From Clinical Consent to Research Consent

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Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.
Examples of Types of Research Studies

- Study having subjects read text, then answer questions (psychology)
- Normal controls in an interventional trial (e.g., exposing them to unapproved drug)
- Natural history trial that collects data on what happens to subjects with illness
- Note: Getting consent for many studies (such as these) may not be that complicated
“Treatment” Clinical Trials

- Clinical decision-making is often complicated
- Some clinical trials involve providing subjects, who have a medical problem, with possible treatments
- Decision to enroll in such a trial is like a clinical decision, but perhaps even more complicated
- Additional complications relate to greater uncertainty about efficacy and risks of treatments, and treatment selection via randomization
“Treatment” Clinical Trials

- In many ways, revisions to consent regulations are designed to treat consent to such trials as similar to clinical consent.
- Already a great deal of learning about how to make complicated clinical decisions.
- We can use that knowledge to improve research consent.
- Biggest area of impact from consent changes.
Learning from Clinical Decision-making

- Can look to practices that are common in making complicated clinical decisions:
  - Explaining the advantages and disadvantages of one treatment versus another: putting it all together to help understanding
  - How often does doctor give you long lists of side effects (such as FDA labeling information)?
Intent of Revised Common Rule

- Highlight that person has a choice to make
- Highlight how depending on person’s goals, either participating or not may be better choice
- *Ask yourself:* how often do consent forms currently spell out reasons why participating might not be your best choice?
Intent of Revised Common Rule

- Goal: consent form as decision aid, not just risk disclosures (compare to drug ads on TV – many risks, nothing about alternatives)
- Form should be written in a way to help make a good decision
Specific changes in regulations

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)
Specific changes in regulations

*Reasonable person* standard used to determine more specifically what information to include

- Long used for clinical informed consent
- Considered most consistent with ethical principles

§__.116(a)(4)
What is Reasonable Person Standard?

- Origin in tort law: standards of care we owe each other (e.g., shoveling snow off sidewalk)
What is Reasonable Person Standard?

- When care providers are members of profession, they have expert knowledge
- They are empowered to set legal standard for fellow members of profession
- Ex: how to remove appendix
What is Reasonable Person Standard?

- Apply that to informed consent – doctors would determine disclosures
- Is that outcome consistent with rationale for allowing members of profession to set standards?
What is Reasonable Person Standard?

- Issue: should risk of paralysis after back surgery be disclosed?
What is Reasonable Person Standard?

- Court created new “reasonable person” standard, to be used instead of “professional” standard
- Viewed as more ethical standard (though many states still use prof. standard)
Example

- Based on *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996)
- Patient had brain aneurysm in hard-to-treat location
Example

- Surgery done by doctor with limited experience, patient became quadriplegic
- She was not told about surgeon’s limited experience and how it affected risks
Example

- Consent issue: would reasonable person have found information about surgeon’s experience material?
Specific changes in regulations

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 a list of isolated facts*

   § 116(a)(5)(ii)
Sufficient detail

- Consent forms commonly criticized for often failing to provide specific information about the research study.
- E.g., benefits discussion that merely says “you may or may not benefit”
- Instead, can give some specific information about type of benefit (cure disease, remediate symptoms) and likelihood
Facilitates understanding; not merely lists

- Note common practice of consent forms having separate benefits, risks, alternative sections – isolated pieces of information, without explanation putting it together

- Goal of new rules is to include that explanation, make it easier to understand
**IF YOU SAY “YES”**

- Your identifiable information and identifiable biospecimens will be stored, used and shared for the kinds of future research described in this broad consent form, without anyone asking your permission for each new study.

- Identifying information may also be removed from your information and biospecimens, allowing them to be used for any future research or other purpose.

**IF YOU SAY “NO”**

- The researchers and institutions identified above will not store, use or share your identifiable information and identifiable biospecimens for the research described in this broad consent form.

- However, identifiers may be removed from your information and biospecimens, allowing them to be used for any future research or other purpose.

- Researchers could come to you again later and ask to store, use and share your identifiable information or biospecimens for research.

**IF YOU DO NOT SAY “YES” OR “NO”**

- If you do not mark “yes” or “no” on this form (if you do not return it, or leave it blank), then it will be the same as if you were never asked to make a choice.

- This means that your identifiable information and identifiable biospecimens may be used for future research if: The researchers ask you to say yes to a specific research study, and you agree; or an IRB allows your identifiable information or identifiable biospecimens to be used in a study that is low risk to you without asking for your consent; or another legal exception applies.
Specific changes in regulations

There is a new requirement that certain *key information* must be provided *first*

§__.116(a)(5)(i)
Why Participate – or Not

That *key information* must be about *why one might or might not want to participate*. It would often include (though not limited to) information about purposes, risks, benefits and alternatives.

§__.116(a)(5)(i)
Concise and Focused

That key information must be provided in a *concise* and *focused* presentation

\[\text{§\__116(a)(5)(i)}\]
Ex: Radiation for Breast Cancer

Should radiation be used for treating breast cancer with 1 to 3 positive nodes?

- Women being treated with radiation and chemo – question is whether to add radiation
- Study randomized women to radiation or not
- Consent form’s entire discussion of why the study was being done: “to find out whether [radiation] treatment after chemotherapy will reduce the risk of breast cancer recurrence and thus help patients to live longer.”
Ex: Radiation for Breast Cancer

In “A Debate on Radiation in Breast Cancer” (http://nyti.ms/2mbqLCg) in the NY Times, Feb 24, 2004, Laurie Tarkan:

- Discusses decision-making *in the clinical context*
- Already know that for women with 4+ positive nodes, adding radiation increased survival
Ex: Radiation for Breast Cancer

- Benefits from adding radiation appeared to become less clear as cancer became more localized.
- “There is no question that if given radiation, these women would further reduce the rate of recurrence by two-thirds, bringing it down to 3 to 5 percent.”
- “But whether that translates into a survival benefit – and how much of one – is not known.”
Ex: Radiation for Breast Cancer

Should the consent form perhaps:

- Include more of this specific information?
- Would a reasonable woman in this circumstance want to know that adding radiation would reduce the likelihood of the cancer recurring by two-thirds (even though unknown whether it extends survival)?
Ex: Radiation for Breast Cancer

Should the consent form perhaps:

- Explain how a woman could use the additional information to make a decision to enroll or not to enroll, based on her values
  - For example, it could point out that a woman who wanted to minimize the chance of the cancer coming back, even at the risk of radiation side effects, and even if it isn’t clear that it increases her survival, should probably not enroll, but instead choose radiation
Ex: Radiation for Breast Cancer

Should the consent form perhaps:

- Also discuss views of a woman who is very concerned about side effects of radiation (such as lymphedema, reduced ability to have breast reconstruction), and who might want to especially avoid that treatment in the absence of clear evidence that it will likely extend her life