

Tuguegarao, Cagayan; 27-28 February 2012

# F: THE INFORMED CONSENT PROCESS

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With Notes from Lecture of Dr. Donald Evans  
FERCAP Training Course, 22-25 October 2001

# Nature of Consent

- Required
- Voluntary
- Informed
- Timely
- Culturally sound
- Recurrent

# “Required”

- Nuremberg Code
- Helsinki Declaration

Lack of or diminished capacity for decision-making: Proxy

- unconscious
- mentally ill
- children
- embryos

# “Voluntary”

- Not coerced
- Not induced
- Not unchangeable

Vulnerability must be mitigated through a sensitive and appropriate Informed Consent Process.

# SURROGACY

- In cases when the research subject is incapable of giving own informed consent because of incapacity.
- Informed consent is sought from a legal surrogate.
  - Substituted Judgement
  - “Best Interest”

# ASSENT

- Process and form used when minors participate in research.
- “A child’s affirmative agreement to participate in research,”
- Recommendation:
  - Below 7 - no sign of dissent
  - 7- below 12 yrs old - verbal assent
  - 12- below 15yrs old - signing of assent form
  - 15 – below 18 yrs old - signing of ICF
- Legal guardians must sign Informed consent Form

# “Informed”

- Information sheet
  - User friendly
  - Take away
  - Tailored
  - Supported
- Comprehensive

# Comprehensive:

- *Title and Purpose of the research*
- *Number of Participants*
- *Duration of participation*
- *Procedure/s*
- *Assignment (Random?) to treatment*
- *Alternative procedures/treatments*
- *Risks/ Benefits*
- *Extent of Confidentiality*
- *Compensation*
- *Withdrawal from participation*
- *Contact person/ Clinic*



## “Timely”

- Unhurried
- Strategic

## “Culturally sound”

- Community involvement
- Individual rights
- Spousal consent

# “Recurrent”

- Review
  - protocol changes
  - withdrawal
  - growing competence
  - trial results
  - follow-up studies

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