Research Compliance Office

Human Subjects Research: IRB Overview

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Topics

- Overview of Stanford IRBs
- Charge of IRB – Human Subject Research
- Protocol Application and Review Cycle
- IRB Review
- What's new with the IRB
  - Accreditation and Organizational Updates
  - Short form consent
  - Privacy and Confidentiality

Overview Stanford IRBs
- *Institutional Review Boards*

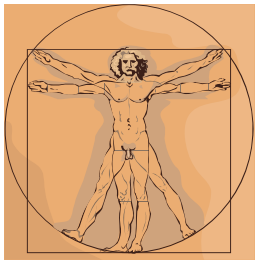
- 8 IRBs
  - Nonmedical (1) and Medical (5)
    - Monthly convened meeting by each IRB
  - Two IRBs devoted to expedited and exempt protocols
    - IRB 6 (medical) & IRB 8 (nonmedical and medical)
    - No convened meetings – rolling approvals
- 2008-2009 Meeting Schedule on website

Overview of Stanford IRBs

- Each IRB must have at least 5 members
  - Diverse and experienced professions
  - Sensitive and knowledgeable regarding community attitudes & vulnerable subject populations
  - Knowledgeable of institutional commitments, regulations, applicable laws, and standards of professional conduct
- Each IRB must include at least one member
  - whose primary concerns are in scientific areas
  - whose concerns are in nonscientific areas
  - who is not otherwise affiliated with the institution
- All proceedings are confidential

Charge of the IRB

- Review and approval ***human subject research***
- Authority vested through FWAs (Federalwide Assurances)
- Our FWA covers research conducted at:
  - Stanford University, Stanford Hospital and Clinics, LPCH, VA and PAIRE



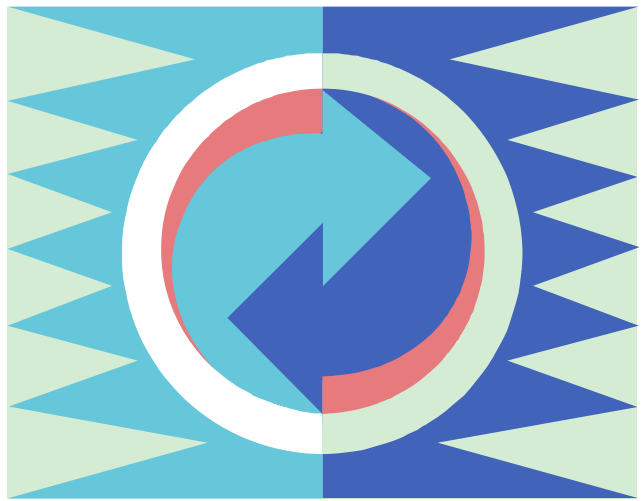
Defining HS Research

- **Research** - A *systematic investigation* designed to develop or contribute to *generalizable knowledge*
- **Human Subject** - A *living* individual about whom an investigator (whether professional or student) conducting research obtains:
  - Data through *intervention* or *interaction* with the individuals, or
  - *Identifiable private information*

45 CFR 46.102 (d) and (i)

Protocol Application & Review Cycle

- eProtocol Application
- Medical or Nonmedical
- Protocol Review Types
- IRB Review
- Approval
- Subsequent Protocol Events



eProtocol Information

- Paperless submission system
  - eProtocol system
- Access via Human Subjects website or http://eprotocol.stanford.edu/irb
- Requires SUNet ID

  to access eProtocol
  - If you need a SUnet ID contact:
    - Linda Wester

eProtocol Information

- Tips for success in eProtocol
  - Allow pop-ups
  - Save frequently
  - Read instructional text in each section
  - Access **Help** from within the eProtocol application
- eProtocol training available

