Consent Issues

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  - Sample consent forms
- Waiver of Documentation and Alteration of Consent
  - Telephone screening and online studies
- Elements of Consent
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- Parental Consent – Research involving children
- Consent Process and Obtaining Consent
- Waiver of Consent
- Short Form Consent Process
- HIPAA Authorization
  - Alteration of HIPAA authorization
- Recruitment Methods
- Other Issues
Consent Options

eProtocol section 13

13. Consent Background

Written, signed consent should always be sought unless there are compelling reasons to seek an alteration of consent, waiver of consent, or waiver of documentation (i.e., signature). See more information on Informed Consent. A protocol should include at least one of the following. Depending on the nature of the research and the subject population, more than one may be included.

- Consent
- Waiver of Consent (e.g., retrospective chart reviews)
- Waiver of Documentation (signature) (e.g., telephone screens, oral consent, web questionnaires, and cases when the primary risk is breach of confidentiality)
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- Short Form Consent (e.g., when you anticipate consenting patients that speak a language other than the language in which the Consent form is written)
Belmont Report: Three Basic Principles

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
Template Consents

- **Stanford University Consent** (HIPAA Authorization not included)  
  rev 8/29/08
- **Stanford University Consent** (includes HIPAA)  
  rev 8/29/08
- **Stanford Minimal Risk Consent** (e.g., for blood draws, data collection, leftover specimens, interviews, surveys, behavioral interventions; HIPAA Authorization not included)  
  rev 7/15/08
- **Stanford HIPAA Authorization**  
  rev 8/24/07

- **VA Palo Alto Health Care System Consent** (VA HIPAA Authorization not included)  
  rev 9/24/08
- **VA Palo Alto Health Care System Consent** (includes HIPAA)  
  rev 9/24/08
- **VA Survey Consent** (for interviews, surveys, behavioral interventions; HIPAA Authorization not included)  
  rev 4/19/07
- **VA HIPAA Authorization**  
  rev 2/22/08
- **VAPAHCS 10-1086** (Required Header and Footer for VA Consent Forms)
Samples Consents  
(minimal risk studies)

**Samples** - minimal risk research  
These are examples of consent forms (including HIPAA) for minimal risk research, for studies involving only:

- Blood draws  
- Data collection  
- Use of leftover specimens

Sample consent forms
Waiver of Documentation and Alteration of Informed Consent

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Waiver of Documentation of Informed Consent

Criteria for IRB Approval
- Risks minimized, research design sound
- Risks reasonable with regard to benefits
- Subject selection equitable
- Informed consent from subject or LAR
- Informed consent documented
- Plan for monitoring data, when appropriate
- Plan for privacy/confidentiality, when appropriate

Available on minimal risk studies or when the only risk is breach of confidentiality

1. Telephone screen
   - In response to an advertisement/referral.
   - All elements of consent in phone screen
   - Full consent process with documentation (signature) required before study procedures begin

2. Also used for survey or questionnaire studies that are low risk (over the phone or on-line)
   - A signature is not obtained
Alternations of Informed Consent

Basic Elements of Informed Consent
- Research statement: purpose, procedures
- Reasonably foreseeable risks or discomforts
- Reasonably expected benefits to participants or others
- Appropriate alternatives
- Extent of confidentiality or privacy protections
- Compensation or treatment for research related injury
- Contact information
- Voluntary participation statement

Alteration of Informed Consent
- Can be used for deception in behavioral studies
- Used less frequently in medical studies
- Not allowed in FDA-regulated research (device or drug safety/efficacy trials)

Only available on minimal risk studies
8 Basic Elements of Informed Consent

1. Study involves research; purposes; duration; procedures; experimental procedures
2. Risks/discomforts
3. Benefits
4. Alternative procedures
5. Confidentiality of subjects’ records
6. Compensation, medical treatments if injury
7. Contact information for questions about research, participants’ rights, injury event
8. Voluntary participation: Refusal OK, Stop OK

