Informed Consent: Friend or Foe?

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Overview

• Academic Medical Center (AMC) Perspectives on Consent
• The Evolving Consent
• The Future of Informed Consent
• Questions
AMC Perspectives on Consent

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AMC Perspectives on Consent

• Three key departments inform most academic medical centers’ review of consent:
  – Contracts Office
  – IRB (Human Subjects Protection Office)
  – Billing/Financial Compliance/Budgeting Office
  – [Clinical Department/Researcher]
AMC Perspectives on Consent

• Contracts Office
  – Negotiates contracts for research between industry or other sponsor and the AMC (“CTAs”)
  – Must ensure compliance with laws, regulations, and policies
  – May be charged with ensuring informed consent document subject injury terms are consistent with terms of the CTA
AMC Perspectives on Consent

• Contracts Office: Main Objectives
  – Minimize risk to the AMC
    • Indemnification
    • Insurance
  – Ensure adequate protection for Study participants
    • Subject injury protections secured in CTA
    • Institutional policy, in part, dictates requirements
    • Distinct from indemnification or insurance in that this is a “third party” benefit the AMC secures for research participants
AMC Perspectives on Consent

• What does Subject Injury mean in the CTA?
  – Legally binding obligation of sponsor to the AMC to pay for certain costs for diagnosis and treatment of study-related injuries
  – Informed Consent Form subject injury section presents, in lay terms, to the participant, what reimbursement might be available for treatment of injuries or illness arising out of the study
  – third-party benefit in the CTA, and not directly related to indemnification or insurance
AMC Perspectives on Consent

• Limitations on Subject Injury Reimbursement
  – AMC’s negligence
  – Natural progression of underlying illness
  – AMC’s failure to follow the protocol
  – Limited to care costs – NOT time off work, damages, etc...
  – Study participant’s failure to follow the investigator’s instructions [?]
  – Reimbursed by Insurance [?]
AMC Perspectives on Consent

• Why does the AMC worry about subject injury reimbursement?
  – Shields subjects and AMC from possibly paying in certain circumstances where a subject’s insurance won’t pay
  – Engenders trust between AMC and research subjects
  – It is an ethically sound requirement
    • It gives study subjects some additional protection in exchange for the risk they may take by enrolling in a study
AMC Perspectives on Consent

• Billing/Financial Compliance/Budgeting Office
  – Protocol and informed consent form review to determine if study is a Medicare Qualifying Trial
    • Leads to accurate billing coding
    • Consistent with applicable federal regulations and guidance
  – Ensure informed consent form accurately reflects the protocol procedures and study budget
  – Reviews subject injury language
  – HIPAA language includes project sites
AMC Perspectives on Consent

• IRB
  – Ensures informed consent form is consistent with applicable federal and state regulations, as well as institutional policies
    • Common Rule
    • FDA/HHS regulations
  – Regulations follow principles found in Belmont Report
    • Respect for Persons, Beneficence, and Justice
  – Declaration of Helsinki
    • Risk not to exceed benefits
    • Principle of informed consent
    • Research review by independent committee prior to beginning
The Evolving Consent

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The Consent: Guiding Principle

• The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

21 Code of Federal Regulations 50
Essential Components of Consent per Federal Guidelines

1. Research purpose and procedures
2. Risk and discomforts
3. Potential Benefits
4. Alternative procedures or treatments
5. Provisions for confidentiality
6. Management of research-related injury
7. Contacts for additional information
8. Voluntary participation and right to discontinue participation without penalty
Additional Consent Essentials When Appropriate

1. Unforeseeable risks
2. Termination of participation by the investigator
3. Additional costs
4. Consequences of discontinuing research participation
5. Notification of significant new findings
6. Approximate number of subjects
A Look Back

• In the 1970’s the average consent was less than a page in length and was typically one to two paragraphs
• Over the last few decades, consent documents have progressively increased in length
• The risk section of the consent has significantly increased in size and complexity

Albala, et al 2010
The Current Consent

• Sharp et al assessed Oncology trial consents and found that none of the consents were below an 8th grade reading level and only 10.5% were below the 10th grade level in 2004

• Consents are becoming more like legal documents to protect from civil litigation, when the consent is to be a communication tool

• The time required to read the consent documents is increasing and it has been suggested that potential subjects are most likely not reading the document in its entirety

Sharp, 2004
The Consent Process

• Even though the trend is that consent documents are continually becoming longer, there are still times when consents are missing important information
  – Per SACHRP recommendation, agencies such as FDA and OHRP should be careful to limit their citation letters to instances where the intent of the regulations was clearly not met, rather than minor oversights.

• Potential subjects listen to what is being told to them verbally during the informed consent process more than what is written in the consent document

• The process is what is important; communication

  Berger, et al 2009
The Future of Informed Consent

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Major Game Changers

- The Federal Agencies
- Technology, Technology, Technology
Federal Agencies

• OHRP announces in fall, 2011, a proposal to change the regulations
• “Many consent forms are too long and hard to understand, and fail to include some of the most important information.”
• Proposal: More specifics for how CFs should be written and what they should contain.
• Goal: shorter, easier to understand, less confusing
Federal Agencies

SACHRP Recommendations:

• Greater focus on the *process*, rather than form
• More use of verbal consent or short form consent
• Less content in main consent; more use of appendices
• Harmonize HIPAA, FDA, and Common Rule
Technology
• Some existing technology which could be used to enhance the informed consent process...
Podcasts
A PI explains the study on a digital player for playback to potential participants
Embedded comments in consent forms
Various procedures in an online consent form have a link to a recorded explanation.
Videos
Can be used to illustrate certain procedures described in the written consent form such as an MRI, drug infusion, device placement, etc.
Interactive Websites
An interactive experience gives the participant the ability to explore in more detail, the study procedures of concern to them.
Electronic Consent

Participants can electronically sign a consent form (like a credit card). The signed consent can be stored in the medical record and emailed to the subject. No more “lost” consent forms.
Just released...

• **Mytus** rolls out first patient-friendly system for informed consent via i-Pad application
• 76% who were consented with the application passed a comprehension quiz versus 54% who consented using traditional paper form
• Claims to shorten time to enrollment and ensure consistent patient education & comprehension
**Systemedicus** has developed a patent pending eConsent platform.

- It **video records** the entire consent process and **records** the page turns as the subject reviews the consent document.
- The subject is shown multi-media content to enhance comprehension and retention.
• An interactive quiz will assess the subject’s understanding and awareness of the materials
• Using facial recognition technology along with a magstripe identity card and signature capture, the subject will authenticate their consent
Questions to Consider

• Will this reduce litigation?
• Does this technology protect the researcher or the patient?
• Does it actually increase confidentiality risks?
• Will this reduce participation?

Too soon to tell...
Questions?
Thank you!
References


