

# Decision-Making Capacity and Consent

Achieving Excellence in DoD HRPP:  
Taking an Active Role

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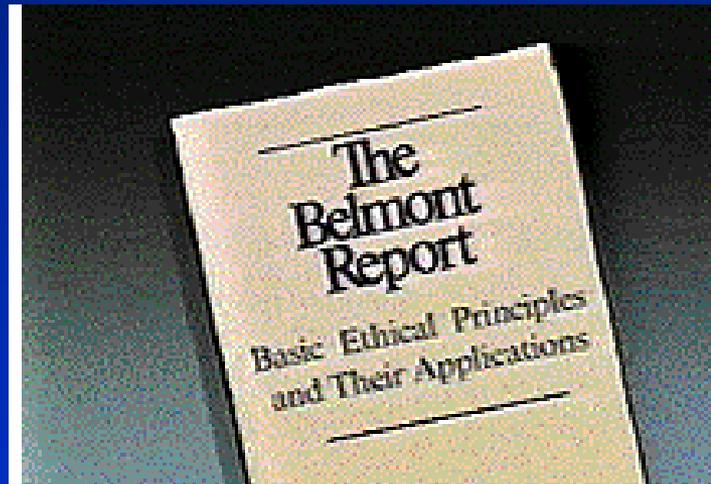
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# Learner Objectives

1. Describe four factors that affect or alter individual's decision-making capacity
2. List three types of subjects whose decision-making capacity may be affected or altered, and methods to address this
3. Describe two strategies for assessing potential research subjects' decision-making capacity

# Ethical Framework

Ethical Principles and Guidelines for the  
Protection of Human Subjects of Research



The National Commission for the Protection of Human Subjects  
of Biomedical and Behavioral Research

April 18, 1979

# The Belmont Report

## Ethical Principle *Related to Informed Consent Process and Decision-Making Capacity*

- **Respect for Persons**

- Treat individual with autonomy
- Protect individuals with diminished autonomy
  - possible 'over protection' ?

