IRB Board Education
Session 6
How Consent Regulations are Implemented in INSPIR

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Thinking Back to the Two Previous Education Sessions

Sue discussed

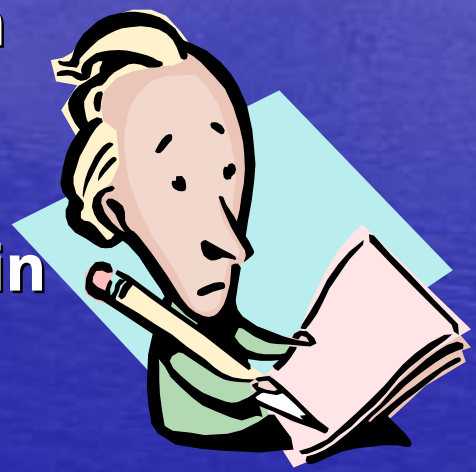
- **45 CFR 46.111**
- **25 CFR 56.111**

Informed Consent Process

Documentation of Consent

INFORMED CONSENT REQUIREMENTS

1. All studies must have informed consent prospectively obtained from each research subject (or LAR)
2. Consent must contain all of the required elements of consent listed in 45 CFR 46.116
3. Informed consent must be documented using a written consent form approved by the IRB and signed by the subject or LAR. A copy must be given to the person signing the form.



1. Legally effective informed consent must be prospectively obtained from each research subject (or LAR)

- This means ALL (Expedited and Full Board) Research
- Exempt research is not subject to these regulations
- Doesn't matter the risk level of the study – even < minimal risk studies are subject to this requirement if they are not Exempt
- Unless the IRB waives the requirement for informed consent

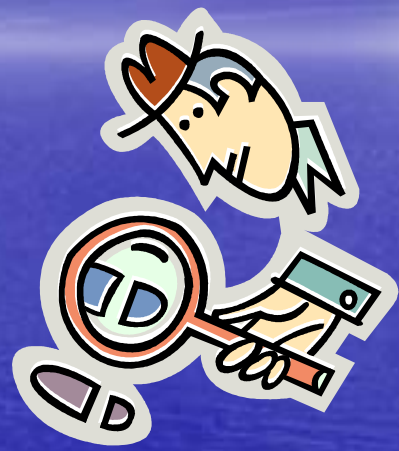
Claims Investigators Erroneously Make About Consent in Section J2 of INSPIR

- "This is a minimal risk study so consent is not necessary"
- " We are only doing interviews. There is no risk to subjects. Consent is not required".
- "The subjects already consented to the main study so consent for this sub-study is not needed"
- "We will read the subjects a statement about our telephone survey. Their willingness to participate by answering the questions will represent informed consent"

Waiver of Informed Consent

- Consent is required for all research unless THE IRB (either expediter or full board) grants the waiver of consent
- Telephone surveys, interviews, etc. are subject to these same regulations
- To be granted a Waiver of Consent- the PI must complete Section J4 of INSPIR – study must meet ALL FOUR CRITERIA
- Waiver can only be granted if the study is no more than minimal risk (first criteria) except when the Emergency Waiver regulations apply
- Criteria #3 (practicability) is hardest to meet

2. Consent must contain all of the required elements of consent



- Unless elements are waived by the IRB
- Required Elements checklist on OHRP website http://www.hhs.gov/ohrp/ (guidance- informed consent- checklist)

- INSPIR: the required elements are “hard-coded” into consent - PI can’t modify
- A subject cover letter summarizing the study that does NOT contain all of the required elements DOES NOT replace the consent
- Short form regulations may apply to foreign language consents

Waiver of One or More Required Elements of Consent

- PI requests removal / modification to the hard-coded language
- Submits request as "note to the IRB" attached in Section S
- Must include justification for why waiver of each element is appropriate
- Study can be no more than minimal risk
- Waiver is approved by Expediter / Full Board
- IRB staff makes the changes to the hard-coded language

3. Informed Consent Process Must Be Documented

- Consent must be documented using a written consent form approved by the IRB and signed by the subject or LAR
- A copy must be given to the person signing the form
- Applies to all studies unless the IRB waives the requirement for documentation of consent

Waiver of Documentation

Section J3 of INSPIR

- ONE of the TWO criteria must be met- completed by the PI
- Must be approved by IRB (expediter or full board)
- If Criteria #2 - study can be no more than minimal risk

If IRB approves a waiver of documentation

- consent process must still occur
- Study must have consent form containing all other required elements
- Subjects must still be provided a copy of the consent
- In INSPIR if J3 is completed then the system does NOT require signature lines on the consent form – a consent form is still required in Section Q

Summary

All studies in INSPIR must have

- **consent form** **or**
- **a waiver of consent** (Section J4) that has been reviewed/ approved by the IRB

Unless

- Exempt

- Sometimes the consent will be attached in Section S (i.e. VA consent forms) or as External Attachment

- If the study is no longer enrolling / consenting subjects the pre-INSPIR “old consent” may be attached in Section S

- If the study is no longer enrolling subjects the consent is deleted from the current version of the protocol (deleted in Section Q) but can be found in archived versions in Section Q