

**Office of Clinical Research Training and Medical Education, NIH Clinical Center
Food and Drug Administration (FDA) Rotation for NIH Clinical Research Fellows**

The FDA Rotation is a program developed to provide clinical research fellows at the NIH with a short-term training experience at the FDA that includes:

Educational modules on FDA regulations applicable to drug development
Tutorials on how to prepare an IND (Investigational New Drug Application)
Tutorials on therapeutic area-specific drug development guidelines

Participants will have the option to rotate through the FDA's Office of Clinical Pharmacology (OCP) or the FDA's Office of New Drugs (OND) and will:

Review pre-clinical and clinical data on investigational drug
Participate in specialized therapeutic team meetings
Contribute to IND "30-day" safety review – approvals
Participate in meetings with sponsors.

NOTE: A minimum commitment of *two months* is required for these rotations. Also, a signed *confidentiality agreement* is required given the proprietary nature of information discussed at FDA meetings. At least 3 months advanced planning is essential given that FDA security screening and administrative processing are required.

Interested parties should:

- Obtain approval of their respective fellowship Program Director at the NIH Clinical Center
- Contact: Robert M. Lembo, MD, Executive Director, Graduate Medical Education, OCRTE, by Email: lembor@cc.nih.gov, or by Phone: 301-496-2636 to:
 - Complete a questionnaire collecting demographic information and elucidating goals/objectives for the rotation,
 - Provide an updated curriculum vitae,
 - Identify a therapeutic area of interest and discuss whether to rotate at OCP or OND, Identify a proposed time frame for the FDA rotation.