

Human Research Protection Update

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Purpose

1. Describe Selected Association for Accreditation of Human Research Program's Recommendations of Changes
2. Discuss Recent Federal Policy Changes

AAHRPP Site Visit

- Site Visitors Approximately 50 Observations for 23 Elements Based on FDA, OHRP, & VA Requirements
(<http://www.hhs.gov/ohrp/compliance/findings.pdf>)

PI Holds IND or IDE AAHRPP Finding

- “When an Individual **Assumes the Sponsor Functions**, the Organization Did Not Evaluate Whether the Investigator Was Knowledgeable About the Additional Regulatory Requirements of Sponsors and Followed Them”

UK Response
Investigator/Sponsor Training

- Initial Response: Dr. Foster Will Provide One-on-One Training
- Long-term Plan: Mandatory Training Based on Materials Developed By UK CRO

PI Holds IND or IDE Educational Materials

- Form A - Medical General Information Sheet (F1.0050)
- Form B - Medical IRB Research Description (F1.0100)
- Initial Full Review SOP (C2.0100)
- A Principal Investigator's Guide to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research (D9.0000)

PI Holds IND or IDE Educational Materials (Continued)

- Investigator Initiated Questions (M3.0000)
- Sponsor-Investigator Clinical Trials with FDA Regulated Products (M4.0000)
- Summary of FDA Requirements for Investigators Who Are Also Considered Sponsors of New Drugs (D44.0000)
- Summary of FDA Requirements for Investigators Who Are Also Considered Sponsors of New Device (D45.0000)

Standard: Devices & Drugs

UK Has Policies and Procedures to Ensure That the Handling of Investigational or Unlicensed Test Articles Meets Organizational **Standards Relating to** Pharmacy, Inventory Control, and Documentation

Device AAHRPP Finding

- “Each Investigator Using an **Investigational Medical Device** Was Responsible to Control the Devices Received in Accordance With Regulatory Requirements. However, the Organization Did Not Evaluate Investigators Conducting Research With Investigational Devices on These Responsibilities and Did Not Evaluate Investigators’ Plans to **Control Investigational Devices.**”

Device Educational Materials

- Medical Devices SOP (C3.0150)
- A Principal Investigator's Guide to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research (D9.0000)
- Quality Improvement Program Directed On-site Review SOP (C5.0050)
- "Form P – Use of Investigational New Device Form" – Medical IRB Expedited & Full Review Applications (F1.1100)

UK Response

- Quality Improvement Coordinator: Periodic Inspections

Significant Financial Interest*

- IRB Must Review All Conflict of Interest Management Plans After They Are Complete

*Conflict of Interest – OSPA (859) 257-9420

Informed Consent Standard

The IRB Reviews the Content of the **Consent Process**, Including the Consent Document, and the Process Through Which Informed Consent is Obtained From Each Participant

Findings

- Informed Consent Process: Changes in Application (e.g., Timing; Non-English Speaking)
- Form*: Changes in Informed Consent Template

UK IRB Template Changes

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

- the sponsor (*only option if industry sponsored and industry trial*) (*insert sponsor's name here*) has agreed to pay for medical expenses incurred by treating injuries that directly result from participating in the study, with some exceptions.

The exceptions are instances such as your failure to follow the sponsor's directions or the investigator's failure to follow the sponsor's directions. If you want information about specific exceptions let the study physician or investigator know right away.

UK IRB Template Changes

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT MY DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

UK IRB Template Changes

**WHO WILL SEE THE INFORMATION
THAT YOU GIVE?**

[IF THE STUDY IS NOT ANONYMOUS:]

Insert description of procedure(s) used for protecting confidentiality of data including paper records, computer records, jump drives and portable storage devices.

UK IRB Template Changes

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may/may not (please indicate choice) take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

UK IRB Template Changes

**WILL YOU RECEIVE ANY REWARDS
FOR TAKING PART IN THIS STUDY?**

If applicable, provide a statement: if you earn \$600 or above by participating in research, it is potentially reportable for tax purposes.

OHRP/DHHS

- PI Must Report Unanticipated Problems Involving Risks to Subjects or Others*
- “Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events”
January 15, 2007
<http://www.hhs.gov/ohrp/policy/AdvEvntGuid.pdf>

*Also PI → IRB Serious or Continuing Noncompliance, Deviations, Exceptions

FDA: New Guidance

- “Guidance for Clinical Investigators, Sponsors, and **IRBs** Adverse Event Reporting – Improving Human Subject Protection”
Draft – April 2007
- Comments Due June 2007

Ledger 4 – Close Out Policy

- This UK IRB policy requires investigators to keep their IRB protocols active until all financial transactions on their sponsored program accounts are complete.

Advice: Use Up To Date Forms

- Use Application Forms On Website
<http://www.research.uky.edu/ori/human/HumanResearchForms.htm>
- Informed Consent Template
Medical:
<http://www.research.uky.edu/ori/ORIForms/Form%20C%20-%20Med.doc>

Nonmedical:
<http://www.research.uky.edu/ori/ORIForms/Form%20C%20-%20Nonmedical.doc>

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