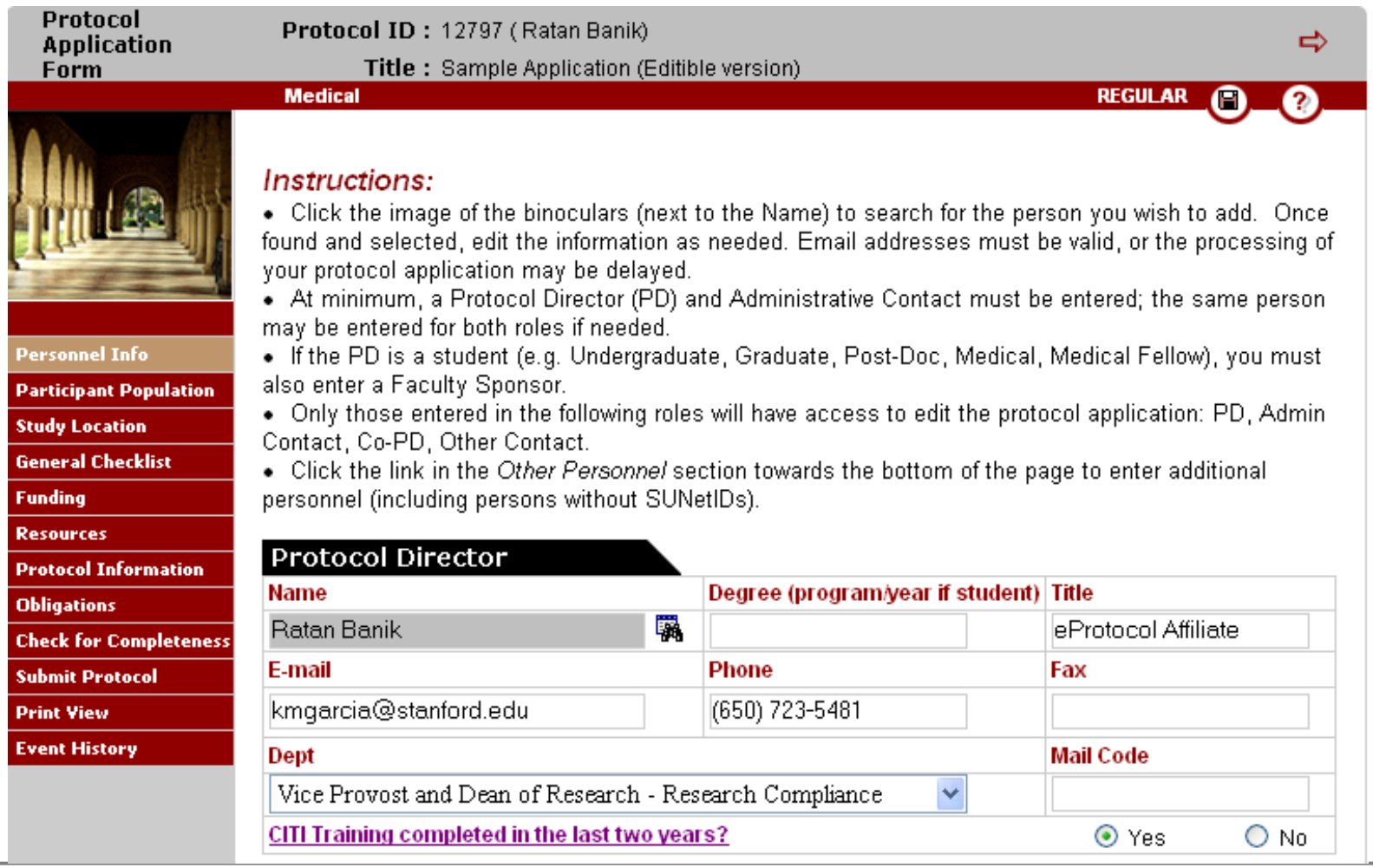
Protocol Events

- Initial Review
- Continuing Review (Renewal)
- Modification (Revision)
- Reportable Events
- Final Report

Protocol Review Types

- Regular review (Presented at convened IRB meeting)
  - All regulations apply
  - Drug or device study, research involving sensitive questions, specific subject populations, invasive procedures
- Expedited review
  - Minimal risk research
  - Non-sensitive information
  - Surveys, noninvasive procedures, venipuncture, voice, video, digital, or image recordings made for research purposes
- Exempt review *(minimal risk)*
  - Research exempt from regulations (continuing review)
  - Not generally applicable to medical research because of HIPAA

eProtocol Application Form



Human Subjects Training

- CITI (**C**ollaborative **I**RB **T**raining **I**nitiative)
  - Web-based program (http://www.citiprogam.org)
  - Refresher course every year for VA investigators
  - Create a username and password (these are not your SUNet ID and password)
  - Remember user name and password to take refresher course
  - Print out completion certificate for your records

eProtocol – Protocol Information

Protocol Application Form

Protocol ID : 12797 (Ratan Banik)

Title : Sample Application (Editible version)

Medical

REGULAR

- Personnel Info
- Participant Population
- Study Location
- General Checklist
- Funding
- Resources
- Protocol Information
- Obligations
- Check for Completeness
- Submit Protocol
- Print View
- Event History

1-3 | 4 | 5,6 | 7 | 8(a-g) | 8(h-m) | 9(a-e) | 9(f) | 10, 11 | 12 | 13 | 14 | 15 | 16