Additional Elements of Informed Consent

1. Risks are unforeseeable
2. Participation may be terminated by investigator
3. Additional costs
4. Consequences of decision to withdraw from research
5. Significant new findings to be provided to subject
6. Approximate number of subjects
Consent Background

eProtocol section 13

- Describe the consent process (e.g. when and where consent will be obtained and by whom)

- Address potential issues of coercion and undue influence
  - Give participants time to consider participation (let them take the consent form home, especially if a complex study)
  - Make clear the distinction between research and treatment and that refusal to participant will not effect treatment, especially when the treating MD is the investigator
a) Describe the informed consent process. Include the following.
   i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)
   ii) When and where will consent be obtained?
   iii) How much time will be devoted to consent discussion?
   iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
   v) What steps are you taking to minimize the possibility of coercion and undue influence?
   vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

PD and study nurse will obtain consent; Consent will be obtained during a routinely scheduled clinic visit; Will allot sufficient time for describing the project and obtaining consent; If it appears the clinic time does not provided sufficient time to review the study, the participant will be asked if they would like to take the consent home and they can come back for another appointment or we will discuss the study with them over the telephone; It will be made clear to participants that their decision to participate is voluntary and that their decision whether or not to participate will not affect the care they receive for their condition. No express or implied pressure to participate will be asserted. Participants will be told they can have a family member or friend join them in the consent process; If both parents come to the clinic appointment, both will be asked to sign the consent. Generally only one parent accompanies the child to their appointment, if only one parent shows, only they will be asked to sign the consent. zx
b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter 14.5 for guidance.

Participant understanding will be determined through an interactive consent process of being open to questions and asking questions of the participant as to their understanding of the research. If a participant does not speak English, will request the use of a short form consent and will obtain IRB approval to use such process prior to enrolling the participant.

c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

Participant understanding will be confirmed through an interactive consent process of asking questions of the participant as to their understanding of the research. If a participant does not appear to be competent to give consent, surrogate consent will be obtained from the participant's legally authorized representative.
Research Involving Children

Parental Permission

- IRB requires the investigator to obtain permission of the child's parent(s) or guardian before enrolling the child in a study.
- Depending on the risk and benefits involved in the study, the permission of one or both parents may be required.
  - The IRB will make this determination and will notify you whether the permission of one parent or two is required.
IRB Determinations

Children’s Findings

- **Minimal risk studies** *(45 CFR 46.404*) - permission of one parent will generally be sufficient

- **Research involving more than minimal risk, but prospect of direct benefit** *(45 CFR 46.405)** the IRB may require the permission of both parents, unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child.
  - Not reasonably available means that the other parent is not present during the consenting process, or will not be available prior to the start of research procedures

- **Research involving more than minimal risk, but no prospect of direct benefit** *(45 CFR 46.406*** the permission of both parents is statutorily required, unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child

*FDA: 21 CFR 50.51 ** FDA: 21 CFR 50.52 *** FDA: 21 CFR 50.53
If your protocol includes children and the children reach adulthood (18 years old) while still participating in the research, you must consent these individuals for their continuing participation in the research or request a waiver of consent from the IRB.

Assent is required for children between 7 and 17 years of age.
Consent Process

- It’s an ongoing process... not a one time event (e.g. sign the consent form)

- Valued Qualities (know your audience)
  - Communication – tone, vocabulary and level of discussion during the consent process
  - Timing – some need time to consult with others and gather their own information
  - Understanding – one understands when the reasons, motivations and expectations are discussed and grasped

