Clinical Research Trial Monitoring

Policy Sections

- **Policy Statement**
- **Reason for Policy**
- **Who Should Know This Policy**
- **Definitions**
- **Procedures**
- **Approval**

Effective Date: June 29, 2015

Supercedes: 09/27/2012

Responsible University Officers: Executive Dean for Research, Research Education and Innovative Medicine and Vice Provost for Research

Responsible Offices: CRORS

Policy Statement

This policy applies to all IND/IDEs held by a University of Miami faculty member for the purpose of conducting clinical studies involving investigational drugs, devices and/or biologics.

For all IND/IDE studies, including outpatient and inpatient, the Sponsor and/or Sponsor-Investigator is required to notify CRORS for a review to determine if all regulatory (federal, local, state, UM) requirements in regard to IND/IDE studies have been met. Sponsor-Investigators must also notify CRORS if they will be conducting any multicenter studies. An IND/IDE study may not be conducted unless a qualified monitor employed by the sponsor-investigator/sponsor or hired by CRORS has been selected, and reviewed by CRORS.

Non-adherence with policy requirements will result in withholding of institutional approval for study enrollment, pending satisfactory completion of corrective actions. Persistent non-adherence with the policy, as determined by the Vice Provost for Research, can result in study termination.

Reason for Policy

For a Sponsor and/or Sponsor-Investigator, an IND or IDE is a request for FDA to authorize administration of an investigational drug, biological product or device to humans.

As required by the code of federal regulations, (21 CFR 312.50, 21 CFR 812.40) and international guidance ICH-GCP (5.18.1, 5.18.3), sponsors are responsible for ensuring appropriate monitoring of the investigation(s). The sponsor (21 CFR 312.53, 21 CFR 812.43 & ICH-GCP 5.18.2) is required to select a monitor qualified by training and experience to monitor the investigational study and its progress.

Who Should Know This Policy

Sponsor-Investigators, Principal Investigators, Study Coordinators, Research Administrators, Miller School of Medicine Office of Research, Office of Research Administration, Vice Provost for Research, IRB and HSRO.

History

Supercedes: 09/27/2012

Effective: 06/29/2015

Definitions

CRO	Clinical Research Organization
CRORS	Clinical Research Operations & Regulatory Support
HSRO	Human Subjects Research Office
FDA	Food & Drug Administration
ICH-GCP	A guideline to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
Monitor	An individual qualified by training and experience designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be employed by the sponsor or a consultant to the sponsor, or an employee of or consultant to the contract research organization.
Monitoring	To oversee an investigation
Principal Investigator	An individual, who actually conducts a clinical investigation under whose immediate direction the test article is administered, dispensed or used.
Sponsor	A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug or device is administered, dispensed or used under the immediate direction of another individual.
Sponsor-Investigator	An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug or device is being administered, dispensed or used.

Procedures

At the time of protocol submission to the FDA, CRORS must be notified to conduct an initial consultation. An IND/IDE study may not be conducted unless a monitor (either employed by the sponsor-investigator/sponsor or hired by CRORS) has been selected, and evaluated by CRORS for appropriate qualifications. If the Sponsor/Sponsor-Investigator and the CRORS representative are in agreement that monitoring will be conducted by CRORS, the fees for these services will be discussed at the time of the initial consultation. CRORS will maintain its regulatory role for any IND/IDE study (such as a review of the monitoring plan, review of monitor qualifications, review of ongoing monitoring reports or follow up letters) even if the Sponsor or Sponsor-Investigator contracts with a CRO or hires his/her own monitor. CRORS can be contacted by phone at (305) 243-6381 or email at CRORS@med.miami.edu for assistance.

Approval

Name	Title	Signature	Date
John Bixby, Ph.D.	Vice Provost for Research	*On File*	6/8/15
Omaida Velazquez, M.D.	Executive Dean, Research and Innovative Medicine	*On File*	6/8/15