

# 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