Informed Consent

Jim Luecht, CCRP

Inova Schar Cancer Institute, Fairfax VA

Alliance Fall Meeting - 02 November 2016

Discussion Objectives

- For You, As a Newer CRP, to:

- Have a Fuller Sense of What Informed Consent Is
- Hear Best Practices from Other Alliance Sites
- Share Questions You or Your Site May Have

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

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

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

It Is More Than Just a Form

- While the original Informed Consent Form is an essential document of a subject's participation…

Informed Consent is a ***Conversation*** – a Verb, not a Noun

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

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

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Do You…

- Read the ICF page-by page to your patient?
- Review the signed form for completeness?
- Insert a note in your patient's record documenting the consent discussion?
- Give the patient a copy?

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Right Consent, Right Patient, Right Time

- Pre-printing an ICF before the day the patient may sign it can risk having them sign an expired consent
- Be sure to have any separate sub-study consents or release of info documents together with the main ICF.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

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.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

It’s about a Patient, not a Subject

- Accruals take a back seat to sensitivity
- Our patients have cancer

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Conclusion

- Questions from Audience
- Answers from Presenter

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

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*

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY