## ORA Services for Clinical Trials

### Who we are and what we do

Our Contracts Department develops and negotiates agreements required for clinical trials and research conducted at Jefferson. We also conduct a Medicare Coverage Analysis for all clinical trials. Please see flow chart for Contract and Budget Process.

Please contact us for more information about the following agreements:

- Clinical Trial Agreement
- Confidentiality Disclosure Agreement
- Clinical Research Support Agreement
- Personal Consulting Agreement

ORA offers the following budgeting services to Principal Investigators and Coordinators for industry sponsored studies conducted at Jefferson. There is **no charge** to the PI or Department for these services. Please contact us if you would like our assistance with the following:

- Negotiate budgets with industry sponsors.
- Draft budgets based on clinical protocols
- Review companies proposed budgets
- Complete Medicare coverage analysis
- Enter PTF budgets
- Medicare Petitions for devices studied under an IDE

### Questions? Would you like more information?

Contact Ron Polizzi, Associate Director, Contracts at 215-503-2127 or refer to the ORA Department Assignments to contact your Contract Associate and Budget Specialist.

### Frequently Asked Questions (FAQs)

#### Contract Tools and Templates

- Clinical Trial Agreement
- Confidentiality Disclosure Agreement
- Clinical Research Support Agreement
- Personal Consulting Agreement

#### Budget Tools and Templates

- Budget Guidelines and Advice
- Overhead and Fringe Rates
- Industry budget template
- Medicare coverage analysis
- Billing Grid
- Contact us for research pricing on labs, tests procedures and JUP fees.
- IRB Fees
- Link to Investigational Pharmacy (IDS)
- Link to Clinical Research Unit (CRU)

### Documents we need you to submit to us to start the process:

- ePTF (Electronic Proposal Transmittal Form)
- CTA (Clinical Trial Agreement – sponsor draft)
- Study protocol (latest version)
- Informed Consent (draft is acceptable)
- Sponsor proposed budget (if available)
- FDA IDE Device Letter (if available and applicable)

### Need more information on the Medicare coverage analysis? Click here.

Other important links
Medicare Coverage Analysis (MCA) Services

Office of Research Administration (ORA) prepares Medicare coverage analyses for clinical research protocols at Thomas Jefferson University.

MCA Flow Chart

Medicare Coverage Analysis FAQs

What is an MCA? When is it required?
A Medicare coverage analysis (MCA) is required for all clinical trials in which tests, procedures and interventions associated with a clinical trial are billed to Medicare or private insurance. Preparing the MCA involves determining the eligibility of the study for Medicare coverage and reviewing clinical events specified in the protocol to determine which items and services can be reimbursed by Medicare. ORA consults with investigators while preparing Medicare coverage analyses so that the PIs’ expertise and insights are reflected in the final documents.

What is the result of the MCA?
When the analysis is complete, the investigator receives a study-specific billing grid that lists all items and services to be provided as part of the clinical trial. The billing grid notes which items and services are covered by the research sponsor’s funding and which items and services are allowed to be billed to Medicare. These billing grids are a valuable tool to ensure appropriate billing. A copy is shared with Business Services, JUP Business Services and Compliance.

Centers for Medicare and Medicaid Services (CMS) Clinical Trail Policy

MCA Presentation

MCA example

Additional Medicare Coverage Analysis FAQs

Devices studied under an IDE
If you plan to bill Medicare for these studies we must submit an IDE petition for reimbursement to our Fiscal Intermediary prior to billing for the first subject. ORA will gather the required documents and send the petition once the study has IRB approval. Novitas Solutions returns a decision letter within 45 days.

Questions? Want more information?
Contact Ron Polizzi (215-503-2127); or Sachit Verma (215-503-9819)