

The Informed Consent Process

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Overview

- Evolution of informed consent
- Two senses of informed consent
- Process of informed consent
- Relevant regulations



The Evolution of Consent

For Medical Treatment

- Patient litigation
- Laws and regulations

For Research

- Early consent practices
- Infamous research



Medical Treatment and The Right to Liberty

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages.” *Schloendorff*



Early Consent Practices for Research

- Recognized as important for research with volunteers
- Not necessarily free and voluntary



Yellow Fever Experiments

- ❑ Conducted in Cuba following the Spanish-American War
- ❑ Written consent in English and Spanish
- ❑ Consent was witnessed



Yellow Fever Experiments

Ethical Difficulties

- ❑ Excessive compensation
- ❑ No ability to withdraw



Infamous Research

- ❑ Tuskegee Syphilis Study
- ❑ Nazi experiments
- ❑ Deception research
- ❑ Jewish Chronic Disease Hospital
- ❑ Human radiation experiments



Human Radiation Experiments

- ❑ Thousands of experiments conducted during the Cold War
- ❑ Most conducted without informed consent
- ❑ Researchers sought to minimize risks
- ❑ Consistent with the norms at the time, physicians decided about enrolling their patients in research



Overview

- Evolution of informed consent
- Two senses of informed consent
 - Autonomous authorization
 - Social rules of consent
- Process of consent
- Relevant regulations



Two Senses of Informed Consent

- Autonomous authorization
- Social rules of consent



Autonomous Authorization

- Ethical principle of respect for persons
- Right to liberty



Two Senses of Informed Consent

- Autonomous authorization
- Social rules of consent



Social Rules

- Consent of minors
- Special forms
- Witnesses



Overview

- Evolution of informed consent
- Two senses of informed consent
- Process of informed consent: Beyond consent forms
- Relevant regulations



Informed Consent Process

Threshold

- **Decision-making capacity**



Informed Consent Process

Threshold

- **Decision-making capacity**
- **Voluntariness**



Informed Consent Process

Information

- Disclosure

Threshold

- Decision-making capacity
- Voluntariness



Informed Consent Process

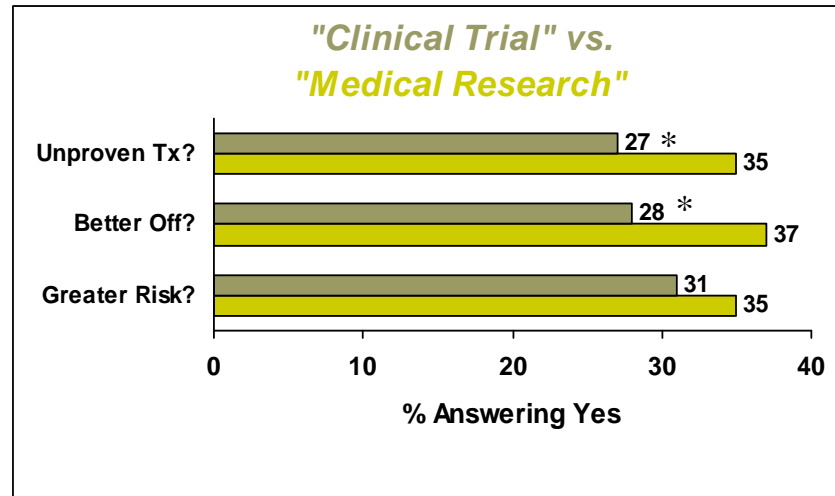
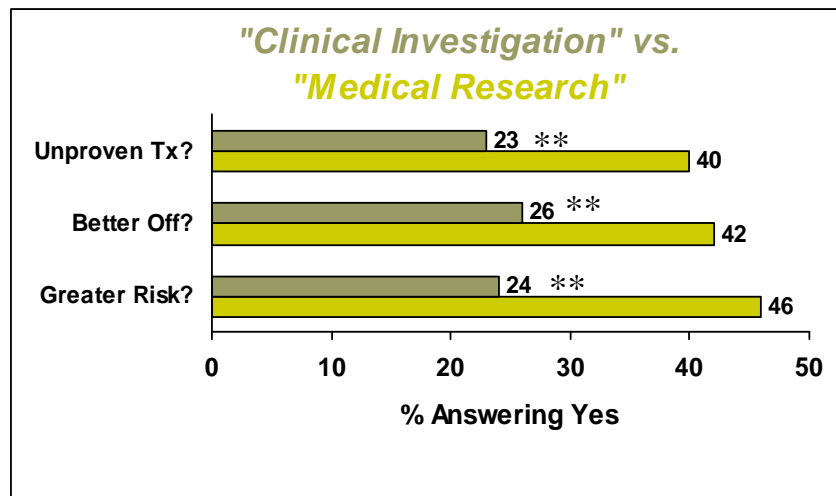
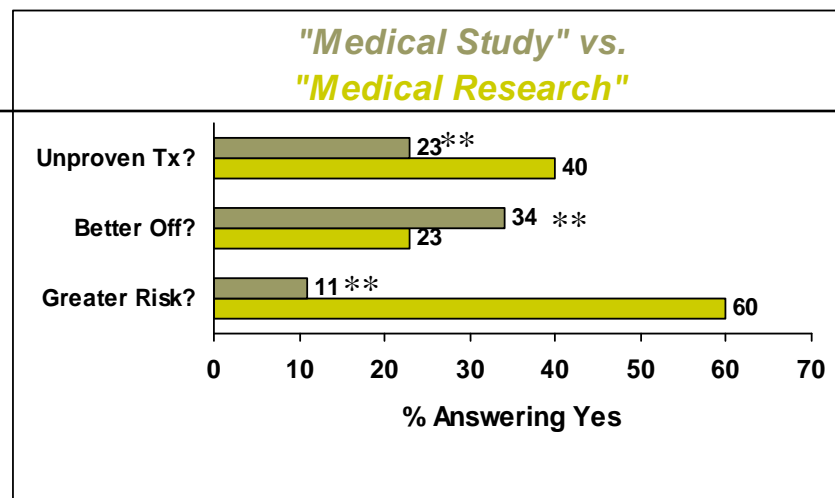
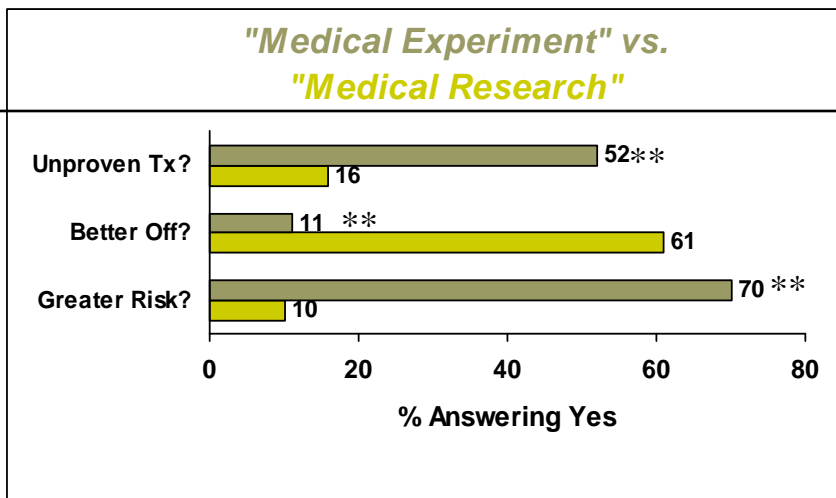
Information

