Informed Consent Process

“Boot Camp”

UC Davis Clinical and Translational Sciences Center

November, 2011
Introduction

- Overview of the Clinical Trials Resource Group and its programs
- ICF module
- Exit survey!
- 3 months re-survey
- Dedicated presentations
- On-line video
At the end of this module participants should be able to understand:

- Informed Consent Process
- Essential elements of Informed Consent Form
- Requirements for consenting minors
- Requirements for translation in other languages
- Relationships between the Consent Form, Clinical Trial Agreement, Budget and Coverage Analysis
- How to write better consent forms
- How to consent different sections of the form
What is the Informed Consent Process

The **process** of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention (American Medical Association 1998)

...*It’s more than a signature on a piece of paper!*
What is wrong with this Informed Consent Process?

- [Link](http://www.youtube.com/watch?v=qp6PwBx5AJE&feature=related)
Why do we need the Informed Consent Process?

The Short Answer:

– It’s the ethical thing to do
– It’s a safety and quality of care issue
– It’s an access/diversity issue
– It’s the law

Another way to put it:

- **Obtaining** informed consent is the provider’s **legal responsibility**. Failure to obtain informed consent renders any U.S. physician liable for negligence or battery and constitutes medical malpractice

- **Granting** informed consent is the patient’s **exclusive right**
Key Historical Influences on Informed Consent

- Nuremberg Code - 1947-48
- Declaration of Helsinki – 1964 (+ revisions)
- Belmont Report - 1979
- FDA: 21 CFR 50 – Protection of Human Subjects
- FDA: 21 CFR 56 – IRB review of Research
- ICH GCP Guidelines - 1996
FDA Inspections of ICF

Each year, ICF-related issues are among the most commonly cited deficiencies seen in CDER GCP compliance inspections.

2009 CDER data: 6%-9% of clinical sites were cited for consent-related issues.

[Handout “What FDA Inspectors Assess Regarding Informed Consent During Clinical Investigator/Site Inspections” (Barnett Educational Services)]
Each year, ICF-related issues are among the most commonly cited deficiencies in CDER GCP compliance inspections.
## Table 2: Distribution of OHRP Citations of Noncompliance and Deficiencies (08/2002–08/2007)

<table>
<thead>
<tr>
<th>Category of Deficiency</th>
<th># of Citations</th>
<th>% of Citations</th>
<th>% of Citations (2002 data)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB-approved informed consent documents/process</td>
<td>260</td>
<td>34%</td>
<td>27%</td>
</tr>
<tr>
<td>IRB initial review process</td>
<td>153</td>
<td>20%</td>
<td>25%</td>
</tr>
<tr>
<td>Written IRB policies and procedures</td>
<td>113</td>
<td>15%</td>
<td>8%</td>
</tr>
<tr>
<td>IRB review of protocol changes</td>
<td>40</td>
<td>5%</td>
<td>10%</td>
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<tr>
<td>IRB continuing review process</td>
<td>37</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>IRB records, including IRB minutes</td>
<td>31</td>
<td>4%</td>
<td>6%</td>
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<tr>
<td>IRB expedited review procedure</td>
<td>26</td>
<td>3%</td>
<td>4%</td>
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<td>Reporting requirements</td>
<td>24</td>
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<td>3%</td>
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<tr>
<td>Research conducted without IRB approval</td>
<td>24</td>
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<td>2%</td>
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<tr>
<td>Other miscellaneous deficiencies</td>
<td>22</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Failure to obtain informed consent of subjects</td>
<td>19</td>
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<td>4%</td>
</tr>
<tr>
<td>IRB membership/training/support/workload</td>
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<td>2%</td>
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<td><strong>Total</strong></td>
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<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
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<td>Area of Noncompliance or Deficiencies Related to Informed Consent</td>
<td># of Citations</td>
<td>% of Citations</td>
<td>% of Citations (2002 data)</td>
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<tr>
<td>---------------------------------------------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------------------</td>
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<tr>
<td>Description of purpose, procedures, and duration</td>
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<td>23%</td>
<td>19%</td>
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<td>Description of risks and discomforts</td>
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<td>17%</td>
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<tr>
<td>Description of benefits</td>
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<td>6%</td>
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<td>Description of alternatives</td>
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<tr>
<td>Other miscellaneous</td>
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<td>2%</td>
<td>10%</td>
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<tr>
<td>Failure to obtain legally effective informed consent</td>
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<td>7%</td>
<td>8%</td>
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<tr>
<td>Documentation of informed consent</td>
<td>13</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Total</td>
<td>279</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
When is Informed Consent Required at UC Davis