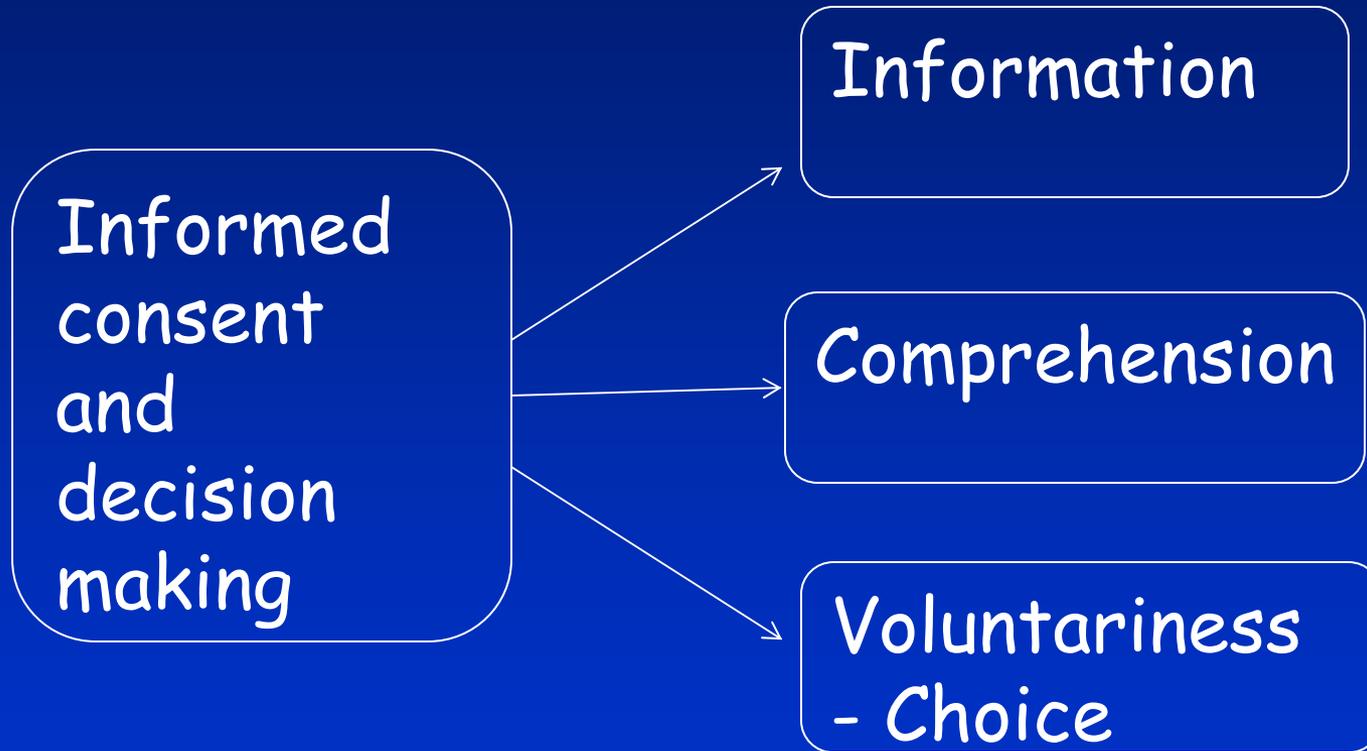
### **Informed consent process**

- to degree possible, give opportunity to choose what happens - or not - to them

# Regulatory Framework

...legally effective **informed consent of the subject** or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative **sufficient opportunity to consider whether or not to participate** and that **minimize the possibility of coercion or undue influence**. The information that is given to the subject or the representative shall be in **language understandable to the subject or the representative**.

# Elements of informed consent



The Belmont Report 1979

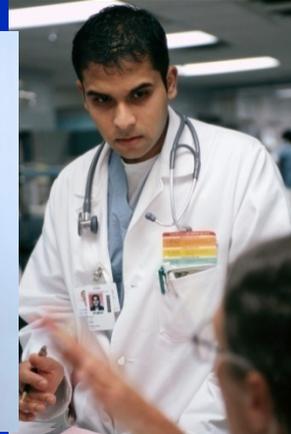
# Elements of informed consent and factors in decision making

Information

Informed consent  
and  
decision making

Factors

- Who presents
- What is presented
- When presented
- Where presented
- How presented



# Elements of informed consent and factors in decision making

## Comprehension

Informed consent and decision making

## Factors

- Reading, seeing, or hearing ability
- Language - level & appropriateness
- Maturity
- Cognitive ability



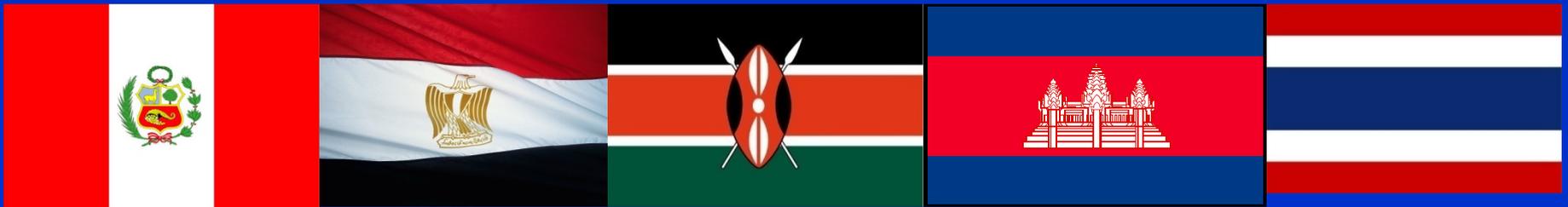
# Elements of informed consent and factors in decision making

**Voluntariness  
- Choice**

Informed consent  
and  
decision making

## Factors

- Who is involved
- When decision made
- Social-cultural context



# What is Decision-Making Capacity?

Is...

an individual's ability to make a decision about whether to participate in research

Is not...

"competence" of an individual in the legal sense as determined by court

# Decision-Making Capacity



# Decision Making

Factors affecting  
decision making



## Situational

- Pregnant women\*
- Pre-surgery or procedure
- Emergency medical situation
- Abusive or violent situations
- Prisoners\*

\* DoDD 3216.02 implements the additional requirements of 45 CFR 46 Subparts B and C



# Decision Making

Factors affecting  
decision making



## Organizational structure & Relationships

- Student-teacher
- Employee-employer
- Military chain of command\*
- Mentor-mentee

\* DoDD 3216.02 describes additional requirements



# Decision Making

Factors affecting  
decision making



## Social & cultural context

- Children
- Parent-child relationship
- Family structure
- Native American tribes
- International populations

•\* DoDD 3216.02 implements the additional requirements of 45 CFR 46 Subpart D



# Decision Making

Factors affecting  
decision making →

## Potential Decision-making Impairments

- Durable - Down syndrome
- Progressive diseases or disorders
- Mental illness or disorders
- Neurological disorders
  - PTSD, TBI



# Other factors to consider...

## State Laws

- Legally Authorized Representative (LAR)
  - Not defined in 32 CFR 219
  - Many states have not defined LAR  
(rare exceptions)
- Legal Age of Majority
  - Generally 18 years of age: also 19 & 21

# What would you decide?

## "Teens Having a Blast"

You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.



# What would you decide?

## “Butter or Bullets?”

You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.

