industry-Sponsored Clinical Trials, from the initial Confidential Disclosure Agreement (CDA) through study close-out.

The CTO is also expanding review of post-award activities, such as payment receipts, invoicing, and budget monitoring. We plan to meet with all Investigators on a regular basis to discuss the status on pending studies, the financial status of their current studies, and plans for future clinical trials. This is also an opportunity for Investigators and their staff to convey any issues they may be experiencing with the Clinical Trials process to their Administrator, and discussion to take place on how to mitigate or resolve these issues going forward.

In addition, the CTO is tasked with the review and approval of Research Billing in LifeChart, and troubleshooting any issues that arise in the research billing process. We also offer training for staff on topics such as completing the

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Coverage Analysis, Building an Internal Budget, and Monitoring Clinical Trial Finances.

Our goal is to provide continuity, timely processing, and clinical trial-specific expertise to Investigators, Study Coordinators, and Sponsors.

Please contact us anytime with suggestions, requests for training, or any clinical-trial related questions.

LifeChart and your Study – Is it Necessary?

On March 29, 2015, Lifespan went live with their new patient record and billing system, known as LifeChart, and life as we knew it in Research Billing changed forever. Navigating this new system has been challenging for everyone, starting with numerous classes and lots of practice, and culminating with the reality of day-to-day use. Issues have arisen as expected but the Research community, with the help of the amazing LifeChart team, has rallied together to make the implementation a success.

So with all of these changes, how does LifeChart affect your Clinical Trial?

<u>It's All About Billing</u>

It's as simple as asking this question. Will you utilize any Lifespan billable services during your study?

Examples include Lifespan laboratory processing, venipuncture, MRIs, x-rays, CT scans, ECHOs, and EKGs – anything that will generate a Lifespan bill. If you answered yes, your study must be entered into LifeChart by a member of the CTO staff.

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Who do I contact for my Clinical Trial?

<u>For the departments listed below, contact Gina Johnson:</u>

Cardiology

Emergency Medicine

Infectious Diseases

Men's Health

Neurology

Ophthalmology

Orthopedics

Pulmonary

Renal

Rheumatology

Urology

Behavioral Medicine

Who do I contact for my Clinical Trial?

For the departments listed below, contact Kim-Marie-Lawrence:

Comprehensive Cancer Center

Cardiothoracic Surgery

Dermatology

Diagnostic Imaging

Endocrinology

Gastroenterology

Neurosurgery

Pathology

Psychiatry

Radiation Oncology

Surgery

Women's Medicine

NOTE: This applies to all Lifespan Research, not just Clinical Trials. Federal, Foundation, Subawards, and Department funded studies that have Lifespan services in the budget must be entered in LifeChart.

The CTO enters all protocols into LifeChart through the collection of the Coverage Analysis (CA) form. The CA can be found at http://www.lifespan.org/clinical-trial-billing-forms.html.

****Things to remember:*

- If a research staff member is doing an EKG or venipuncture, they do not go into LifeChart. This salary cost will be charged to your study via Time and Effort Reporting.
- If the study subject will be registered for an office visit that will be charged to the study, that also must be entered into LifeChart.
- Non-billable (NB) items are those that could not be charged to a study or to a patient. Examples include; time to complete the informed consent, concomitant medications, vital signs, adverse events, telephone contacts, and questionnaires. The cost for these services is included in the salary charged to the study for staff member performing these duties.
- If you have a study that will be entered into LifeChart, you must have a trained Coordinator with access to the LifeChart system. This person will be responsible for linking patient with a study, and also reviewing all charges that post for the patient, even those that are non-study related. The Coordinator will also make any necessary corrections if a charge was incorrectly entered as Study-Related or Non-Study.
- Finally, the more detailed information you include on the Coverage Analysis, the better. Let us know if a venipuncture will be necessary, if labs are local or central, who is doing the EKG, etc.

For Coordinators who need LifeChart training:

- ✓ The employee's Manager should submit an IAM request for LifeChart access to "Research Coordinator" for that employee.
- ✓ The employee or manager should email Adam Rojek, copying Peggy McGill to have the training for that employee set up in NetLearning.

In next Quarter's issue:

- ✓ How to Build a Complete and Accurate Coverage Analysis
- ✓ The Internal Budget (aka Clinical Trial Workbook)