- **Most studies**
  - involving human participation
  - greater than minimal risk
  - the use of human organs, tissue or biological fluids
  - clinical data or other sensitive personal information

- **Prior to**:
  - *Screening procedures* performed solely for eligibility determination
  - *Altering the subject’s care* for the purposes of research
When is the Informed Consent NOT Required

- Observation of *legal public behavior*
- Study of *existing publicly available data/records*
- *Normal* educational practices
- Where the researcher *does not manipulate* the subjects’ behavior and the study does not involve more than minimal risk.
- Surveys and questionnaires involving *perception, cognition, or game theory* and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
Waiver of Informed Consent

Request for Waiver to Informed Consent Process
Required to justify the following four points, for review by the IRB:

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practically be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

[DHHS45 CFR §46.116(c),(d) & 45 CFR §46.117(c)(1)]
UC Davis Standard Consent Form(s)

1. Biomedical Standard Model Consent Form
2. Social and Behavioral Standard Model Consent Form
3. Model Assent Form for Minors in Research
4. Consent for the Use of Leftover Biological Specimens  (This consent form is only for studies where the researcher is collecting normally discarded tissue removed from non-research related related surgeries.)
Required Elements of Informed Consent

1) Study involves research
   Purpose of research
   Expected duration for subject
   Description of procedures
   Identification of experimental procedures

[Handout: IRB Standard Biomed Consent Form and its relationship to the 8 required elements]
2) Reasonably foreseeable risks or discomforts
3) Reasonably foreseeable benefits to subject or others
4) Alternative procedures or treatments
5) Confidentiality (plus HIPAA)*
6) Compensation for research related injury
7) Who can answer questions about study; and who can answer questions about subject’s rights
8) Voluntary participation

[Handout: IRB Standard Biomed Consent Form and its relationship to the 8 required elements]
1. May involve unforeseeable risks
2. Situations in which investigator may terminate subject’s participation
3. Any additional costs to subject
4. Consequences and procedures for subject’s early withdrawal
5. Revelation of new findings
6. Approximate Number of subjects

[Handout: IRB Standard Biomed Consent Form and its relationship to the 8 required elements]
Special Considerations for the Informed Consent Form

- Financial Obligations of the Subjects
- Consent vs. Contract
- Language Issues
- Conflict of Interest Disclosure
- Vulnerable Populations
Financial Obligations of the Subject in the Consent Form

(WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?)

[Include ONE of the following statements):

[If there are no charges to the participant and insurer (including standard of care costs) include]: There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

[OR]

[If the sponsor/department is paying for the research, and the participant/insurer is paying for standard of care costs, include]: Standard of care and other routine costs will be billed to you or your insurance carrier, Medicare, or Medi-Cal, where appropriate. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. If not covered, you will be expected to pay for these costs. An estimate of the costs will be discussed with you. Only the costs of research or experimental procedures will be paid by the sponsor/department. [An estimate of the costs should be included]
What are study costs?

1. The investigational item or service itself, unless otherwise covered outside of the clinical trial

2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., additional blood draws for biomarker discovery)

3. Items and services customarily provided by the sponsors free of charge for any enrollee in the trial

   1. Items or services required solely for the provision of the investigational item or service (e.g., administration of a investigational chemotherapeutic agent).

   2. The clinically appropriate monitoring of the effects of the item or service (e.g., extra blood draws for signs of liver failure), or prevention of complications

   3. Items or services that are needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications

   1. Items or services that are typically provided absent a clinical trial
Documentation of Financial Obligations of subjects

- **Coverage Analysis** is a tool to document who pays for what

- **Consists of 2 parts:**
  - QCT form (answers the question “Is the trial qualified to bill insurance for expanded care?”)
  - Billing grid (delineates all charges by payor)

[Handout: QCT form]
Consent Form is Harmonized with QCT Form

The Consent Form:
• there are no charges to the participant and insurer
• the sponsor/department is paying for the research, and the participant/insurer is paying for standard of care costs and expanded care costs

The Qualifying Clinical Trials Form:

CONTRACT terms affect Coverage, and therefore, affect ICF!
Billing Grid helps to explain the financial obligations

