

# Informed Consent

## ... how do you know?

CAMH Brown Bag  
Research Discussion Groups  
Friday Feb 11, 2011      12:00 – 1:00 pm



**Michelle Nash** MSc, HonBSc  
Transplant Research Manager  
St. Michael's Hospital  
Toronto, Ontario, Canada

# Audience Survey

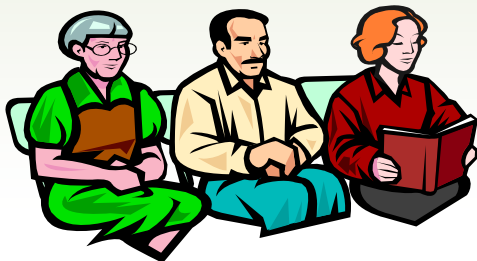
- How many people are involved with obtaining informed consent for research?
- How many people use a tool to help determine consent comprehension?

# Overview

- Informed consent process
- Barriers to informed consent process
- Tools:
  - Consent questionnaire
  - Fact sheet
  - Consent process checklist
  - Consent form summary
  - Telephone logs
- Hazards
- Mistakes to prevent

# Why do patients do research?

- Altruism
- Potential direct benefit
- Social interaction
- More attentive follow-up
- Feel pressured
- Feel like they owe a debt
- Feel quality of care may decrease if they say no
- Wanting to please the physician

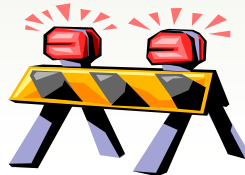


# Consent Process Elements

- provide information
- assess comprehension
- ensure voluntary nature understood
- documentation

# Consent Barriers

- Literacy
- Language
- Culture
- Age
- Vision
- Medications
- Time constraints
- Anxiety
- Illness
- Environment
- Relationships
- Length of consent form



# Dealing with Barriers

- Time
- Planning and Anticipating
- Consent Questionnaire

# Consent Questionnaire

## Introduction

- Created back in 1996
- New Research Coordinator
- Recruiting in the ER 24 hours a day
- Stressful environment
- Time constraints

# Consent Questionnaire

## PURPOSE

- To ensure that the patient has read the consent form
- To find out about language and literacy barriers
- To provide an opportunity to re-emphasize key study points
- To satisfy regulatory requirements

# Consent Questionnaire 'Risks'

- More patients may refuse to participate in the study
- Patients may be deemed ineligible even after signing the consent form

# Consent Questionnaire 'Benefits'

- Prompts patients to ask more questions
- Increases compliance with protocol mandated activities
- Decreases patient drop-out rate

# Reasons Questions Not Asked

- Do not know what questions to ask
- Do not want to offend the person obtaining consent nor appear to be challenging their authority
- Feel foolish for not having understood
- Completely trust the investigator and delegate the decision-making authority

# Consent Questionnaire

# Examples of CQ usefulness

- Patient hands you a consent form already signed and says they have no questions
  - No way of knowing whether or not the patient has read the ICF
  - Numerous times I've discovered patient's either have skimmed the ICF or have not read it (no glasses with them, don't feel like, have difficulty reading English)
- Potential language barrier, illness or comprehension barriers
  - If the patient can answer the questions on the CQ, it let's the research team know that they have sufficiently understood the ICF

# Examples of CQ usefulness

- In the study specific questions:
  - you realize that a patient thought they could choose which study group they were going to be assigned to
  - they thought they would know which group they would be in for a blinded trial

# Fact Sheet

# COMMENTS



The only way to get credit for the  
good work that you do is to...

**DOCUMENT**

**DOCUMENT**

**DOCUMENT**

Your consent process must be able to be demonstrated on  
an audit that could take place 15-25 years after consent  
has been given.

# Consent Process Checklist

# Consent Form Summary

# Telephone Log

# Shared Responsibilities

- **Site Research Staff**
- **Clinical Investigators**
- **Research Ethics Boards**
- **Sponsors / Monitors / CRO's**
- **Regulatory Agencies**

# Successful research involves

- **Planning**
  - **Coordination**
  - **Documentation**
  - **Team work**
  - **Communication**
  - **Transparency**
  - **Continuous attention to detail**
  - **Trouble shooting**
  - **Prompt responses to problems once identified**
  - **Plans to prevent similar problems from occurring in the future**
- ...and more

# HAZARDS

- Inadequate staffing
- Fatigue or burnout
- Poor communication
- Lack of oversight
- Large numbers of participants
- Lack of audit potential
- Monitoring 'light'
- Inadequate training
- Persuasive patients

...in very rare cases - fraud



# Mistakes to Avoid

1) Failure to obtain consent prior to starting a study

**Risk:** screening procedures, wash-out periods

**Tip:** know your protocol

2) Using the wrong version of the ICF or implementing a protocol amendment test or procedure without re-consent

**Risk:** multiple amendments; time delay between provided the ICF and signatures; high volume studies and multiple staff – easy to make an error

**Tip:** consent form summary

# Mistakes to Avoid

3) Failure to maintain proper records including the original consent document and documentation of the consent process

**Risk:** fast recruiting studies, poorly organized files, behind on filing

**Tip:** scan ICF into secure electronic files, keep extra printed copy in source documents, use consent process form and telephone logs for documentation

# Questions for You...

**What is your consent process?**

**Is your patient population vulnerable?**

**What are barriers specific to your group of patients?**

**25 years from now, would an auditor be able to see what your consent process was?**

# Take Home Points

- Use forms – they help!
- Develop forms that address your needs
- Try to anticipate problem areas and come up with a solution before the problem snowballs out of control



# TRAINING \* DISCIPLINE \* DOCUMENTATION

*We get a dress rehearsal every day to practice our precision and accuracy in preparation for the day when it really counts and there are consequences!*

# Contact Info

- **Michelle Nash** MSc, HonBSc
  - Transplant Research Manager
  - St. Michael's Hospital, Toronto, Ontario, Canada
  - [nashm@smh.ca](mailto:nashm@smh.ca)
  - 416-867-3692