A Look Into the Consent Process

Presented by the “DRIC Players”

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Please rely on the following case studies and assumptions as the foundation for these extreme scenarios...and ENJOY!

Case Studies & Assumptions
ACME University was awarded a grant by the Oncology Pharmaceuticals, Inc. to support a double-blind study on which Dr. Needbucks would like to serve as the PI, to determine whether a particular compound produced by Oncology Pharmaceuticals, Inc is effective in treating certain forms of breast cancer.

The standard of care for the particular breast cancer at interest is effective. The Investigator feels the study involves greater than minimal risk with unknown potential for direct benefit. No literature related to previous human trials utilizing this compound has been provided to the IRB.

The data collection will include information from the participant’s medical chart. Utilizing a CRF provided by the sponsor, participants are screened solely by Dr. Needbucks. The participants will have a genetic test performed in conjunction with the study, and Dr. Needbucks plans to submit the study data to the Genome Wide Association Studies (GWAS) repository.
Dr. Needbucks Assumptions

- The written consent has been approved by the ACME IRB and is flawless from a regulatory standpoint
- All of the required elements are present
- The informed consent document is written at an 8th grade level
- The ICD is available in all of the languages typically seen at the facility
- Human Subject Protection Education certifications are on file for all study staff & all staff are listed on the application
Dr. Needbucks Summary

- Insufficient/inappropriate time for subject to consider study & ask questions
- No true “process” of providing information necessary for the subject to make an informed decision
- Study offered with limited or no consideration of timeframe following disclosure of diagnosis to patient/subject
- Inadequate training of coordinator who is delegated by PI to obtain consent
And Now for Something Completely Different....
Dr. Dracula Case Study

Dr. Dracula, a pediatrician, has filed an application with the ACME IRB in order to establish a specimen bank. The intent of the study is to collect blood samples prospectively from neonates and their mothers, and to continue to collect additional samples during routinely scheduled visits until the infants have reached the age of 18. The plan is to use the specimens for unspecified future research purposes.

Dr. Dracula plans to obtain the informed consent of the mothers prior to delivery by adding language to the admissions forms. Dr. Dracula’s study is currently self-funded, but word on the street has it that she is seeking funding from other private sources in order to grow the bank.

In addition to the specimens, Dr. Dracula will be prospectively collecting medical record data. She also anticipates releasing identifiable data with the specimens to other researchers if so desired.
Dr. Dracula Assumptions

- The study has been approved by ACME IRB for 12 years
- The ACME IRB has required that the ICD be separate from the admissions form
- All required data sharing agreements are in place
During the consent process with the expectant mother, confusion over age of patient and which consent document (consent v. assent) is appropriate led to the inappropriate consent procedure and the potential for legally ineffective consent.

- Did not obtain assent from child at age of assent (age 7 – 17), as required by the regulations and IRB policies.
Moving Right Along...
Dr. Duwrong, a clinical psychiatrist who maintains a private practice, has submitted an amendment to a study in which she is working with a population of subjects with diminished mental capacity.

The aim of the amendment is to increase the number of subjects in her study by double. She plans to screen the participants on her other open study by reviewing their medical records to determine eligibility. She also plans to include the information obtained in the older study in the new study.

Dr. Duwrong also maintains privileges at Hometown Hospital, where she will screen the entire inpatient population on psych floor 2-SW for potential inclusion, even though not all are her patients.
Dr. Duwrong Assumptions

- The PI obtained approval for a Legally Authorized Representative to consent on behalf of the persons with diminished capacity
- All potential HIPAA violations have been reconciled
Failed to formally reassess the subject’s mental capacity and resultant ability to consent

Failed to respect the subject’s right to autonomy, as indicated by her lucid protests, new information from the nurse regarding the subject’s improved mental capacity, and overhearing a lucid conversation between the LAR and the subject
And In Conclusion...
Extreme Examples: Providing a Reminder

- Willing participants are a valuable resource
- Remember that consent is an ongoing process between the subject and the study team
  - Belmont principle of respect for persons
- Above all else, subject autonomy must be protected
- The IRB Administration is available as a resource
  - Policies & Procedures
  - Quality Assurance/Quality Improvement Program