Documentation of the Informed Consent Process

USC Office for the Protection of Research Subjects (OPRS)

Session Overview

- Purpose of Informed Consent (IC)
- IC Process and Documentation
  - Short Form
  - "Conditional" Process
  - Witnesses to Consent Process
  - Dates on IC
  - Errors or Omissions
  - Double-Check Documentation
- IC Audit Findings
- Resources / Contacts
- Quiz

Purpose of Informed Consent

Consent ("autonomy" *from the Belmont Report*)

- **Protects human subjects**
- **Ensures subject understand the study and are informed about its risks, benefits and procedures**
- **Provides subject an opportunity to ask questions**
- **Allows subjects to voluntary decide whether or not to participate in research**

Informed Consent is a Process

This presentation is focused on IC documentation, however:

- **Remember that Informed Consent is not just a form…it's a process that involves ongoing exchange of information**
- **Subjects must be informed about changes or new information about the study that may affect their willingness to participate**

Informed Consent Process

- Use the current IRB-approved, stamped consent for the study
- Provide subject or Legally Authorized Representative (LAR) a consent Form in his/her language *(or use Short Form Process)*
- Ensure subjects/LARs have sufficient time to consider participation, free of coercion or undue influence
- Provide subject/LAR an opportunity to ask questions about the study

Informed Consent Documentation

- Subject/LAR must sign and date the form
- Person Obtaining Consent must sign and date the form
- Provide a copy of the signed consent to the subject/LAR
- Document in the subject's chart or medical record that consent was obtained and file Consent Form in subject's record
- Document use of a translator on subject's chart, if applicable

Short Form Process

- ***When non-English speaking subjects are anticipated in a study, the consent form should be translated in the subjects' language***
- **Use the Short Form Process for the <u>unexpected</u> enrollment of subjects when a consent is not available in the subject's language**
- **A witness and translator must be present during the consent process (translator may serve as witness)**
- **CA Subject Bill of Rights in the subject /LAR's language (if applicable) ****Tip: see pg 1 of consent***
- **Short Form and Subject Bill of Rights templates are available in thirteen languages on the HSIRB website at: http://www.usc.edu/admin/oprs/hsirb/forms**

Short Form Process

- **Subject /LAR is presented with a copy of the Short Form and Bill of Rights (if applicable) in a language he/she understands**
- **Translator orally translates the current, IRB approved study consent in the subject's/LAR's language in the presence of a witness**
- **Ensure subjects/LARs have sufficient time to consider participation, free of coercion or undue influence**
- **Provide subject/LAR an opportunity to ask questions about the study**

Short Form Process Documentation

- Subject/LAR dates and signs the Short Form and Subject Bill of Rights, if applicable
- Witness dates and signs the Short Form and Consent
- Person Obtaining Consent dates and signs the Consent
- Subject /LAR receives a copy of the signed Short Form, Bill of Rights (if applicable) and Consent
- Document that consent was obtained from the subject/LAR in the subject's chart or medical record and file Short Form, Bill of Rights (if applicable) and Consent in subject's chart

Conditional IC Process

- Certain conditions *(e.g., illiteracy, blindness)* may impede documentation of subject consent
- Conditional consent process can be utilized
- A witness must be present during the consent process
- Ensure subjects/LARs have sufficient time to consider participation, free of coercion or undue influence
- Provide subject/LAR an opportunity to ask questions about the study

Conditional IC Process Documentation

- Subject makes a “mark” on the consent form, if possible
- Witness signs and dates consent form
- Person Obtaining Consent signs and dates consent form
- On consent form, note the method used for communicating with subject and the means by which subject communicated agreement
- Subject receives a copy of the signed consent
- Document that consent was obtained from the subject in the subject’s chart or medical record and file Consent

Consent Witness

- Not required unless using the Short Form or the Conditional Process
- Additional considerations may be imposed by:
  - FDA and ICH GCP: “impartial witness” when the subject or LAR is illiterate
  - Study sponsor
  - Institutional
- Refer to the study protocol, investigator, sponsor or IRB to determine requirements for your study

IC Documentation

If the Study Subject... ↓	Subject (or Legally Authorized Representative) Signs	Person Obtaining Consent Signs	Witness Signs	
Understands language of Consent	Consent*	Consent	N/A	→ *Subject Receives Signed Copy of Consent*
Does not understand language of Consent	Short Form + Bill of Rights** *(in subject's language)*	Consent	Short Form and Consent	→ *Subject Receives Signed Copy of Short Form, Bill of Rights** and Consent*
Is capable of providing consent but has a condition that impairs consent documentation (e.g., illiteracy, blindness)	Consent* *(makes "mark", if possible)*	Consent	Consent	→ *Subject Receives Signed Copy of Consent*
	On consent form, note the method used for communicating with the subject and the means by which subject communicated agreement			

***if consent includes California Subject Bill of Rights, subject must sign Bill of Rights (1st page) and consent (last page)**
**** Bill of Rights, if applicable (check if English version of consent includes Bill of Rights on 1st page)**

Tip sheet available at:
http://www.usc.edu/admin/oprs/private/docs/hsirb/forms/Consent_and_Short_Forms_Final.pdf

Dates on Informed Consent

- **Signature dates of person obtaining consent and subject or LAR do not have to match** ***(e.g., investigator may sign and date consent during process and subject may sign and date consent after discussion with relatives)***
- **Subject or LAR must sign and date consent before any study procedures are conducted** ***(FDA-regulated studies: if subject signs consent on the day study procedures begin, subject chart should document that consent was obtained prior to study procedures)***
- **Check sponsor guidelines**
- **Do not "back date" consent!**

IC Errors or Omissions

- **If an error is made on the consent:**
  - **Strikethrough the mistake with a single line, write the correct information next to it and initial and date the correction *(i.e., original entry must be visible)***

John Smith	John Smith	JS 2/5/11 ~~2/6/10~~ 2/5/11
Name of Research Participant	Signature	Date Signed (and Time)

- **If an entry was inadvertently omitted:**
  - **Initial and date any entry made after the consent process *(should be done by person making entry)***
  - **Include explanation in the subject's record or Note to File**

Double-Check IC Documentation

After consent is signed or completed, double-check to ensure the following:

- **IRB approval on consent has not expired**
- **Current consent version is used**
- **Fill-in sections of consent are complete, if applicable**
- **Names, dates and signatures from subject/LAR, person obtaining consent and witness (if any) are included**
- **HIPAA Authorization was signed, if applicable**
- **Subject or LAR receives copy of consent/HIPAA documents**
- **Subject's medical record or chart documents that subject/LAR agreed to participate in study**
- **Consent, Short Forms, Bill of Rights and HIPAA are filed in subject's medical record, as applicable**

IC Audit Findings

Most common:

- **Use of expired consent**
- **Use of older version of consent**
- **Missing entries on consent**
- **Signature date errors**

Other:

- **Study staff fill-in subject or LAR sections of consent**
- **Consents are not handwritten *(e.g., dates stamped)***
- **Use of one consent for multiple subjects**

Resources

Informed Consent templates and Short Forms:
http://www.usc.edu/admin/oprs/hsirb/forms/

OPRS Informed Consent in Human Subjects Brochure:
http://www.usc.edu/admin/oprs/private/docs/oprs/brochures/IFC_Booklet.pdf

HSIRB Website:
http://www.usc.edu/admin/oprs/hsirb/

Contacts

http://www.usc.edu/admin/provost/oprs

Health Sciences Campus
General Hospital, Suite 4700
1200 North State Street
Los Angeles, CA 90033
Tel: (323)223.2340
Fax: (323)224.8389
E-mail: irb@usc.edu
http://www.usc.edu/admin/provost/oprs/hsirb/

University Park Campus
837 Downey Way
Stonier Hall, Room 224a
Los Angeles, CA 90089-1146
Tel: (213)821.5272
Fax: (213)821.5276
E-mail: upirb@usc.edu
http://www.usc.edu/admin/provost/oprs/upirb/

Office for the Protection of Research Subjects
3720 South Flower, Third Floor
Los Angeles, CA 90089-0706
Tel: (213)821.1154
Fax: (213)740.9299
E-mail: oprs@usc.edu
http://www.usc.edu/admin/provost/oprs/

Office of Compliance
3500 Figueroa St.
University Gardens Building, Room 105
Los Angeles, CA 90007
Tel: (213)740.8258
Fax: (213)740.9657
E-mail: complian@usc.edu
http://www.usc.edu/admin/compliance/

IC Documentation Quiz

- 5 questions (multiple choice)
- Passing grade: 80%; two attempts per question
- **Enter your name and email address when prompted**
- Results will be sent automatically to OPRS to confirm completion of training
- OPRS will email confirmation of receipt
- To start the quiz, proceed to the next slide

IC Documentation Quiz