The Queen's Medical Center
Research
MCA (Medicare Coverage Analysis) Request Process

All new and legacy prospective studies require a review or a completed Medicare Coverage Analysis/Coverage Analysis (MCA or CA) regardless of funding sources (ie. Extramural industry or private funding, extramural non-profit or government funding, and/or intramural funding). This includes investigator-initiated, cooperative group, industry, and federal studies.

The MCA/CA is the driver for negotiation of contract, budget, and informed consent documents. It determines whether the clinical study is a Qualifying Clinical Trial and which clinical services, items, products are:

- billable to insurance or
- must be paid for by sponsor

Justifications are included in the MCA/CA to ensure proper billing and are supported by industry guidelines which meet the "generally accepted in the medical community" standard guidelines and government regulations. A Consistency Checklist accompanies the MCA to ensure that the required sections are included and aligned with the MCA, Informed Consent Form (ICF), protocol and contract/grant. MCAs must be completed prior to final contract with sponsor and prior to enrollment of any study subject. The process for requesting a MCA, MCA completion and notification of study changes including required information and documentation are provided below.

This MCA request process will also serve as the mechanism for building a "shell" in Clinical Conductor for those studies that do not require an MCA.

A. REQUESTING a NEW MCA

The starting point for obtaining an MCA/CA begins with serious consideration of a study.

1. Send an email to the following recipients:
   jvillasin@queens.org and enichols@queens.org
   with a cc: to sdelacruz@queens.org , dtani@queens.org , and rohta@queens.org.
   if the study involves a drug, cc: kewatanabe@queens.org
2. Include the following in the Subject of the email:
   - MCA Request: [Short Name of Study] [PI]
   - Example: "**MCA Request: CSTUDY Doe**"
3. In the email provide the following information about the study:
   - Study Title:
   - PI name:
   - Primary Study Coordinator name, email, phone number:
   - Any other study coordinator who will link patients and do visit completions in CCS:
   - Number of expected subjects:
   - IND/IDE#:
   - NCT#:
   - Name of IRB and approval status (or pending):
   - If there are sub-studies, which will QMC participate in:
   - If the entire study will not be done at QMC, specify which items/services will be done at QMC:

4. Provide the following soft copy documents as attachments for the applicable study types:

NCI/Cooperative group studies	Pharma/Industry (including Registry/Data Collection type)	Investigator-initiated	Other
Protocol*	Protocol*	Protocol*	Protocol*
ICF**	ICF**	ICF**	ICF**
Funding Sheet	Prelim budget	Prelim budget	Prelim budget
NCA*** (if there is one)	Prelim contract		Prelim contract
Investigator's Brochure	Investigator's Brochure	Investigator's Brochure	
*Please note which sub-studies QMC will participate **Please note whether the consent is a template or the proposed version for QMC ***NCAs (National Coverage Analysis) are provided for certain Oncology Cooperative Group studies from NCI. It is expected that each institution reviews the NCA and make any modifications that are justified to create an institution MCA.			

B. MCA COMPLETION

- Jeremiah (or Erin/designee) will build the MCA in Clinical Conductor and communicate with the requesting study coordinator for questions.
- Study Coordinator/PI complete initial review in excel file or Clinical Conductor and request necessary changes.
- Jeremiah (Erin/designee) will complete appropriate changes and push to Clinical Conductor site for final review.
- When final, Jeremiah (Erin/designee) will initiate the Consistency Checklist.
    - Study coordinator confirms ICF and Protocol are consistent with MCA, then forward to
    - RBO/SPO/RRO will confirm that grants/contract/budget consistent with MCA/ICF/Protocol
    - Final review by Rebecca
- An "RA# Assignment" email from Rebecca will begin the cascade workflow to activate the study in Clinical Conductor and CareLink. It will also allow request for Cost Center with Finance.
- Sheila will send final green light to begin.
- Study coordinator or PI must have pdf version Consistency Checklist and MCA signed by the Principal Investigator and given to the grants/contracts contact person in Office of Research Development.

C. NOTIFICATION OF STUDY CHANGES

Amendments/modifications to the study protocol or contract require a change in Clinical Conductor and may require updates to the MCA. Changes also include PI or staff.

1. Send an email to the following recipients:
   jvillasin@queens.org and enichols@queens.org
   with a cc: to sdelacruz@queens.org , dtani@queens.org , and rohta@queens.org.
   if the study involves a drug, cc: kewatanabe@queens.org

2. Include the following in the Subject of the email:
   - [Type of Change]: [RA Number] [Short Name of Study] [Amendment/Revision Number]
   - Example: "**CCE Amendment: RA-2023-XXX CSTUDY A5**" or "**CCE PI CHANGE: RA-2023-XXX CSTUDY A5**"

3. In the email provide the following information about the study, as applicable:
   - Study Title:
   - Amendment/Revision Number:
   - PI Change:
   - Study Status (ie Enrollment, Closed to Enrollment – Continue Visits):
   - Number of patients on study:
   - Indicate if you feel MCA and/or contract need to be updated
   - Indicate whether the amendment or revision has received IRB approval

- If already approved and ready to go, the revised MCA will be set as active
- If not IRB approved, the older version will remain active until you notify Jeremiah of IRB approval/active status

4. Provide the following soft copy documents as attachments for the applicable study types:
   - IRB Approval Letter
   - Track Change **and** Clean version of amended Protocol/document, or Detailed summary of changes.
   - Track Change **and** Clean version of revised Informed Consent Form
   - Revised Funding Sheet or proposed revised Contract/Budget
   - Any other additional documents, as required (eg. HIPAA Authorization, Supplemental Info Sheet, etc.).

5. The "MCA Completion" steps will be repeated prior to finalization of the amended or revised protocol.

QUESTIONS/CONCERNS:

Please contact Rebecca Ohta at 808-691-4106/rohta@queens.org or Jeremiah Villasin at 808-691-4645/ jvillasin@queens.org