All

If you have a new clinical trial starting please read the attached...basically the new information is:

Effective Aug. 1, 2020, the Clinical Research Support Office (CRSO) will begin charging fees for coverage analysis for new pharmaceutical industry-sponsored clinical trials. The office will not charge fees on studies that have already started or are in the process of starting before Aug. 1.

The CRSO will charge $3,200 for new studies and $1,000 for any significant sponsor-driven amendments that alter the study visits, procedures, or calendar. The office will invoice this fee directly to sponsors, but study teams must include it in their study budgets. In coming years, the CRSO is also looking to add a clinical trial management system fee for new pharmaceutical industry-sponsored clinical trials, but this is not yet in place. More information will be provided as it becomes available.

So if you have a new pharmaceutical industry-sponsored clinical trial please remember to budget for this analysis ok?

Thanks all!

Luciana

From: Kostrub, Elizabeth R. <elizabeth.kostrub@uky.edu>
Sent: Friday, June 26, 2020 8:50 AM
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Subject: Quarterly Newsletter

Good Morning Everyone,
I have attached our Quarterly Newsletter update to this email. Please let me know if you have any questions and I’d be more than happy to help!

Enjoy your day,

Elizabeth Kostrub

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https://research.med.uky.edu/research-crso
CRSO/CTMS Implementation Quarterly Update

CRSO is on Telework Through July 17th

Please be advised that the CRSO is currently on telework through July 17th. All staff are available by phone, email, and Zoom. The situation is fluid and decisions to extend telework beyond July 17th will be made in consultation with Dr. Geddes and CoM leadership.

Key Milestones:

Met with Health Colleges for OnCore Demonstration

- College of Health Sciences 04/08/2020
  - College of Dentistry 04/15/2020
- College of Public Health 04/28/2020
  - College of Pharmacy 05/05/2020

Held Implementation Meetings with Health Colleges

- College of Nursing: 01/21/2020
- College of Health Sciences 04/08/2020
  - College of Dentistry 04/15/2020
- College of Public Health 04/28/2020
  - College of Pharmacy 05/05/2020

New CRSO Fees

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directly to sponsors, but study teams must include it in their study budgets. In coming years, the 
CRSO is also looking to add a clinical trial management system fee for new pharmaceutical 
industry-sponsored clinical trials, but this is not yet in place. More information will be provided as 
it becomes available.

The CRSO was established to support the success and expansion of clinical research across 
the University of Kentucky’s campus by helping reduce administrative burdens, enhance 
compliance, and remove barriers to enable efficiency, collaboration, cost recovery, and growth 
of clinical trials. The office provides services such as protocol building services in OnCore, 
OnCore training, coverage analysis, billing integrity, and financial assistance to clinical research.

To request a service, including a coverage analysis, click the blue “Request a Service” button at 
https://cctsdata.uky.edu/membership/. Those with questions should contact Jessica Heskel at 
Jessica.Heskel@uky.edu.

CRSO List Serv

If you would like to subscribe to the CRSO Listserv go to: 
https://lsv.uky.edu/scripts/wa.exe?SUBED1=CRSOCTMS&A=1

Information regarding the following will be communicated through the list serv:

- Open Office Hours
- OnCore Downtime
- General Communications
CTMS Team Updates

The CTMS Team is hard at work testing and validating an OnCore upgrade from version 15.4 to the newest 2020 version. Our intent is to have this upgrade live for July. Please look for opportunities to sign up for training on new features, new/updated training documents, and the official Go-Live date on our CRSO Website or through our Listserv.

The CRSO has started initial kickoff discussions to start building the integration between OnCore and Epic. We will commence design discussions to decide what fields will be communicated by OnCore into Epic future state starting at the end of June.
If you have not yet signed up to our CRSO Listserv and would like to, you can sign up here:  https://lsv.uky.edu/scripts/wa.exe?SUBED1=CRSOCTMS&A=1

Finance

The CRSO has paused entering financial data into OnCore due to a number of process and technology issues. These functions will resume once new processes and training are developed.

The Pharma-Sponsored Clinical Trial Workgroup is assembled and we are meeting on a biweekly basis to discuss best practices for financially managing pharma-sponsored clinical trials. We have nearly completed our work on pre-award activities and will work on post-award activities next. Our goal is to have a best practices proposal to Dr. Stoops and Dr. Geddes by 07/23/20.

The finance team is working with RFS to develop reconciliation template for payments for better oversite and communication to be utilized by all finance teams.
To learn more contact the CRSO Support Office at [https://research.med.uky.edu/research-crso](https://research.med.uky.edu/research-crso)

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**COVERAGE ANALYSIS TIPS**

- **You are encouraged to submit as soon as your protocol is final** using the new [Service Request Form](https://research.med.uky.edu/research-crso)!
  - You no longer need to wait for IRB approval to start the coverage analysis process.
  - The coverage analysis should also be submitted before the budget negotiation; however if you already have a budget, it is important to review it to avoid duplicate billing to sponsors and insurance.
- **Amendments are required to be submitted to the CRSO via the [Amendment Submission Form](https://research.med.uky.edu/research-crso) for all Qualifying clinical trials.**
- As a reminder, the following documents are required:
  1. Final protocol
  2. Draft consent(s)
  3. Draft budget (if applicable)
  4. Draft CTA (if applicable)
  5. IND or IDE documentation (if applicable)
- **To obtain a plan code, the CRSO Coverage Analysis letter must be presented even if you believe your trial is non-qualifying or does not have billable services.**

Questions? Contact the CRSO at [CRSOALL@l.uky.edu](mailto:CRSOALL@l.uky.edu)