Human Research Compliance

Overview

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DATA AND SAFETY MONITORING BOARD (DSMB)

- Review is deemed necessary by the IRB or requested by the Principal Investigator
- Reviews interim data to evaluate research subject safety, rates of accrual, and efficacy of experimental intervention
- Makes recommendations for protocol modification, continuation or termination
- Email: dsmb@med.cornell.edu

CLINICALTRIALS.GOV

- Service of the NIH National Library of Medicine that acts as a registry and results database of clinical studies of human participants
- HHS, FDA, NIH, Declaration of Helsinki, WHO, and ICMJE all require the public registration of clinical trials
- Email: registerclinicaltrials@med.cornell.edu

Clinical Trial Reporting Requirements

Reporting Requirement	ICMJE Policy (effective in 2005)	HHS Final Rule (Issued in 2016)	Final NIH Policy (Issued in 2016)
Scope	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1 or small feasibility device studies	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All (e.g., including behavioral interventions)
Funding Source	Any	Any	NIH
Enforcement	Refusal to publish	Criminal proceedings and civil penalties (up to $10,000/day); Loss of HHS funding; Noncompliant records Identified on ClinicalTrials.gov	Suspension or termination of grant or contract funding; Can be considered in future funding decisions; Noncompliant records Identified on ClinicalTrials.gov

Registering at ClinicalTrials.gov

- Registration must be completed prior to enrollment of the first subject (NIH, HHS, ICMJE)
  - Interventional investigator-initiated NIH-funded WCM studies
  - Interventional investigator-initiated WCM studies evaluating at least one FDA-regulated drug, biological, or device product (except for phase 1 and small device feasibility studies)
  - Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes
- Updating of the record is required every 6 months, with results reporting required for some studies 12 months after study completion

Human Research Audit Program

AQuRET: Assuring Quality Through Review, Education, and Training

Goals and Objectives

- **Ensure Compliance**
  - **Ensure that the rights, safety, and well-being of participants in human research are properly protected in adherence to all research requirements of the IRB, WCM policy, and applicable regulations**
  - **Evaluate and categorize non-compliance**

- **Improve Performance**
  - **Investigator-specific management and training**
  - **Develop, revise and/or modify institution policies**

- **Establish Education Standards**
  - **Ensure that educational and training requirements are fulfilled by research professionals and determine if any additional training are required**
  - **Assist investigators with assessment tools and processes for self-assessment of research compliance**

AUDIT PROCESS

Study Conduct

- Interviews with Principal Investigator, research staff members, and participants
- Review of regulatory binder, including IRB approvals
- Review of personnel credentials and training
- Tour and review of research facility and document storage

Protocol Adherence

- Approved Protocol follow accordingly
- Participants Inclusion and exclusion criteria
- Proper randomization
- Deviations
- Amendment implemented accurately

Informed Consent

- Informed Consent Documentation
- Observations of Informed consent process
- Surveying research participants enrolled in a study about their experience

Investigational Product/Device

- Thorough accountability
- Proper dispensing and dose modification
- Appropriate storage and destruction

Subjects Records (Verification, Retention and Storage)

- Review of participant records reviewed for adherence to protocol
- Copies of clinical assessments and results
- Adverse events are assessed and reported
- Review of information security process

Contacts

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