To Consent, Assent or Re-consent.
Is that the question?

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Objectives

• Define:
  • Consent and the consenting process
  • Waiver of consent
  • The 5 “W”s
CHSS Data Center

**Mission:**

- Improve care for patients with congenital heart disease through collaborative research on behalf of the Congenital Heart Surgeons Society and our patients.

**Vision:**

- The Data Center is a research engine and an academic resource which serves to extract knowledge from the collective clinical experience of the membership.
Definitions

• Consent:
  • Legal Term/Process

• Assent:

The US Office for Human Research Protections (OHRP) is very specific about this. Parental permission is a legally authorized representative of the subject, signing, to allow a subject to participate in a study.
Definitions

• Consent:
  • Legal Term/Process
  • What are you agreeing to?
  • Choices
  • Benefits
  • Risks
  • Alternatives

https://www.hhs.gov/ohrp/
Definitions

• Assent:
  • Age of subject at the time of assent
  • Institutional practices policies.
  • Assessing capacity
  • How often do you need to try and assent a patient?
  • Ward of the court
Definitions

• Re-Consent:
  Changes to the protocol
• Continuing Consent
  Age of maturity/majority obtained
Definitions

• Waiver of consent for deceased patients
• Part of Protocol
• No contact with patient or family
5 W’s
Who, When, Where, What, Why

• Who
  • PI and Study Staff

• When
  • Timing is everything

• Where
  • Quiet place with no distractions

• What
  • Details of what the study requires

• Why
  • It’s the law
THANK YOU

QUESTIONS