



Clinical Research Support Services

ROLE OF OFFICE

Clinical Research Support Services (CRSS) is an office created to provide centralized support and ongoing instruction to clinical research teams regarding Prospective Reimbursement Analysis (PRA), budget development, budget negotiation with commercial sponsors and Insurance and Research Participant Financial Responsibility Information that is detailed in the informed consent form.

A Prospective Reimbursement Analysis (PRA) is a systematic review of a clinical research study protocol, draft contract and sponsor budget, proposed Informed Consent Form (ICF) cost language and other documents, when applicable, including the Notice of Grant Award (NOGA), Investigator's Brochure (IB) and information regarding the FDA status of the investigational item(s). PRAs are necessary for all research studies that have the potential to generate a hospital facility charge and/or professional charge.

PRA's are drafted and uploaded into eIRB for review and approval. All study team members listed to receive eIRB notifications can view the draft PRA, however the Principal Investigator only has approve or disapprove privileges. Principal Investigators should discuss any discrepancies with the Coverage Analyst. Upon approval, the PRA is uploaded into eIRB for IRB review. The PRA is finalized after IRB approval and contract execution, if applicable.

Clinical Research Support Services monitors Clinical Research Billing Orientation (CRBO) and Clinical Research Management Systems (CRMS) online courses and enters completion dates in eIRB. CRSS also participates in a monthly training course Clinical Research Revenue Cycle. This course is open to faculty and staff. Prerequisites include Clinical Research Billing Orientation (CRBO) and Clinical Research Management Systems (CRMS). All three courses are located in My Learning under Catalog, Research Ethics and Compliance. We are also available for individual training via request to CRSS@jhmi.edu.

Budget development and negotiation are upon request and should be sent to CRSS@jhmi.edu. The budget is drafted from the PRA and is forwarded to the Principal Investigator and study team for review and approval. Upon internal budget approval, negotiations will begin with the PI and study team copied on all correspondence to the sponsor.

Key Personnel
Director, Karen Roz
Associate Director, Lisa Wallace

Clinical Research Support Services has maintained 100% employee retention.

PERFORMANCE IN THE PAST YEAR

CRSS PRA Summary	
July 2017 to June 2018	
Protocols reviewed for PRA Determination	2532
PRA Required	559
Further Study Action reviewed for PRA revisions	7060
Further Study Action PRA revisions Required	870
Time Allocation	
Average Time to assign PRA (calendar days)	6
Average Time to complete first draft PRA (calendar days)	2

CRSS tracks efficiency based on PRA requirement to Coverage Analyst assignment and PRA first draft completion. A significant barrier for PRA first draft completion is lack of required documentation. Timely communication with CRSS/Coverage Analyst is critical. PI’s or study team members can contact the assigned coverage analyst or CRSS@jhmi.edu directly for guidance.

Comprehensive **internal study budgets** are critical to accurately assess the costs associated with conducting the trial and to ensure funds from study sponsors or other sources are sufficient to cover these costs. Potential study related costs include:

- Startup fees
- Patient care including lab tests and procedures
- Personnel
- Pharmacy, drugs and supplies
- Facilities and Administration (F&A)
- Miscellaneous

A pre award budget checklist as well as a commercial budget template are available on the ORA website https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/clinical_research.html

The PI Approved PRA is the basis for internal budget development as it identifies which patient care costs must be paid for by the study account. Once complete and PI approved, the internal budget is used to assess the financial feasibility of performing the study and, if applicable, to negotiate commercial sponsor coverage of study related items and services. This service is available to all School of Medicine faculty and staff upon request. A request can be sent to CRSS@jhmi.edu indicating the level of requested budget service. You will be asked to provide any information CRSS has not received to complete the analysis.

CRSS Budget Summary of Services Offered	
July 2017 to June 2018	
Total Budget Requests	174
Develop Internal Budget	16
Develop Internal Budget and Negotiate Budget with Commercial Sponsor	119
Budget Amendments	39

We currently do not collect length of negotiation data and will report that data point in FY19.

CHANGES IN THE PAST YEAR

Clinical Research Support Services participated in the SOM clinical research financial training required for all employees with financial responsibility regarding clinical trials.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

Clinical Research Support Services has added a post award financial management service available to all SOM faculty and staff. The service will include training to manage study accounts to include sponsor invoicing, patient tracking and study close out. CRSS is also available upon request to centrally manage study accounts.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

CRSS will continue to apply a Clinical Research Finance Fee for all commercial study budgets developed and negotiated by CRSS. The fee is sponsor supported and only collected if reimbursed by the sponsor.

BEST WAY TO WORK WITH PROGRAM

CRSS welcomes any suggestions or concerns via our central mailbox or phone number CRSS@jhmi.edu 410-361-8372 or contacting Karen Roz directly 410-361-8351 rozka@jhmi.edu.