Human Research Compliance

Overview

Gabrielle Gaspard, MPH
Assistant Director, Human Research Compliance

4.10.17
<table>
<thead>
<tr>
<th>DATA AND SAFETY MONITORING BOARD (DSMB)</th>
<th>CLINICALTRIALS.GOV</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Review is deemed necessary by the IRB or requested by the Principal Investigator</td>
<td>• Service of the NIH National Library of Medicine that acts as a registry and results database of clinical studies of human participants</td>
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<tr>
<td>• Reviews interim data to evaluate research subject safety, rates of accrual, and efficacy of experimental intervention</td>
<td>• HHS, FDA, NIH, Declaration of Helsinki, WHO, and ICMJE all require the public registration of clinical trials</td>
</tr>
<tr>
<td>• Makes recommendations for protocol modification, continuation or termination</td>
<td>• Email: <a href="mailto:registerclinicaltrials@med.cornell.edu">registerclinicaltrials@med.cornell.edu</a></td>
</tr>
<tr>
<td>• Email: <a href="mailto:dsmb@med.cornell.edu">dsmb@med.cornell.edu</a></td>
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## Clinical Trial Reporting Requirements

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<tbody>
<tr>
<td>Scope</td>
<td>Registration</td>
<td>Registration &amp; Results Reporting</td>
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</tr>
<tr>
<td>Phase</td>
<td>All</td>
<td>Not Phase 1 or small feasibility device studies</td>
<td>All</td>
</tr>
<tr>
<td>Intervention Type</td>
<td>All</td>
<td>Drug, biologic, &amp; device products regulated by the FDA</td>
<td>All (e.g., including behavioral interventions)</td>
</tr>
<tr>
<td>Funding Source</td>
<td>Any</td>
<td>Any</td>
<td>NIH</td>
</tr>
<tr>
<td>Enforcement</td>
<td>Refusal to publish</td>
<td>Criminal proceedings and civil penalties (up to $10,000/day); Loss of HHS funding; Noncompliant records Identified on ClinicalTrials.gov</td>
<td>Suspension or termination of grant or contract funding; Can be considered in future funding decisions; Noncompliant records Identified on ClinicalTrials.gov</td>
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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
  o 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
  o Evaluate and categorize non-compliance

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

• Establish Education Standards
  o Ensure that educational and training requirements are fulfilled by research professionals and determine if any additional training are required
  o 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

• Gabrielle Gaspard, M.P.H.
  Assistant Director, Human Research Compliance
  (646) 962-4073
  gag7001@med.cornell.edu

• Lauren Odynocki
  DSMB & QIU Operations Coordinator
  (646) 962-4065
  lao2003@med.cornell.edu