Research Compliance Office

IRB Annual Update

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Overview

- Accreditation and Organizational Updates
- Participant Withdrawal
- Short Form Consent Process
- Scientific Review of Protocols
- Privacy and Confidentiality
- Institutional Conflict of Interest (ICOI)
- Reviews by Continuous Quality Improvement Group and Common Observations

Accreditation and Organizational Updates

AAHRPP Accreditation

- FULL Re-Accreditation, March 2009
- Met all 77 Elements, 5 with Distinction
  - Scientific Review of Research Projects
  - Institutional Official's Role in Human Research Protection Program (HRPP)
  - Design and Ease of Use of eProtocol System
  - Communication among various entities comprising HRPP
  - Institutional Conflict of Interest (ICOI) Policy

Organizational Updates

- Economic Downturn
- Fewer Staff, More Responsibilities
- Help is still available…
  - IRBeducation@stanford.edu or 724-7141
  - Panel Managers (http://humansubjects.stanford.edu)
  - Continuous Quality Improvement (CQI) team
  - HelpSU ticket for eProtocol technical issues

Participant Withdrawal

Participant Withdrawal
Partial vs. Complete

- **New draft guidance from the Office for Human Research Protections (OHRP) (11-7-08)**
  - Partial Discontinuation – for example, discontinue *intervention* but allow continued *interaction* (interviews, physical exams), review of *medical record*, and research on *specimens* that were already collected if described in the IRB approved protocol.
  - Complete Discontinuation – *all further activities* described in the IRB approved protocol involving participation are *stopped*.
- **Harmonizes with Food and Drug Administration (FDA) guidance:**
  - *Data collected* on participant to point of withdrawal may be required – might not be allowed to remove it from database

Participant Withdrawal
IRB's Expectation

Researchers will:

- Communicate with participants when participation terminates, thus have the opportunity to discuss "partial" vs. "complete" withdrawal,
- Anticipate that withdrawals may occur, and include details of continued interaction in consent form and protocol application, and
- Report to IRB at continuing review the number of and reasons for withdrawals.

Short Form Consent Process

Short Form Consent Process

- Indicate your intention to use short form consent process: Add “Short Form Consent Process” in section 13 - Consent Background.

- If the RCO-provided translated short form consent documents are to be used, do not attach the actual form.

Chinese	Russian
Farsi	Spanish
Japanese	Vietnamese
Korean	

Short Form Consent Process

What to submit for IRB approval

- Check box to confirm that you will follow the procedures for obtaining consent using the short form consent process.

  ☑ I have read and will follow the above procedures.

Scientific Review of Protocols

Criteria for IRB Approval

- Procedures are consistent with sound research design

- Risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Scientific Review – Who performs it?

- NIH Study Section (or NSF, DOE, DOD, NCI)
- FDA during IND or IDE evaluation
- VA Research & Development Committee
- Cancer Center Scientific Review Committee
- CTRU
- Industry Sponsors

If no other scientific review is performed?

- Required: Review of Scientific or Scholarly Validity by the Division Chief, Department Chair, or appropriate School Dean or designee (or Faculty Sponsor when student is PD).

- Required: Scientific Review Protocol when study is medium or high risk and has no other scientific review.

The Scientific Review Protocol

- 10 point outline sent by Panel manager.
- http://humansubjects.stanford.edu – see Medical Research Forms

Privacy
&
Confidentiality

Privacy of Participants

- Respecting an individual's right to be free from unauthorized or unreasonable intrusion.
  - Extent, timing and circumstances of obtaining personal information from or about an individual.
- Examples
  - Recruiting, screening, meeting & enrolling people
  - Collecting data from people (where are physical exams, tests, interviews, surveys taking place?)

What's new?
eProtocol Section 11 updated….

Privacy Protections (a)

Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

Confidentiality of Data

- Respecting a potential or current participant's right to be free from unauthorized release of information.
  - relationship of trust
  - expectation that data will not be given to others without permission
- An agreement (via ICF or HIPAA Authorization) established between **investigator** & **participant**
- Agreement maintained by **handling, management & dissemination** of research data

What's new?
eProtocol Section 11 updated….

Confidentiality Protections (b) – (i)

- Specify the PHI – what data will be used?
- How data will be maintained?
- How data or specimens will be labeled?
- Who will have access?
- How will data be coded?
- Who will maintain the key to the code?
- How will data be transferred or transmitted?
- How will you educate research staff?

Institutional Conflict of Interest (ICOI)

ICOI Policy

The Policy addresses:

- Institutional conflicts of interest arising from the financial holdings or investments of Stanford University

- Potential conflict of interest when an institutional leader has a financial interest related to human subjects research

http://rph.stanford.edu/4-7.html

e-Protocol Application – 12. Potential Conflict of Interest

Two items have been revised:

b) To your knowledge, does anyone in a supervisory role to you have a conflict of interest related to this study?

c) To your knowledge, does Stanford University have an ownership or royalty interest in any intellectual property utilized in this protocol?

Continuous Quality Improvement Review Activities (CQI)

CQI Review Activities

- Informed Consent Forms (ICF) - performed regularly
- Observations of Consent Process - performed periodically.
- Sponsor-Investigator Research (SIR) Compliance - performed annually.
- Other Compliance Reviews - in process
- Reviews of RCO processes

Some Noted Issues

- **Informed Consent Form**
  - signed ICFs substantially inconsistent with IRB approved versions
  - signed HIPAA authorization missing
  - hand written alterations to IRB approved ICF
  - persons obtaining consents (POC) did not sign and/or date consent
  - Inattention to completion of dates and signatures

- **Sponsor-Investigator Research**
  - Lack of document retention such as original FDA applications, financial disclosures, delegation of authority logs

- **Other Compliance Reviews**
  - Studies with children: Both parents' signatures missing when required, Reasons for lack of signatures from both parents not documented when required, Incomplete "*Description of Representative's Authority to Act"* section

Questions?

Thank you!