Title

Sample Application (Editible version)

Complete Sections 1 - 16. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose

a) **In layperson's language state the purpose of the study in 3-5 sentences.**

answer

Pre-Review IRB Process

- Submitted protocol is reviewed for completeness by intake staff
  - Incomplete protocols will be returned
- Assigned to IRB for review & meeting date
- IRB review, issuance of comments, if any
  - Voting for approval at convened meeting
    - Protocols or events subject to regular review
  - Approval – by single reviewer (online)
    - Protocols subject to expedited and exempt review

IRB Review

Ethical Principles & Regulations

- The Belmont Report
- The "Common Rule"
- FDA
  - Test Articles
- HIPAA
- State Law

The Belmont Report

- Published in 1979
- Filled a void of ethical oversight
- "Ethical principles and guidelines for the protection of human subjects of research"
- Consists of three basic principles
  - Respect for persons
  - Beneficence
  - Justice
- Foundation for later regulations

The Belmont Report

Respect for Persons

⇩

Informed Consent

- Obtain & document informed consent
- Voluntariness/ coercion
- Protect privacy
- Consider additional protections for those with limited autonomy

Beneficence

⇩

Risks & Benefits

- Procedures with least risk
- Risks reasonable in relation to benefits
- Maintain confidentiality
- Monitor data for more than minimal risk research

Justice

⇩

Enrollment

- Select participants equitably
- Avoid exploitation of vulnerable or convenient populations

IRB Approval Means...

- Risks minimized, research design sound
- Risks reasonable with regard to benefits
- Participant selection equitable
- Informed consent (from participant or representative)
- Informed consent documented
- Plan for monitoring safety and data
- Plan for privacy and confidentiality
- Vulnerable participants safeguarded

What's new with the IRB?

- Accreditation and Organizational Updates
- Short Form Consent
- Privacy and Confidentiality

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

Non-English speaking participants

- The Stanford HRPP and OHRP encourage the use of a full consent form translated into the participant's language whenever possible

- However, with prior approval of the IRB, federal regulations permit the use of a short form consent process (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2)

