It All Starts Here: Obtaining Informed Consent in the Real World

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Discussion Objectives

- The CRP Committee hopes you take away from this discussion:

- How to engage with challenging investigators or family dynamics
- The appropriate use of a short form and interpreter
- Discuss a trial with a newly-diagnosed or distraught patient

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Conflict of Interest Declarations

- Neither Facilitator Has Any Conflicts of Interest Relating to This Presentation

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What Is Informed Consent?

- Legal Requirement Stemming from Historical Abuses
- A Written Document Demonstrating a Patient's Study Participation
- Notation in the Patient's Record Describing the Informed Consent Conversation

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Have I Got the Cure for You!

- Site staff and investigators should never present a study as what the physician 'recommends' – a study is only an option
- No therapeutic benefit should ever be implied

We are guardians of the study's integrity, the investigator's compliance and above all else, patient welfare

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Let Me Break Cancer Research Down to You Like This…

- Informed Consent Forms must be written in a language and at a level a fifth-grader could understand.
- Our conversations with patients should follow suit – keep it simple and human
- These conversations and consents sometimes require the use of non-English speakers and consents

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Family Members Should Not Translate

- Possibility of undue influence
- Likelihood that medical terms may be mistranslated or incompletely explained
- Presents an opportunity for embarrassment to the patient if a family member knows more about their care than the patient would like – such as a minor translating for a parent

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The Dreaded Short Form

- Involves a general statement that the treatment involves research

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Repetition is a Good Thing

- Consider beginning the conversation with “So what did the doctor tell you thus far?”
- Take time-outs during the conversation so the patient or loved one can repeat back the discussion you’ve been having.

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It’s about a Patient, not a Subject

- Accruals take a back seat to sensitivity
- Our patients have cancer
- Sometimes now isn’t the right moment
- Sometimes I’m not the right messenger

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Conclusion

- Questions from Audience
- Answers from Presenter

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References

- 45 CFR 46.116 *General Requirements for Informed Consent*
- 45 CFR 46.117 *Documentation of Informed Consent*
- *Draft 2014 FDA Guidance http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf*

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