- **Disclosure**
- **Understanding**

Threshold

- **Decision-making capacity**
- **Voluntariness**

How do patients understand terminology?



Slide courtesy of Dan Nelson

Sugarman, et al, IRB 20:1-7, 1998



Informed Consent Process

Information

- Disclosure
- Understanding

Threshold

- Decision-making capacity
- Voluntariness

Authorization

- Indication of agreement
- Consent forms:
 - Consistent with disclosure
 - Readable



Overview

- Evolution of informed consent
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- Relevant regulations
 - 45 CFR 46, Parts 116 & 117



Relevant Regulations

45 *CFR* 46

Part .116 - Requirements for consent

- Required elements to be disclosed
- Conditions for waiver of elements of consent

Part .117 - Documentation

- Requirements for documentation of consent
- Conditions for waiver of documentation of consent



Required Elements of Consent

- Nature of the proposed intervention:
 - purpose of the research
 - duration of participation
 - procedures to be followed
 - procedures which are experimental



Required Elements of Consent

- Nature of the proposed intervention:
 - purpose of the research
 - duration of participation
 - procedures to be followed
 - procedures which are experimental
- Potential risks and benefits
- Alternative procedures
- Protection of confidentiality



Required Elements of Consent

- For research involving greater than minimal risk: compensation and treatment, if any, for possible injury
- Contact information
- Assurance that participation is voluntary



Additional Elements Where Appropriate

- Unforeseeable risks
- Termination of participation
- Costs to subjects
- Consequences of withdrawal
- New findings
- Number of subjects



Conditions for Waiver of Required Elements

1. Minimal risk;
2. Would not adversely affect the rights and welfare of the subjects;
3. Could not be practicably carried out without the waiver; AND
4. Subjects provided with additional information after participation.



Requirements for Documentation

- Written consent
 - embodies required elements
 - signed by the subject or the subject's legally authorized representative
- Short form
 - states the required elements have been presented orally
 - witness needed
 - IRB approves summary signed by witness
 - copy of short form and summary to subject



Conditions for Waiver of Documentation

1. The only record linking the subject to research would be the consent document, and the principal risk relates to breach of confidentiality;



Conditions for Waiver of Documentation

1. The only record linking the subject to research would be the consent document, and the principal risk relates to breach of confidentiality;

Or,

2. No more than minimal risk and involves no procedures for which consent is required outside of the research context.



Summary

- *Respect for persons* is manifest in the expectations of a meaningful informed consent process
- US regulations emphasize need for *written informed consent* and the *elements to be included* in the consent process, but not the process itself
- When aimed at enhancing protection of subjects, *modifications* to the informed consent process *can be authorized* by the IRB