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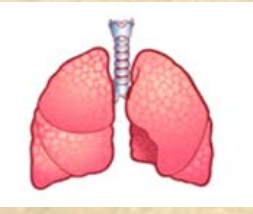

Pulmonary Research News

A publication of the UofL Pulmonary Division's **Lung Health Initiative**

I would like to welcome you to the first edition of Pulmonary Research News (PRN). Our purpose is to share exciting new research happenings occurring in the Division of Pulmonary, Critical Care, and Sleep Disorders Medicine. We welcome you to submit your new trials and publications to be distributed to your staff and colleagues.

WHAT'S NEW?

We have recently undergone some organizational changes in the area of clinical research and have adopted a Program Model –

- Sleep
- ILD - Interstitial Lung Disease
- COPD - Chronic Obstructive Pulmonary Disease
- IP - Interventional Pulmonology
- Critical Care
- CF - Cystic Fibrosis
- Lung Transplant
- PAH - Pulmonary Hypertension
- VA Research

Each Program has an assigned PI as the Team Leader and study coordinators who are experts in the specific area of study. We have had success with this model in the past and the goal is the creation of multiple Programs of Excellence under the umbrella of a unified Respiratory Health Center.

Here is a list of some of the centralized services we will be offering to assist each program in the conduct of their clinical trials:

- Financial tracking of your clinical trial accounts
- Invoicing sponsors/vendors
- Reconciling research accounts
- Assistance with IRB and regulatory matters as needed
- Oversight of coordinator effort and funding
- Study Coordinator education
- Resource for the conduct, feasibility, and logistics of your clinical trial
- Scientific Review
- Protocol Review
- Protocol and consent development
- Assistance with the hiring of study coordinators
- Maintenance of a site Biosafety Committee approval
- Maintenance of annual site CV's and medical licenses

UofL CLINICAL TRIAL UNIT (CTU)

The UofL CTU, under the direction of Dr. Craig McClain, is a clinical area located in the HCOC on the 4th floor designed specifically for seeing research patients. It consists of 6 exam rooms, an infusion room with 4 chairs, a medicine room, a lab processing room, coordinator work areas, and a patient check-in area and waiting room. It is available to all UofL researchers.

The area is finished and looks wonderful (even has that new smell). It looks like our timeline to begin seeing our pulmonary research patients will be the third week in April (just in time for Thunder). The CTU folks are working on an internal scheduling system and will provide access, training, and tours in the near future. Stop by and take a look when you get a chance – you can take the elevator to the 4th floor and go to the left or take the stairs next to the new ACB pedway and it will be a short distance down the hallway on the right.

OTHER ANNOUNCEMENTS

Caitlin Clarke has accepted a new position under Christy Haden in the DOM for financial management of our industry sponsored clinical trials. She has been transitioning from the COPD Program scheduling, regulatory and IRB management to this new position. This new position brings a number of new skills for Caitlin as well as requiring a lot of catching up on our clinical trial finances. Her responsibilities will include monthly financial tracking, reconciliation, posting AR, procurement card reconciliation, swift card auditing, invoicing, vendor payments, etc. for all of our trials. She will be asking you for tracking sheets, receipts, verifying payments, posting checks, etc.

We are excited that Caitlin has accepted this role – please congratulate and support her in this new role!

Caitlin previously provided assistance to the COPD Program teams with patient/procedure scheduling, IRB submissions, and regulatory file maintenance.
Her change in role will require each individual research team to take on the responsibility for these activities for each of their trials. For those of you who have never done this part of clinical research, we will work with you on an individual basis to make sure you receive the necessary training and that there aren't any lapses in submissions. I have already worked with several of you on IRB submissions and have received positive feedback.

In the conduct of trials, it is important to be a part of things like the writing of the consent or knowing how a trial is budgeted or how the billing for research procedures occurs. I call it *"primary care coordinating".* It doesn't take away the "Team Approach", nor does it create redundancy. It's learning to balance those activities that are appropriate for centralizing and keeping other activities decentralized. Decentralized activities include recruitment of patients, patient education, patient visits, etc. This creates an environment in which patients can feel safe and secure while taking part in an experimental drug or device trial. Our expertise in a specific area is why patients come to see us and is what makes our pulmonary group different from the private practice physician. And it contributes to patient retention which is critical for the integrity of the trial.

ALLSCRIPTS AND RESEARCH VISIT SCHEDULING

Many of our investigators enter Research Visit Progress Notes in Allscripts as it follows usual clinical care of our patients. It also falls under GCP – Good Clinical Practice Guidelines for clinical research. I've heard people say – "but, they're only guidelines." They are only guidelines if you haven't agreed to follow them in the clinical trial contract or in an FDA approved protocol. Read those contracts you've signed and read the last few pages in the protocol. If it says you will follow GCP, then you must follow GCP. Basically, GCP is taking care of your patient while participating in your clinical trial – patient safety. It's notifying their primary care physician that they are in a clinical trial, it's following up on adverse events and making sure the patient has been referred for problems that arise during the trial or addressing it in an appropriate manner. It's not just signing "CS" or "NCS" (clinically significant or not clinically significant) on a lab report or ECG.

Currently, coordinators schedule their research visits in Centricity and the doctors will enter progress notes at designated times. Not every visit requires a physician note. You will need to discuss this as a team and determine what your standard operating procedure (SOP) will be for each trial. I always remind folks to develop SOPs reasonably – as you will be held accountable for documenting that you followed your SOP.

Not all of our coordinators have access to scheduling research appointments and entering notes – we have requested this access and expect it to be completed within the next week. Dr. Rivas-Perez has expressed an

interest in creating a “clinical warning” in Allscripts, much like what the VA uses. Currently, this information can be entered into “clinical alerts”, but it is limited to a specific number of items and is pretty much like entering an allergy for the patient. It doesn’t allow for additional information like study contacts, etc.

A Research Folder can be generated in the Chart Menu. Consent forms can also be scanned into the medical record and it will automatically create the research folder. We can talk to the clinic folks more about this as we might be able to enter a “Research Notification” that includes a brief description of the study and study contacts. Our group could be the ones that take the lead on developing a standard template to be used by all – More to come on this subject.

I would like to thank each of our clinical research coordinators for their contributions to not only the conduct of the trials, but also for their care and compassion of our patients – Crissie Despirito, Bryan Beatty, Heidi Wilson, Dena Shofner, Caitlin Clarke, Leslie Haysley, Joan Hamlyn, Belica Graf, and Caitlin Lantier. The Pulmonary Division has come a long way in the 5 years since coming to UofL – we have gone from 2 coordinators to 9 and a handful of trials to over 30. This is a tremendous accomplishment!

Next edition - a listing of our pulmonary clinical trials and clinical trials in the news. Stay tuned . . .

“A thought can prompt. Words can stir. But it takes action to attain a dream.”

Richelle E. Goodrich