MONTEFIORE MEDICAL CENTER

Office of Clinical Trials Study Coordinator Support Policy

SUBJECT: STUDY COORDINATOR SUPPORT SERVICE
OWNER: OFFICE OF CLINICAL TRIALS
EFFECTIVE DATE: 1/1/15

Policy:

The Office of Clinical Trials (OCT) may provide experienced study coordinators to Principal Investigators (PI) and/or study teams conducting clinical trial research at Montefiore Medical Center (MMC). Study coordinators provided by the OCT may assist the PI with the following activities:

- Regulatory document preparation, IRB submission, and maintenance
- Data management
- Recruitment/retention of subjects and overall protocol execution (putting subjects through the protocol)

Purpose:

The purpose of this policy is to provide support for novice and/or underfunded investigators looking to conduct clinical trial research at Montefiore Medical Center (MMC), as well as to improve patient care via clinical and translational research.

Scope:

This policy applies to all Principal Investigators conducting industry-sponsored clinical trial research at MMC and meeting the criteria outlined below.

- **Pre-Qualifications:** In order to qualify for the OCT Coordinator Support Service, the Principal Investigator **must**:
  - Complete the **OCT Study Coordinator Support Request Form**
  - Be a novice investigator at Montefiore Medical Center (conducted no prior studies at MMC or its affiliates) **AND/OR** have limited study funding sources as acknowledged by OCT **AND/OR** not have his/her own study coordinator, **AND** have no access to a department funded coordinator
  - Sign the **OCT Coordinator Support Acknowledgment**

- **Approval.** The Office of Clinical Trials may approve, deny, and/or revoke study coordinator support provision to a Principal Investigator at any time.
• **Cost.** The Office of Clinical Trials shall review an investigator’s corresponding clinical trial budget before approving or denying provision of the Study Coordinator Support Service. After review of the final budget:
  
  o The OCT may procure all or a portion of any coordinator/start-up funding negotiated in the budget to help defray the costs of OCT study coordinator support provided.
  o The OCT will determine the exact amount to be procured based on work required to activate the study at MMC.
  o The OCT reserves the right to seek further compensation for provided services based on an evaluation of ongoing study finances.

• **Duration of Service Provision.** OCT study coordinator support will be provided on a temporary and conditional basis determined by the Office of Clinical Trials, and not to exceed 180 days. Service provision duration may be extended on an ad hoc basis pending OCT approval and review of the clinical trial budget and PI resources.

• **Compliance.** If and when OCT Study Coordinator Support is granted, the Principal Investigator is expected to demonstrate:
  
  o Adherence to all applicable federal laws and regulations pertaining to human subject research.
  o Adherence to the standards of Good Clinical Practice (GCP) as outlined by the International Conference on Harmonisation Guideline E6 and consistent with the Einstein IRB & GCP Policy in all aspects of the conduct of clinical research activities throughout the life of the research protocol at MMC.
  o Adherence to all institutional research policies, including Institutional Review Board (IRB), Office of Clinical Trials, Research Billing Compliance, Research Misconduct, and Patent Policies.
  o Adherence to the Research Sponsor’s guidelines and requirements as outlined in the Research Protocol.
  o Intent and Good faith effort towards the acquisition of a his/her own full-time study coordinator for any and all research study(ies) being supplemented by OCT’s Study Coordinator Support Service.

Principal Investigator failure to comply with the terms outlined above may result in immediate revocation of Study Coordinator support.

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Executive Director, Office of Clinical Trials

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