<table>
<thead>
<tr>
<th>VISIT/WEEK</th>
<th>Baseline Visit</th>
<th>Week 6 Visit</th>
<th>Week 12 Visit</th>
<th>Week 18 Visit</th>
<th>Week 24 Visit</th>
<th>Week 30 Visit</th>
<th>Week 36 Visit</th>
<th>Week 42 Visit</th>
<th>Week 48 Visit</th>
<th>Week 54 Visit</th>
<th>Early Withdrawal</th>
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<tbody>
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<td>Medical History</td>
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<td>Urine Pregnancy Test*</td>
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<tr>
<td>Study drug Injection</td>
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<td>S</td>
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<td>X-Ray</td>
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</tbody>
</table>
Other Financial Obligations of the Subject

- Can the study pay co-pays and deductibles?
- Can the study pay for travel?
- Can the study pay stipends?
- Difference between Medicare and Medicare Advantage patients
- What if the patient is not insured? Can the study pay for their costs?

[Handout: Coverage Analysis Q&A]
Protocol, Funding, ICF, Budget, and Coverage Analysis are related!
Consent vs Contract

The Consent Form:
• Is not a contract, but an acknowledgement
• Between the University and the Patient
• Necessary for regulatory compliance purposes
• Project specific

The CT Agreement:
• Is a contract for services provided by the University
• It is between the University and the Sponsor (the PI and the study subjects are not parties to the contract)
• Is necessary to cover the legal risks between the parties in exchanging services for payment
• May be a template or master and not project specific
• Is required only when we are being paid by a Sponsor to conduct a trial
• Subject injury language is only required in Sponsor-Initiated studies
Sponsor-initiated trials
UC is required to provide services for injuries that occur during clinical trials (in ICF)
  • This is our obligation to the patient (in ICF)

Sponsor is required to reimburse us for the cost of these services if the injuries are related to the study materials or study procedures required by the Sponsor protocol
  • This is Sponsor obligation to UC (in Contract)

Either insurance or UC will pay for the rest

Investigator-initiated trials
UC is required to provide services for injuries that occur during clinical trials (in ICF)
  • This is our obligation to the patient (in ICF)

Either insurance or UC will pay for these services
WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the Researcher if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. You do not lose any legal rights by signing this form.
“Sponsor shall reimburse the Institution for the cost of reasonably necessary medical treatment provided to Study subjects for any injuries directly resulting from a Study Material or research procedures performed in connection with the Study Protocol; provided, however, that Sponsor shall not be responsible for the costs of treating any injury to the extent that it is the result of negligence, willful misconduct or failure to reasonably act on the part of an agent or employee of the Institution. Institution shall not bill any costs incurred in accordance with this Section that is paid by Sponsor to a third party insurer.”
Issues

While we have flexibility with the language as approved by UC legal, there are some Sponsor suggestions that we do not agree to, such as:

- Sponsor does not want to pay for subject injuries
- Sponsor wishes to pay for injuries only if insurance will not pay
- Sponsor wants to treat the study subjects as a party
- Sponsor wants to dictate when and how we bill to insurance
Further Questions?

If you have other questions or concerns about this issue, feel free to contact us at 916-734-2345 to schedule a call or meeting or visit our clinical trials website at:

http://www.ucdmc.ucdavis.edu/healthsystemcontracts/
Disclosure of Financial Conflict of Interest on ICF

Required on University of California, Davis ICF Form

Inserted under the section:

Does the researcher have a financial interest in this research study?

[Handout, example]
Language-related Issues

The FDA fully expects that a version of the ICF is provided \textit{in their language}.

A person \textit{who reads and speaks} this language should administer the consent.

Translator is OK.

Medical Interpreting Services at UCD:

http://www.ucdmc.ucdavis.edu/interpreting_services/

(916) 734-2321

[Handouts – Non-English speakers & Short Form in Spanish]
Vulnerable Populations

- Pregnant Women
- Human Fetuses & Neonates
- Children
- Cognitively Impaired Persons
- Prisoners
- Students/Employees/Subordinates

The inclusion of a vulnerable population in research must be justified and adequate safeguards are required to be in place to minimize the risks unique to the particular vulnerable population.
Vulnerable Population
Pregnant Women or Fetuses

The woman’s consent is obtained according to the informed consent provisions outlined in IRB SOP “Informed Consent”, if:

