ESSENTIAL ELEMENTS OF INFORMED CONSENT

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BEST PRACTICE

- YOUR IRB WILL HAVE A TEMPLATE AND SO WILL THE SPONSOR
- READ IT
- KNOW WHAT IS IN IT
- MAKE SURE YOU FOLLOW IT
- BETTER YET --MAKE SURE YOUR COORDINATOR/RESEARCH NURSE/DESIGNEE FOLLOWS IT

WHY?

BECAUSE BEHIND EVERY ESSENTIAL ELEMENT IS A STORY OF WHAT COULD AND DID GO WRONG

AND

BECAUSE IF ANYTHING GOES AMISS

YOU ARE ACCOUNTABLE…..

(SEE THE NEXT SLIDE)

PERFUSE

GENERAL REQUIRMENTS

THE LAW OF THE LAND STATES:

"No investigator may involve a human being…in research unless the investigator has obtained

- Legally effective informed consent… from the person or the Legally Authorized Representative (LAR)
- Under circumstances… that provide sufficient opportunity to consider whether to participate and
- That minimize… coercion and undue influence
- In language understandable to the subject…"

P.L. 93-348 : 21 CFR 50.20; 45 CFR 46.116

BASIC ELEMENTS

- Involves research
- Purpose of the research
- Duration of Participation
- Description of the procedures
- Identify experimental procedures

BASIC ELEMENTS continued 1

- Risks and discomforts to the subject
- Reasonably expected benefits to the subject or others
- Alternative procedures or treatments advantageous to the subject
- Extent of confidentiality of records

BASIC ELEMENTS continued 2

An explanation whether in the case of injury there is

- Compensation
- Treatment
- What they consist of
- Whom to contact for further information

BASIC ELEMENTS continued 3

Whom to contact for answers to questions

- About the research
- About the subject's rights
- In the event of injury

BASIC ELEMENTS continued 4

Statement that

- Participation is voluntary
- Refusal will involve no penalty or loss of benefits
- Subject may discontinue without penalty or loss of benefits

ADDITIONAL BASIC ELEMENTS AS APPROPRIATE

- Risks to the subject, embryo or fetus currently unforeseeable
- Circumstances in which participation may be terminated without the subjects consent
- Costs to the subject
- Consequences of withdrawal and procedures for orderly withdrawal

ADDITIONAL BASIC ELEMENTS AS APPROPRIATE

- Disclosure of significant new findings related to the willingness of the subject to continue
- Number of subjects involved
- A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law.

AND JUST IN CASE WE MAY HAVE FORGOTTEN SOMETHING

"The IRB may require that information, in addition to that specifically mentioned in 21 CFR 50.116 and 45 CFR46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects." 21 CFR56.109 (b) and 45CFR 46.109 (b)

SOME REGULATORY CREEP

- WHO IS IN CHARGE?
- WHO IS THE SPONSOR?
- EXCLUSION CRITERIA
- FINANCIAL CONFLICT OF INTEREST
- PARTICIPATION IN OTHER STUDIES
- REPRODUCTIVE WARNING FOR MALES/FEMALES
- PAYMENT (including IRS notification)

PAPERWORK

- “IT AIN’T OVER TILL THE PAPERWORK IS COMPLETE.”
- WHAT ISN’T IN WRITING CANNOT BE PROVED.

DOCUMENTATION

- IS IT THE CURRENTLY APPROVED FORM?
- MAKE SURE IT IS SIGNED AND DATED AT THE TIME CONSENT IS OBTAINED
- MAKE SURE THAT YOU FOLLOW METICULOUSLY THE POLICIES OF YOUR SPONSOR, MONITOR, INSTITUTION/HOSPITAL/CLINIC

  FOR DOCUMENTING CONSENT

- IS THERE AN APPROPRIATE LAR?

DOCUMENTATION continued

- IS IT WITNESSED? HAS THE WITNESS SIGNED AND DATED? IS THE WITNESS INDEPENDENT?
- ARE THE DATES FOR
  - THE WITNESS
  - THE PERSON OBTAINING THE CONSENT
  - THE PERSON CONSENTING IN AGREEMENT?

DOCUMENTATION continued

- HAVE YOU OR AN AUTHORIZED SUB-INVESTIGATOR SIGNED AND DATED IN A TIMELY FASHION?

- HAS THE CONSENT PROCESS BEEN DOCUMENTED IN THE MEDICAL RECORD?