Patient Engagement Council

Webinar 2:

Informed Consent

October 2014

Funding for PORTAL was provided by the Patient-Centered Outcomes Research Institute (PCORI), grant number CDRN-1306-04681. Principal Investigator: Elizabeth McGlynn, PhD, Vice President, Kaiser Permanente Research.

This toolkit was developed in full partnership with the PORTAL Patient Engagement Council (PEC) patient stakeholders. These materials may be used to help engage patients as research partners. The PEC is no longer a funded or active group. If you would like to reach out to one of the PEC members to engage them in a future project, please email Carmit McMullen, PhD, Senior Investigator, Kaiser Permanente Center for Health Research: Carmit.McMullen@kpchr.org.
Outline of Webinar

• Recap of last month's webinar
• How is research regulated?
  • What is an IRB?
  • What is informed consent?
  • Elements of informed consent
• Informed consent in different types research
• PEC input:
  • What do patients need to know about participating in different types of research?
  • What is the best way to obtain informed consent?
  • When might written informed consent not be necessary?
PORTAL is building capacity to do research

In our last two meetings, we talked about what matters most to patients regarding research; and

This month we'll talk about how we conduct research, and

How we protect participants in research
Have you had any experience with research?
(participant, research team, etc.)

Have you ever given informed consent to participate in research?
### What is an IRB?

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<th><strong>Who:</strong></th>
<th>IRB (Institutional Review Board; AKA Committee for the Protection of Human Subjects) includes researchers, lawyers, physicians, community members...</th>
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<tr>
<td><strong>What:</strong></td>
<td>The IRB protects the rights and welfare of research participants and supports the institution's research mission.</td>
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<td><strong>How:</strong></td>
<td>Through ongoing review of research protocols and related materials, the main objective of the IRB is to protect human subjects from physical and psychological harm.</td>
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<td><strong>Why:</strong></td>
<td>Prior to IRBs, research studies did not need approval from any review board, research participants were not protected against unethical experiments like the Tuskegee Study, in which researchers enrolled African American male participants with syphilis to observe the natural history of the disease. Participants were not treated with penicillin after it became available.</td>
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Federal regulations allow for **some** studies to be exempt from IRB review

- Quality Improvement projects (Not considered research)
- Observation of public behavior, if subjects **cannot** be identified, directly or through identifiers linked to the subjects
- Some research involving the analysis of existing data, documents, records, pathological specimens or diagnostic specimens, if subjects **cannot** be identified, directly or through identifiers linked to the subjects
What is Informed Consent?

• A process that has 3 key features:
  • Provides potential research participants with sufficient information about a study to help them make an informed decision on whether or not to participate in the study
  • Facilitates understanding of information needed to make informed decision
  • Promotes idea that participation in research is voluntary
Informed Consent Process

- Discussion should be in language that participant can understand
  - Language - 6th grade reading level
  - With prior IRB permission, non-English speaking person may be presented with this information verbally
- Participants should be given opportunity to ask questions/receive answers
Basic Elements of Informed Consent

- Research
  - Purpose
  - Duration
  - Procedures
- Risks, discomforts
- Benefits
- Alternatives
- Confidentiality
- Costs/payment
- Compensation for injury

- Whom to contact about the research, subject’s rights, in the event of research related injury
- Participation is voluntary
- Right to refuse, withdrawal without penalty
Obtaining a signature on a consent form is just one step. Informed Consent is an ongoing educational PROCESS.
Informed consent can sometimes be waived

• In a research study:
  • That involves no more than minimal risk to the participants
  • When waiving does not adversely affect the rights and welfare of the participants
  • When study cannot be carried out with informed consent (for example data-only study)
Implications for Informed Consent in different types of studies

- Traditional Clinical Trials
- Pragmatic Clinical Trials
- Observational Studies
PCORI Pragmatic Study: Aspirin Trial

- Background: Aspirin has been shown to be an effective therapy to prevent negative outcomes from coronary artery disease (such as stroke, heart attack); yet little is known about which dose of aspirin (81mg or 325mg) is the most effective with the least side effects.

- To definitively answer this question, PCORI is designing a large randomized pragmatic trial to determine what is the long-term dose of aspirin that is both safe and effective for the general population of patients with coronary artery disease.
As this study is being designed, PEC members can provide important feedback to PCORI.

Imagine that large numbers of patients with a history of coronary artery disease (including MI or bypass surgery) will be randomized to receive either high-dose (325 mg) vs. low-dose (81 mg) aspirin to find out which has better outcomes with fewer side effects.

What kind of informed consent process do you think would be needed to participate in this study?

- Notification only?
- Written consent? Verbal consent
- In person vs online?

Would you be willing to answer 1-2 questions at the end of the consent process so that researchers can find out whether patients understand the trial's purpose and major details?
What are your thoughts about this script?

<table>
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<th>Suggested Script for Disclosing Randomization in a Pragmatic, Randomized Clinical Trial.*</th>
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| “[As we’ve talked about, you have high blood pressure. . . . We’ve already tried exercise and diet, and unfortunately they have not worked. . . . I can treat you with drug A or drug B. They’re both approved by the Food and Drug Administration, and I commonly use either one of them in patients to control high blood pressure; they are both taken once a day and they have similar side effects, which are . . . ]

But honestly, we doctors really don’t know if one is better than the other. So our hospital is doing a study by randomly (like a flip of a coin, so that we can obtain an unbiased answer) giving patients one or the other drug and then comparing results over a period of 1 year. You might remember that ours is a learning health care system and this means that we do the study as part of providing care, so there won’t be any special procedures or visits. And if at any point you or I think it would be good to try another medication instead, we can do that. So unless you have a preference for drug A or B, I’d like to include you in the study.

[Do you have any questions?]” |

* Kim and Miller NEJM 2014
Basic Elements of Informed Consent

- Research
  - Purpose
  - Duration
  - Procedures
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Questions for the PEC

What do patients need to know about participating in different types of research?
--- Observational study? Traditional clinical trial? Pragmatic clinical trial?

How would you prefer to obtain all of the necessary information on a study and give consent?
--- Online? Written brochures? Conversation with researcher or provider?

What are your ideas on how to ensure participants truly understand studies?
Questions?
November Webinar

Topic of Discussion:

Privacy Training