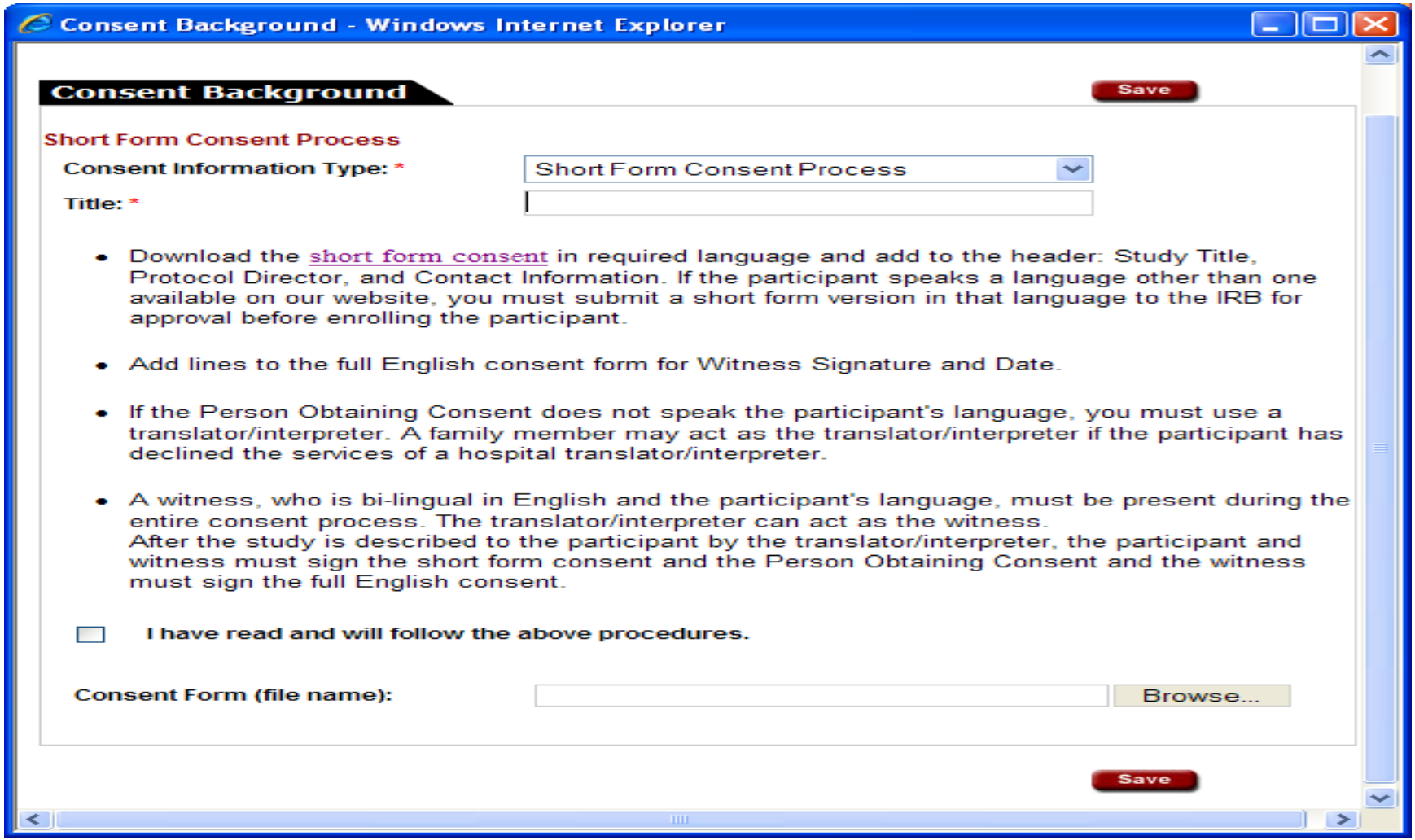
Short Form Consent Process

- 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	

Protocol Application



What to submit for IRB Approval

Summary Form (Modified English consent form):

Modified to have a signature line and text added on the last page beneath the Person Obtaining Consent section, as follows:

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature Date

(e.g., staff, translator/interpreter, family member, etc.)

Interpreters and witnesses who are they and what do they do?

- The assistance of a interpreter and the presence of a witness are required for the short form consent process.

- Who can be the interpreter?
  - Preferably, a hospital interpreter
  - A family member of the participant (only if the participant has declined the use of a hospital interpreter)
  - Study staff, if they speak the participant's language

Interpreters and witnesses
who are they and what do they do?

Who can be the witness?

- There must be a witness to the oral presentation who speaks both English and the participant's language.
- The witness may be staff, the interpreter, a family member, or other person.

During the consent process

- **The interpreter should briefly explain the consent process to the participant.**
- **The short form document in the participant's language should be given to the participant to read.**
- **The interpreter should translate the English consent to the participant.**
- **A copy of the signed and dated short form should be given to the participant or their legally authorized representative.**
- **A copy of the Summary Form (the modified English consent form) should be given to the participant or their LAR.**

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?)

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….

Privacy Protections (a)

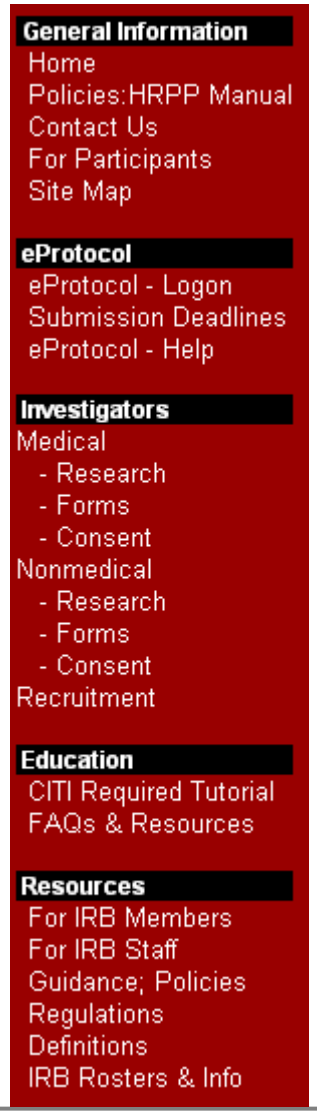
Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

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?

Finding What You Need



Human Subjects Website

- http://humansubjects.stanford.edu
- Policies and procedures
  - Human research Protection Program (HRPP)
- Guidance
- CITI information
- eProtocol Information
- Template consent, assent and HIPAA documents
- IRB contact information

Research Compliance Staff

- Interacting with the Research Compliance Office (RCO) staff facilitates IRB approval
- IRB Manager & IRB Associate per panel
  - See Human Subjects website **Contact Us** page
- HRPP Education/IRB Training Specialist
- Senior RCO Management

Contact Us

- IRB Education
  - 724-7141, IRBeducation@stanford.edu
- eProtocol Technical Support
  - Submit a HelpSU ticket (see the HS website)
  - You can also call the eProtocol HelpDesk: (650) 724-8964
- Human Subjects website http://humansubjects.stanford.edu/