Clinical Trials
Where World Class Care Begins
We seek to attract novel, innovative and transformational research and devices to our medical center and its stakeholders, and serve as an easy partner giving industry sponsors access to our skilled investigators, our experienced study coordinators and our active and involved patient population.

We offer:

- Business development for new trials
- Negotiation of Confidentiality and Non-Disclosure Agreements
- Contract negotiation and execution
- Budget preparation and negotiation assistance
- Regulatory support for institutional review board (IRB) submissions
- Post-award study finance management and invoicing
- Study coordinator training and education
- Patient recruitment and retention techniques and tools

THE OFFICE OF CLINICAL TRIALS

Opened in May 2011, the Office of Clinical Trials (OCT) serves Montefiore Medical Center and Albert Einstein College of Medicine in managing all aspects of clinical trials of pharmaceuticals and medical devices for both industry-sponsored and investigator-initiated studies.

We help prepare IRB submissions, build and negotiate budgets, craft and negotiate contracts, and engage in business development. OCT is committed to serving the needs of our principal investigators (PIs) and their study coordinators as well as study sponsors, clinical research organizations (CROs), IRBs, regulatory agencies and patients.

Activating a trial is a major undertaking for the investigator and team, and we provide guidance, assistance and counsel to facilitate all steps from budget building to study initiation. We are committed to eliminating barriers, waits and delays in clinical research and recognize that investigators’ need for support does not end when subject enrollment begins. We search nationwide for trials and best practices to bring to our investigators, our Centers of Excellence and our patient community.

The mission of the Office of Clinical Trials is to encourage and support investigators at Einstein and Montefiore in the conduct of clinical research by providing resources, expertise and best practices to facilitate efficient, compliant and ethical study conduct and management.

We strive to provide exceptional support to our physicians and to our community to foster better health outcomes for our patients and afford them access to state-of-the-art therapies and drugs.
STUDY BUDGET
OCT collaboration and processing begin with a review of the visit schedule of your protocol. This review, done with the PI and sponsor, is required to determine which procedures are considered “purely for research” and which are considered “standard of care” as part of a formal Medicare Coverage Analysis.

The PI and the research team are intimately involved with the budgetary process. We examine all budgetary planning and proposed charges and fees prior to execution of the Clinical Trial Agreement (CTA) to ensure competitive and adequate reimbursement for trial work and patient needs, as well as inclusion of appropriate fees and overhead. OCT oversees the process to be sure planned expenses include appropriate costs for tests and procedures, hospitalizations, equipment, staffing, IRB fees, storage and institutional overhead. We help you to identify the proper charges for each of these fees, which include but are not limited to Clinical Research Center (CRC) fees, startup fees, pharmacy and radiology fees, and study site activation charges.

THE CLINICAL TRIAL AGREEMENT
Clinical Trial Agreements are legal documents that define specifically what will be done, to whom and when, as well as who will be responsible for costs and sequelae thereof. OCT manages, negotiates and finalizes contracting between sponsor and investigator. The final contract includes the mutually agreed upon budget as an amendment to the contract itself. Legal counsel is available within OCT and attends to all PI research and team legal issues.

REGULATORY DOCUMENT AND IRB SUBMISSION
We help with study and research team submissions of required regulatory documents and assist in preparing the IRB package. An OCT Regulatory Specialist works closely with the PI, study coordinator, IRB and Sponsor/CRO. Our goal is to reduce the number of outstanding items to be addressed after an initial IRB review and facilitate a more rapid IRB approval.

IRBs
All research involving human subjects must be approved by an IRB. The IRB is charged with protecting the rights and welfare of subjects in all research studies. We will work with you in navigating your path through the IRB, be it the Einstein IRB or the Biomedical Research Alliance of New York (BRANY) IRB.

STARTUP PROCESS
To initiate the process of activating a clinical trial, the OCT needs to be notified of your intent. This is done via completion of a formal STUDY ACTIVATION form, available at www.einstein.yu.edu/centers/ictr/clinical-trials.

For a new study protocol application:
- If your trial is industry-sponsored, submit your protocol with the STUDY ACTIVATION FORM to OCT@montefiore.org or OCT@einstein.yu.edu.
- Your department head’s signature is required on your request, both to ensure that he or she is informed of the trial and to confirm approval.
- For more information regarding initial submission of Clinical Trial Studies, visit OCT’s website: www.einstein.yu.edu/centers/ictr/clinical-trials.

STUDY MANAGER REVEAL
The Office of Clinical Trials uses Study Manager Reveal, a clinical trials Internet-based management system used to track and account for the work of trials that we administer. This system allows our office to record study information; store and organize electronic documents; schedule and track patient appointments; administer budgets; manage financials, invoicing and collections; reconcile charges and payments; and generate customized reports. Study coordinators use this software to help manage their trials with their own protected usernames and passwords.
GREENPHIRE CLINICARD
OCT uses a Web-based system—Greenphire—that enables subjects to be compensated for their time, travel and expenses in as little as one business day. This debit card system enables prompt subject compensation for any trial that is managed by OCT. With protected usernames and passwords, PIs and study coordinators are able to process reimbursements included in a study budget on the day of a subject’s visit.

Employing Greenphire will:
- Reduce paperwork and processing time for dispensed funds
- Increase subject retention and compliance
- Improve patient satisfaction

STUDY TEAM AND COORDINATOR SUPPORT
OCT also assists PIs and study coordinators with:
- Negotiation of Confidentiality and Non-Disclosure Agreements
- Completion of Site Feasibility Questionnaires
- Preparation for Sponsor’s Pre-Site Selection Visits (PSSV)
- Preparation for Sponsor’s Site Initiation Visits (SIV)
- Preparation for Sponsor’s Close-Out Visits (COV)

PATIENT ENROLLMENT AND SUBJECT RECRUITMENT
An OCT Recruitment Specialist works with the PI to generate a formal recruitment plan to promote the study, incorporate and disseminate information to other practitioners at Montefiore and Einstein to assist in finding subjects, help to generate study flyers and brochures, formulate advertisements, and employ social media recruitment materials.

Contact:
OCT@montefiore.org

CONTACT US
We are here to meet your needs, be they study activation, coordination, recruitment, finances or logistics. Please call upon us, visit with us, and let us know how we can make your work life as a trialist easier. As executive director, I welcome hearing from you.

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The Office of Clinical Trials on YouTube:
http://www.youtube.com/watch?v=QVvA4Eei-el

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