- (a) the prospect of *direct benefit* to the pregnant woman,
- (b) the prospect of a *direct benefit* both to the pregnant woman and the fetus, or
- (c) *no prospect of benefit* for either when risk to the fetus is not greater than minimal and the purpose of the research is the *development of important biomedical knowledge that cannot be obtained by any other means*,

**There is no requirement of obtaining the fetus’ father’s consent. (for above scenario)**
Vulnerable Population
Pregnant Women or Fetuses

If the research holds out the prospect of direct benefit only to the fetus then:

- consent of both the pregnant woman and the fetus’ father is required
- However, the father’s consent need not be obtained if:
  - the father’s unavailability, incompetence,
  - temporary incapacity
  - when the pregnancy resulted from rape or incest.
- Each individual providing consent above, must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate
Vulnerable Population
Pregnant Women or Fetuses

For minors who are pregnant, assent and permission are required to be obtained in accord with the provisions of IRB Policy “Informed Consent”
Neonates of uncertain viability may **not** be involved in research **unless**: The IRB determines that:

- (i) the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability and risk is the least possible for achieving that objective, or
- (ii) the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and no added risk to the neonate resulting from the research

The legally effective informed consent of either parent or of either parent’s legally authorized representative (if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity)

**However, the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.**
In research involving a person with impaired decision making capacity who cannot give informed consent, federal regulations require that consent be obtained from the person’s legally authorized representative, as determined by state or local law.

[DHHS 45 CFR 46 Subpart A]
Surrogate Consent

- Included in Protocol
- Only Studies related to
  - Cognitive Impairment
  - Lack of Capacity
  - Life-Threatening Conditions

- Self-Certification of Surrogate Decision Makers

[Handout]
Emergency Room Situations

In an emergency room setting:

- for research conducted in California (outside the VA System), **hierarchy** of the Legally Authorized Representative, from whom Surrogate Consent is obtained, **does not apply**

However...

- No Surrogate Consent may be utilized if there is a disagreement whether to consent among any available surrogates
Vulnerable Population
Prisoners

No biomedical research shall be conducted on any prisoner in the State of California
Vulnerable Population
Students/Subordinates/Employees

If any member of these groups
- Being Graded
- Performance Evaluated
- Receiving a Paycheck

Should not be approached for recruitment into the study
Vulnerable Population
Children/Minors (under age 18 yrs-CA)

The UC Davis IRB may approve research that involves children as subjects of research if any of the following requirements are met

- (a) The research *does not involve greater than minimal risk*;
- (b) The research involves greater than minimal risk, but presents the prospect of *direct benefit* to the individual subjects; or
- (c) The research involves minor increase over minimal risk and there is no prospect of direct benefit to individual subjects, but is likely to yield *generalizable knowledge* about the subject’s disorder or condition.
Consenting of Children/Minors

Parental Consent is required:
State laws define the age when the assent is required
At UCD:

- 8 - 11 year old informational letter (no signature)
- 12-17 year old assent (with signature)
- Other factors considered (maturity, psychological state)

IRB makes a decision on assent based on the protocol
IRB may waive the assent if:

- minimal risk
- does not adversely affect the rights and welfare
- the investigation cannot be practicably carried out w/o waiver
- Addt’l information may be provided after participation

[Handout – Assent of Minor Participating in Research]
Consenting of Children/Minors

Consent of one parent is sufficient if:
- < minimal risk
- > minimal risk, but with direct benefit to the subject

Consent of both parents is required if:
- > minimal risk, with no direct benefit, will yield generalizable knowledge of the condition
- > minimal risk, with opportunity to understand a serious problem affecting health and welfare of children

...unless one parent is deceased or lacking legal custody
Questions?
Informed Consent

PROCESS
What do we need to do to improve the Informed Consent Process

1. Readability: Forms written in simple sentences and in the language of the patient

2. Comprehension: Use “teach back” or questions during the informed consent discussion, engage the patient in a dialogue about the nature and scope of the procedure
½ of the American adults read at or below 8th Grade Level

Survey of Consent Forms:
1980 Morrow: (n=60) slightly less difficult than medical journals
1996 Golstein: (n=284) <10% at < 10th grade
2004 Paasche-Orlow: (n=61) av. grade = 10.6
2004 Sharp: (n=107) 10.5% < 10th grade

Basic Principles of Readability
• Use common, everyday words
• Define complex words using “Alternative words suggestions” or Glossary of Human Subject Terminology
  http://www.research.ucdavis.edu/home.cfm?id=OVC,1,1081,1433,1064
• Use visual aids, examples, analogs
How to determine your document’s reading level:

• Fry Formula
• Fresch-Kinkade formula

Click the **Microsoft Office Button**

Click **Word Options**.  Choose **Proofing**

Select **Check grammar with spelling**

Select **Show readability statistics**

Select the paragraph.  From **Review Panel** click on **ABC Spelling and Grammar**
The Single Cell Analysis Congress (London, May 11-13, 2011) brings together the leading experts in novel single-cell detection, imaging and molecular analysis platforms. The cutting edge technologies presented at the second annual meeting are truly “forward technologies”, the innovative solutions that enable a quantum leap forward in our understanding of how cellular interactions translate into higher order functions. It seems that analysis of individual cells is becoming a close reality. Single cell signatures may tell us a lot about the tissue microenvironment, differentiation, aging or regeneration. For instance, tumor microenvironment contains multiple cell types, including immune cells, stroma, cells of blood vessels and all their chemical signals. The communication of tumor cells with their microenvironment helps drive the tumor progression. Single cell analysis can explain this communication in great detail, potentially yielding new therapeutic approaches for targeting these communication signals.
What will happen to you if you are in the study?
Some of the children in this study will wear an eye patch over one eye. If you are in the study, you will not get to choose whether you wear the patch or not. A computer program will decide whether or not you will wear a patch. This is like flipping a coin to decide if you will wear a patch. If you are chosen to wear the eye patch, you will need to wear it for 3 hours every day for at least 3-5 months. In the study, you will come back 7 times over the next 3 years to have your eyes checked. The eye doctor will check how straight your eyes are, how well your eyes work together, and how well you see. Sometimes these things will be checked more than once. At some visits, you will get drops in your eyes that will help the doctor find out if you need glasses or a change in your glasses. These drops may sting for a few seconds and will make lights seem brighter for a few hours. At every visit you and your parent will also be asked to answer some questions about how you feel about your eyes.
To review, if I am in this study:
- I understand that I may need to wear an eye patch for 3 hours every day for at least 3-5 months. I will not be able to choose whether I wear the patch or not.
- I understand that I will not see as well if I am wearing a patch, (while I wear the patch).
- I cannot ride a bike, ride a skateboard, rollerblade, or do other things where I could get hurt.
- I understand that I will need to come back to the doctor 7 times over the next 3 years.

Handout – sample text
Readability Guidelines continued...

Use short sentences < 15 words

Use active form (first person)

Use formatting (Bullets, white spaces, shaded boxes) to improve the visual understanding
Example of Layouts

• Using bulleted text
• White spaces
• Bold font
• Checklist on the left
• Stop! At the end of each page
Common Problems with Informed Consent Content and Readability

Handout : Barnett Educational Services
Pre-testing with community groups to:
assess comprehensibility,
identify strong and weak points,
determine personal relevance, and
gauge confusing, sensitive, or controversial elements

Individual interviews or focus groups (a local adult education group)
Match geographic and disease population if possible

Provide Introductory statement: explain the baseline scenario along with some basic medical facts about the condition, the proposed procedure, and their options.

Not “being tested”
Delivery of Informed Consent
Steps in the Informed Consent Process

1. A clear **discussion** of the information in the Informed Consent Form

2. A **signed and dated** Informed Consent Form

3. **Source document** containing a progress note/chart note
What do we need to do to improve the Informed Consent Process

1. Readability: Forms written in simple sentences and in the language of the patient

2. Comprehension: time, “teach back” or questions during the informed consent discussion, engage the patient in a dialogue about the nature and scope of the procedure
Who typically reviews Informed Consent Forms with prospective study subjects?

2007 National Survey of Study Volunteer Experiences (CenterWatch)
27% of cases: subject reviewed alone
73%: physician/nurse/CRC was involved

2002 National Survey of Study Volunteer Experiences (Center Watch)
14% signed the form w/o reading
30% did not understand if the study will carry risks/discomforts
11% were unsure that they can quit anytime
37% did not understand blinding and randomization
Take Time

Make patient comfortable
Use proper environment (quiet room)
NO LIMIT should be placed on time – no time pressure
Children, older adults, disabled, non-English speakers may require more time
Document time spent on consenting process
Improve Comprehension

Use a teach-back process in one-on-one sessions.

Ask follow-up questions to assess comprehension.

Make the process adaptive to various communications challenges: less well educated, mentally ill, elderly populations.