IRB is requesting to observe the consent process
Obtaining Consent - Process

- **Face-to-face** – obtain signature from participant before beginning any research related activity
- **Over the phone** – send (mail or fax) consent to participant, then consent process is conducted over the phone – signature is faxed or mailed back (no research related activities can take place until signature received)
  - Bifurcate the process – (screening consent and study consent)
    - Screening consent (oral consent/waiver of signature) for telephone screening, then full study consent signed in face-to-face meeting if qualifies for the study
- **Oral consent**
  - In person – man on the street research (hand out information sheet)
  - Phone survey or questionnaire (waiver of signature)
- **On-line consent**
  - Secure computer system
  - Completing online survey/questionnaire evidences agreement to participate
  - Waiver of documentation (no signature)
Waiver of Informed Consent

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Consent – Waiver of Consent

Basic Elements of Informed Consent
- Research statement: purpose, procedures
- Reasonably foreseeable risks or discomforts
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- Extent of confidentiality or privacy protections
- Compensation or treatment for research related injury
- Contact information
- Voluntary participation statement

Most often used for retrospective record reviews and other studies when it is impracticable (not just inconvenient) to obtain consent before conducting research.

Not allowed on FDA regulated research (drug and device studies).

Only available on minimal risk studies
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Short Form Consent Process

- The IRB approves a request to use the short form process and the full English consent form, with the witness signature and date lines, provided:
  - Demonstrate understanding of the process (consent background)
    - Roles of research staff, witness and interpreter/translator

- The IRB does not need to approve the short form foreign language consent forms, provided:
  - Use one of the forms on our website
    - Spanish, Korean, Chinese, Russian, Farsi, Vietnamese, Japanese
  - Download form and insert study specific information before using

You do need IRB approval of the short form consent form if in a language other than one of the seven on our website
HIPAA Authorization Form

- Separate signature needed, even if the authorization is embedded in the consent form
  - *Must obtain 2 signatures* – one on the consent and one on the authorization

- Uses of PHI listed in the authorization should be limited to the least amount of information needed to accomplish the purpose of the research
Alteration of HIPAA

- Use when the design of the project makes it impracticable to get signature on authorization
  - Entire study will take place over the phone
  - Internet study
- Participant is provided with HIPAA information
  - Orally or written
- Participant gives consent/authorization
  - Orally or by completing research activity

No signature on authorization
Identifying Participants

How are you getting participants?

- Clinic patients, tell then about the study at clinic visit
  - Can be your patients or referrals to clinic for clinical care
  - For former patients, you can send them a letter telling them about the study – if interested contact you

- Referrals for research (not for clinical care)
  - Tell colleagues or send them letters letting them know about your study
  - Colleagues can give your contact information to the patients or with the patient’s permission, give you the patient’s contact information
  - Colleagues can send their patients a letter about your study, interested participants are instructed to call you
    (All letters need prior IRB approval)

- Advertisements
  - No cold calls and no passive consent!!
Managing Consent Forms – eProtocol

- Consent Form Changes
  - Track changes in consent and assent forms

Practice Tips:
- When protocol is approved, go to the approved eProtocol and download approved consent form – **accept the tracked changes** and save on your computer
- When submitting a subsequent event, attach the saved consent
  - If new event includes changes to the consent, again track the new changes
Consent Form Retention

- Must keep copies of signed consent forms for 3 years after completion of the study
  - This is noted on the approval letter

- HIPAA regulations: communications required to be in writing (e.g. signed authorization forms) must be retained for 6 years from date of its creation or the date when last in effect, whichever is later
Stanford HRPP received full accreditation in March 2006

- 3 year accreditation period – ends in March 08
- Expect a site visit in December 2008
  - Anticipate site visitors will want to interview investigators and research personnel again – about 100 people in total will be interviewed
Contact Us

- Questions, concerns, comments or suggestions
- Feedback on IRB processes
- Request IRB education
  - Individualized
  - Small or large group presentations
  - Topic specific
- Suggest topics for upcoming presentations
Contact Us

- Kristin Frazier, HRPP Education Specialist
  - 724-7141, kristin.frazier@stanford.edu
- Research Compliance website
  http://humansubjects.stanford.edu/