


## Clinical Research Support Office (“CRSO”) STANDARD OPERATING PROCEDURE

<b>SOP NUMBER</b> CAD-SOP-1004	<b>TITLE</b> MCA Fee Processes
<b>EFFECTIVE DATE</b> 8/6/20, reviewed 3/11/21 V2 5/26/23	<b>WRITTEN BY</b> Jessica Heskell

<b>APPROVAL</b>	
 <a href="#">William W. Stoops (May 25, 2023 15:43 EDT)</a>	<p style="font-size: 1.2em;">May 25, 2023</p>
<b>SIGNATURE</b>	<b>DATE</b>

1. PURPOSE

THIS SOP OUTLINES THE PROCESS AND PROCEDURES SURROUNDING CHARGING AND INVOICING FOR THE MEDICARE COVERAGE ANALYSIS (MCA) FEE.

2. SCOPE

This fee will be charged to all industry sponsored, non-IIT, qualifying, clinical trials with billable items to insurances, for which the CRSO receives a service request form on, or after August 1, 2020 and to all substantial content amendments to those studies. The fees are not retroactive. A substantial content amendment includes anything that adds items, services or visits that will affect the coverage analysis and therefore require research and new designations.

3. PROCEDURE

A. General Fee Information

- a. MCA Fees will be charged to sponsors on any industry sponsored, qualifying, study that submits a SRF to the CRSO on, or after, August 1, 2020
- b. The Billing Integrity team will determine if a study is qualifying
- c. If the industry sponsor offers to cover all items and services of a qualifying clinical trial, the MCA fees are waived
- d. The start up fee will be charged when the contract is fully executed
- e. Any amendment fees will be charged to substantial content changes that alter

the billing grid or MCA, sponsor driven, amendments after the processing is complete

B. Internal process to communicate

- a. Finance team will use OnCore reports to track new MCA and substantially modified amendments
  - i. The report for new MCA will also be sent to SRAS bi-weekly so they can check contracts and eIAFs to confirm that our new fees are included

C. Invoices

- a. Invoices will be sent by the CRSO Finance team
  - i. Invoices will list the physical mailing address as the remit to address. Wire transfer/ACH information will be provided to sponsors on request
- b. AR will be monitored by the Finance Team
- c. Check Information:
  - i. Physical checks are to be sent to the CRSO mailing address and be processed by the CRSO finance team
  - ii. ACH/Wire Transfers should be sent to the bank information referenced on the attached bank letter
  - iii. Checks will be made out to the University of Kentucky
- d. Finance team will review the daily ACH and Wire transfer emails for payments
  - i. Payments will be processed using the wire or check transfer transmittal process
- e. If a sponsor does not pay this fee after 60 days with regular follow up from the finance team, the team will escalate the issue to the Operations Director
- f. If a study CTA will not be finalized per OSPA the MCA fee will be written off

D. OSPA

- a. OSPA will email [CRSOFinance@uky.edu](mailto:CRSOFinance@uky.edu) when a contract is signed and the fee is OK to be charged. This email will include the final contract and the sponsor invoice contact information.

E. Escalation if sponsors refuse to pay

- a. If a sponsor refuses to include this fee in the contract, the CRSO will not wave this fee.
  - i. The department can include this as part of the general start up fee and JV the funds to the CRSO (Note: the department will need to inform the CRSO and OSPA so F&A is not charged)
  - ii. The department can chose to pay the CRSO out of department funds. The CRSO will perform the JV once the department provides an account number
- b. If a study team does not include this cost in budget negotiations, this cost will be the responsibility of the department.

- i. CRSO will work with RFS to correctly JV funds from the account designated by the department.

4. ATTACHMENTS

Wire transfer banking information and bank letter

5. REFERENCES







# MCA Fee Processes SOP-V2

Final Audit Report

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