Extra meeting(s) if necessary.

These measures will not diminish accrual.
Sample Questions to Ask

- What’s your general reaction to this study?
- Is anything confusing?
- What words do you not understand?
- What questions do you have after reading this form?
- What is the procedure/treatment that is described? What does it do?
- What are the benefits of this procedure?
- What are the risks? The alternatives?
- Do you understand that you can refuse to have this procedure?
- Would you need more information before you decided? What information?
Patient repeats *in his/her own words* all the information he was given during the informed consent. Studies have found that teach back, also called “the show me technique”, greatly improves recall and retention of information by patients.
Teach-back Questions

- "I want to make sure we have the same understanding..."
- "Can you tell me, in your own words..."
- "Tell me what you think will happen to you in this study."  
  (To assess research purpose.)
- "What do you expect to gain by taking part in this research?"  
  (To assess benefits and compensation knowledge.)
- "What risks would you be taking by being in this study?"  
  (To assess knowledge of risks.)
- "Tell me what the alternatives are if you decided not to be in the study."
- "Who can you call if you have any questions?"  
  (To assess knowledge of contact information.)
- “What questions do you still have?”
Helpful Video on How to Administer Informed Consent

http://www.uth.tmc.edu/orsc/guidelines/informed_consent.html
Preparation for Live Demo

Read the indicated consent form excerpts
Two of you will be selected to deliver the consenting with our community volunteers
Use teach-back method or questions methods using the portions of the consent form.
Break for Live Demo
Documentation of Informed Consent
Who Signs the Consent?

*Signature/Date* required from the subject AND the person obtaining consent

- Generally speaking the dates should be the same. If they aren’t, document why

ICH GCP does not require specifically for the investigator to sign the informed consent; could be a designated individual

But the Protocol or the IRB may require the investigator to sign

Copy of the ICF, provided to the patient, does not have to be a signed copy
Documentation of Consent

- Make sure all checkboxes *are completed*
- DON’T sign or date the consent for the subject
- DON’T white out, cross out or otherwise change any part of the approved consent form
- Any *revisions* must be submitted to the IRB as an amendment and approved prior to implementation
- Make sure to *provide the subject with a copy* of the entire consent
  
  If the subject refuses to accept the Form, document the offer
- Keep *the original* of the entire consent, not just the signature page
Documentation of Consent

• Document the *process* (relevant sequence of actions) in the progress note/case history
  • Who?
  • What?
  • Questions raised & answers given
• *Time given to review* document (not an FDA requirement, but highly recommended) - to document that consent process was not rushed
  • Subject understanding
  • Agreement to participation
  • Date/Sign

[Handouts – Consent Process Checklist & Ophthalmology op note]
Witnesses to IC

When witness may be required:

- OHRP & FDA: only when presented orally and short form is used
- ICH: presented orally; subject or LAR is unable to read

Sponsors provide guidance as to whether a witness signature line is mandatory or optional - should be *in protocol*

Witness should be...

- Someone *unaffiliated* with the research
- Who *cannot be unfairly influenced* by people involved in the trial
- Who *attends the informed consent process* & reads the informed consent document
Consent Documentation AFTER Subject Withdraws from the Study

*Data prior to withdrawal* - remain a part of the study records, no limitation on access

At the point of withdrawal from *interventional portion*:

- Inquire whether the subject will consent to continued follow up and data collection
- **If yes**, new, limited Informed Consent may be required
- **If no**, then PI may not further access the clinical data

Re-consent maybe required with *new long-term safety/toxicity data*

[Handout: FDA Guidance “Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials”]
Need to Re-consent

Study participation is ongoing and
- Minor Subject reaches age 18
- Subject regains competency

New study information
- Substantial Amendments
  - Changes in study procedures
  - Changes in risk
  - Changes in subject payment
  - New treatment became available

The FDA does not require re-consenting of subject who completed their active participation in the study
[Handout – ICH Guideline E-6 4.8.2]
Conclusions

Informed Consent is *not just form, and not just a signature!*

It is a *Process* that occurs with each interaction with subjects

*Documentation* is critical!

*Synchronized* with other essential documents

It’s our professional responsibility to the subjects.
Questions?

- Contact: Denise Owensby, Sr CRC,
- Clinical Trials Resource Group, CTSC
- denise.owensby@ucdmc.ucdavis.edu
The End!

Please fill out the exit survey and get your certificates of completion