

August 25, 2011

## **Clinical Trials Monitoring Assistance Program for FDA Regulated Human Subjects Research**

The CUMC Compliance Program for FDA-regulated human subjects research is the responsibility of the Executive Vice President for Research, in close collaboration with the P&S Senior Vice Dean. The Program has two arms: oversight and audit, led by the IRB, and education and operational support for investigators, led by the CTO.

In January 2010, the IND/IDE Assistance Program (“IAP”) was established in the CTO to provide education, training and support for CU faculty members who are sponsor-investigators (“S-Is”) in research involving INDs or IDEs.

The Clinical Trials Monitoring Assistance Program (“CTMAP”) has been established in the CTO to assist S-Is in meeting FDA requirements with respect to the monitoring of S-I studies. The CTMAP will be managed by the Director of Regulatory Affairs and Clinical Development of the CTO and a Clinical Monitoring Specialist.

**Monitoring** is “the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).” (ICH E6, 1.38; ICH E6, 5.18)

**Monitoring is part of the clinical trial and is the responsibility of the S-I.** (21 CFR 312 subpart D: Responsibilities of Sponsors and Investigators, and 21 CFR 812.46: Monitoring Investigations)

The CTMAP includes the following components:

- Guidance and instruction for the S-I in the initial design and development of a monitoring plan and strategies for the implementation of the plan. S-I’s are encouraged to consult with the CTMAP in the early stages of development of a trial. **The CTMAP will not monitor the study for the S-I.**
- In connection with the IAP review of IND and IDE annual reports to the FDA, mandatory review of evidence that an appropriate monitoring plan is being implemented and documented.
- Routine and random assessments of the S-I’s adherence to the monitoring plan of the trial (including review of significant findings/facts, deviations and deficiencies, conclusions and actions taken or to be taken) and if necessary, recommendation of actions to secure compliance.
- Education for the S-Is and research teams on proper clinical monitoring procedures and reporting.

The IRB and CTO will continue to work together to assist CU investigators in meeting research compliance standards. However, the IRB is responsible for overseeing the conduct of research it approves and is therefore responsible for ensuring that the requirements of FDA regulations are met. It will continue to include S-I Research in its not-for-cause audit program. In addition, as it already

does, the IRB will investigate incidents of FDA noncompliance, and, when necessary, will work with the S-I, the IRB Chairs and the CTO to establish a corrective action plan. If appropriate, the IRB may suspend research studies until the corrective action plan has been implemented.

**New York State Psychiatric Institute**

- A collaborative relationship between the NYSPI IRB Monitor and the CTMAP personnel will work to ensure the requirements of FDA regulations are met for S-I studies at NYSPI.
- The consultative services of the IAP and CTMAP described above will be available to NYSPI S-Is and other research staff at NYSPI.
- The provisions of CTMAP will apply to all NYSPI S-Is.