NIH-Funded Clinical Trials Dissemination Plan
For Albert Einstein College of Medicine/Montefiore Medical Center

As recipient of this award, I will ensure all clinical trials under the award are registered and results information is submitted to ClinicalTrials.gov according to the timelines and requirements specified in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149). Registration will occur no later than 21 days following enrollment of the first subject. Updates will be made within the required timeframes, no less than once every 12 months, to reflect any material change in the study status and to keep the record current. Results summary and required documents will be submitted within the timeframes specified in the regulation.

I will ensure the Informed Consent Forms for all clinical trials under this award include the following FDA-specified disclosure statement, exactly as written, notifying subjects that the study will be submitted to ClinicalTrials.gov: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

My institution, Albert Einstein/Montefiore Medical Center, has a written internal policy requiring registration and results reporting on ClinicalTrials.gov, in compliance with NIH and FDA requirements. In addition, the internal policy requires timely updates to the study record as required by FDA regulations and NIH policy. To ensure compliance with NIH’s registration deadline, the Institutional Review Board (IRB) requires the registration NCT# before the study protocol can receive IRB approval. To enable compliance with all ClinicalTrials.gov reporting requirements, Albert Einstein/Montefiore Medical Center sends notifications on activities required to keep the study record current and provides personnel, training, and any additional resources needed.