Informed Consent

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Poll

Have you, personally, asked people for informed consent to participate in research?

A. Yes
B. No
Poll
Who handles informed consent at your institution?

A. Lead investigator
B. Other investigator
C. Clinical research coordinator
D. Research assistant
E. Other

20% 20% 20% 20% 20%
Participating in Research: Clinical Trials

(https://youtu.be/5VCW31AnEpI?list=PLrl7E8KABz1Ex7n0cjhxVgGDDF7xWHpF1)
Discussion

- What is the function of the informed consent process?

- What is the role of the person asking for consent?

- What are some of the issues with and obstacles to the informed consent process?
Poll
Have you ever been asked for your consent to participate in a research study?

A. Yes
B. No
Discussion

- Describe your experience (or the experience of those whom you know well).

- What did you look for? What made you decide to participate (or not)?

- Were there things that could have been done differently that might have impacted your decision about whether to participate?
THE HHS REGULATIONS ON INFORMED CONSENT IN RESEARCH
Ethical Principles

- Respect for persons
  - Promote autonomy

- Beneficence
  - Maximize benefits, minimize harms

- Justice
  - Ensure equitable distribution of burdens & benefits
Framework of Shared Responsibilities

**Regulations** → Provide a framework that guides action

**Institutions** → Provide assurance to promote ethical research and regulatory compliance

**IRBs** → Balance protection of research subjects & public good of research

**Investigators** → Respect individuals’ autonomy & ensure protections
Significance of Informed Consent

- Demonstrates respect for persons
  - Individuals make autonomous, informed decisions about participation

- Subjects’ Part in Protection
  - Individuals make decisions about the risks that are acceptable to them
    - Heightens their awareness if and when risks become reality
Regulatory Requirement for Informed Consent

No investigator may involve a human being as a subject in research...unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

§46.116
Legally Effective Informed Consent

Who is the “human subject”?
Living individual about whom an investigator obtains:
1. Data through intervention or interaction with the individual, or
2. Identifiable private information §46.102(f)

Who provides consent?
The subject or their legally authorized representative (LAR)
- Local laws
- Parental permission/child assent

Obtain & document (unless waived)
Informed Consent Process

- Understandable information
- Opportunity to consider
- Minimize coercion and undue influence
- No exculpatory language
  - Generally considered as language that has the effect of freeing an individual/entity from malpractice, negligence, blame, fault, or guilt

Coercion and Undue Influence

- **Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.

- **Undue influence** ... occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance.

  The Belmont Report, 1979
Required Elements of Informed Consent

1) Research Description
   - Purpose
   - Duration
   - All research procedures
     • Identify experimental procedures, if any

2) Risks, discomforts

3) Benefits, if any

4) Alternatives, if any

5) Confidentiality

6) Compensation for injury

7) Whom to contact

8) Voluntariness and right to refuse or withdraw without penalty

§46.116(a)
Additional Elements (As Appropriate)

1) Statement about unforeseeable risks
2) When investigator may terminate subject participation
3) Potential costs to the subject
4) Consequences of withdrawal
5) Sharing of significant new findings
6) Approximate numbers of subjects

§46.116(b)
Informed Decision Making

Key factors:

- Information
- Voluntariness
- Comprehension
Information

“The study involves research”

Be clear and help subjects understand:

- What the study is about
  - They decide if they share an interest

- What the study entails
  - They decide whether the risks/benefits of participation are acceptable to them
Voluntariness

A statement indicating:

- Participation is voluntary
- Refusal to participate will not incur penalty/loss of benefits
- Participation may be discontinued at any time without penalty/loss of benefits
Comprehension

Information must be understandable for potential subjects.

- Lay language
  - No scientific jargon or legalese
- Revise when needed

*Think of it as a teaching tool, not a legal instrument!*
Communication: Providing Context

Consent 1 – Risks/Side effects

<table>
<thead>
<tr>
<th>Neurological</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Chronic nerve damage</td>
</tr>
<tr>
<td>□ Peripheral nerve damage</td>
</tr>
<tr>
<td>□ Psychological intolerance (fear of loss of LAP monitoring function)</td>
</tr>
<tr>
<td>□ Stroke/transient ischemic attack</td>
</tr>
<tr>
<td>□ Subdural, epidural hematoma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiac</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Acute coronary syndrome (sudden worsening of chest pain, heaviness or pressure)</td>
</tr>
<tr>
<td>□ Arrhythmias (irregular heart rhythm)</td>
</tr>
<tr>
<td>□ Acceleration of arrhythmia (make irregular heart rhythm go faster)</td>
</tr>
<tr>
<td>□ Atrial septal defect (hole in the tissue between upper chambers of the heart)</td>
</tr>
<tr>
<td>□ Cardiac arrest</td>
</tr>
<tr>
<td>□ Cardiac perforation</td>
</tr>
<tr>
<td>□ Cardiac tamponade</td>
</tr>
<tr>
<td>□ Damage to heart valves</td>
</tr>
<tr>
<td>□ Emergency heart surgery</td>
</tr>
<tr>
<td>□ Emergency vascular surgery</td>
</tr>
<tr>
<td>□ Low cardiac output state</td>
</tr>
<tr>
<td>□ Heart block</td>
</tr>
<tr>
<td>□ Hypotension</td>
</tr>
</tbody>
</table>

Consent 2 – Risks/Side effects

Those more **likely to occur** include:

- Nausea and or vomiting following drug injection. You will be monitored for 12 hrs following the injection, should any of these effects occur, we will examine you and give you appropriate medical care.

Those **less likely to occur but are serious** include:

- Hypoglycemia (low blood sugar) during testing days. You will be monitored during your testing. If symptoms such as …. occur, we will measure your blood sugar and if it is low, we will stop the test and give you juice or candy and retest your blood sugar.

- Serious allergic reaction to the drug. If this happens, the study regimen will be stopped and you will receive the appropriate treatment and management.
Process of Informed Consent

- Continuous engagement
- Respect for the rights & welfare of research subjects

It’s not just a form!
Participating in Research: What is research?

(https://youtu.be/4pLsHhP7yTw?list=PLrl7E8KABz1Ex7n0cjhxVgGDDF7xWHpF1)
BREAK!
INFORMED CONSENT UNDER THE REVISED COMMON RULE
SUMMARY OF MAJOR CHANGES
Goal of Changes to Informed Consent: Promoting Autonomy

Changes are intended to make informed consent more meaningful so that research subjects will have the necessary information to make informed decisions.
General Improvements (1)

The revised Common Rule explicitly establishes a new standard: to provide the information needed to make an informed decision about whether to participate.

§ 116(a)(4)
General Improvements (2)

- The revised Common Rule has a new requirement that certain key information must be provided first.
- That first section must provide a *concise and focused* presentation of *key information* regarding why one might or might not want to participate.

§__116(a)(5)(i)
General Improvements (3)

Information presented in **sufficient detail**, and organized **and presented** in a way that facilitates subject’s understanding of reasons why one might or might not want to participate

- Not merely provide lists of **isolated facts**

§__116(a)(5)(ii)
Additional Changes

- One new required element of informed consent (§116(b)(9))
- Three new additional elements of informed consent (§116(c)(7)-(9))
- New requirement to post clinical trial informed consent form on a publically available website (§116(h))
New OHRP Resource: About Research Participation

- Link: https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html
Contact OHRP

- Website: [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)
- Email: ohrp@hhs.gov
- Phone: (240) 453-6900
  (866) 447-4777

- Join OHRP’s ListServ for Event Updates:
QUESTIONS?
Thank you!