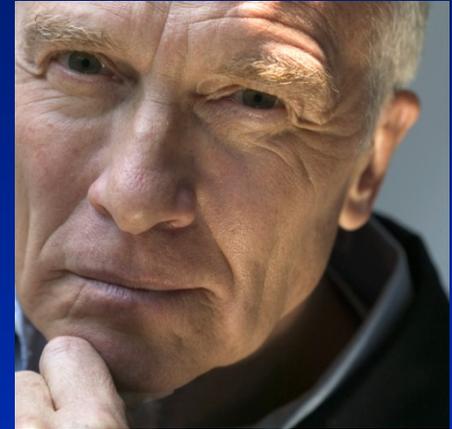


# What would you decide?

## "Senior Shots"

You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.



# What would you decide?

## "Baby on Board"

You are invited to participate in a study to find out if an active denial system is safe to use in dispersing a crowd of people. You will be asked to stand with about 30 people in a fenced outdoor area where the researcher will randomly shoot sponge-like bullets into the crowd.

The risks to you include cuts or bruises from contact with your skin, possible injury to your eyes if you do not wear the eye protectors; possible injury to your head resulting in headache, dizziness, and rarely loss of consciousness.



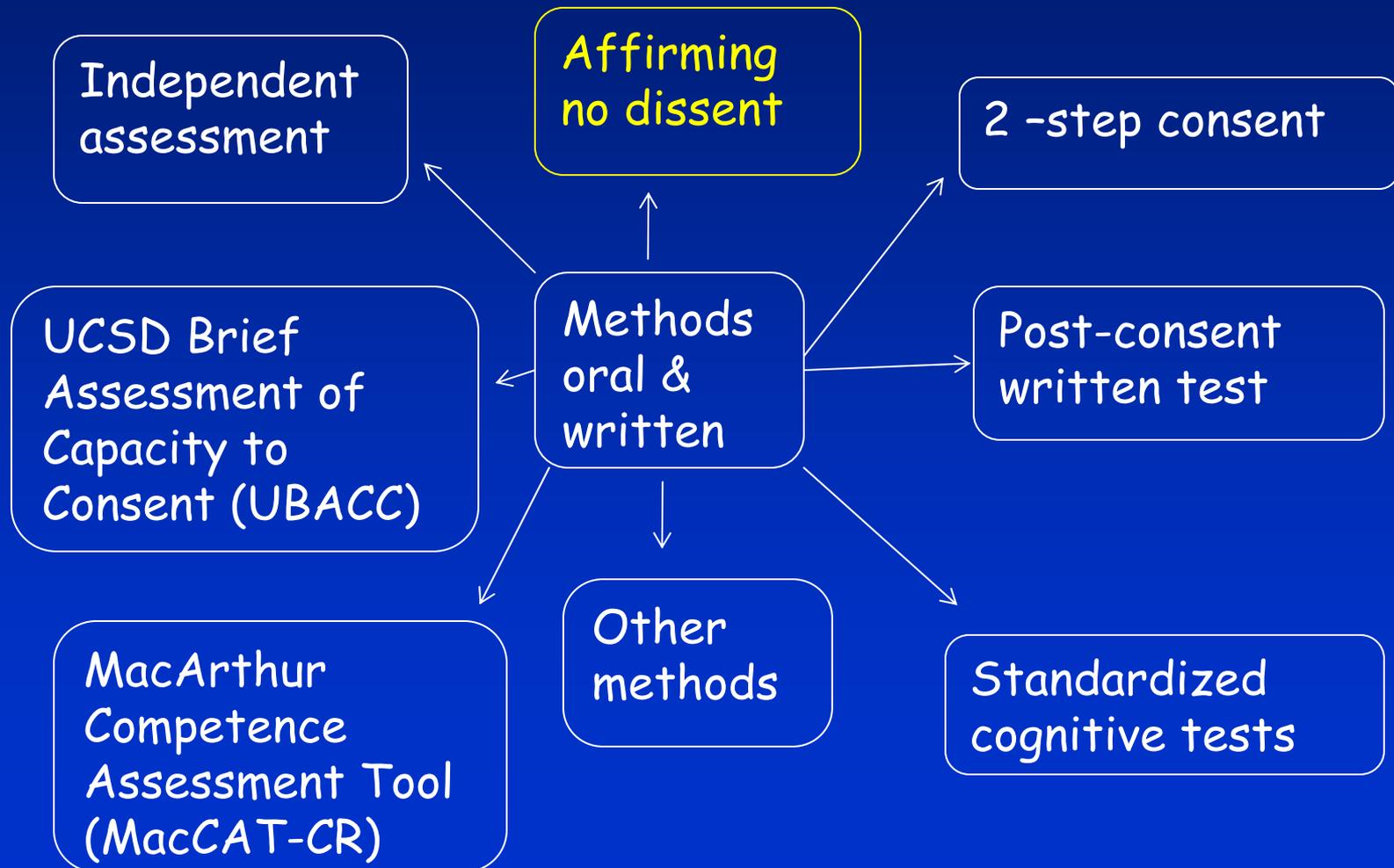
# Assessing Decision-Making Capacity

# Early thoughts....

"On occasion, it may be suitable to give some oral or written tests of comprehension."

The Belmont Report 1979

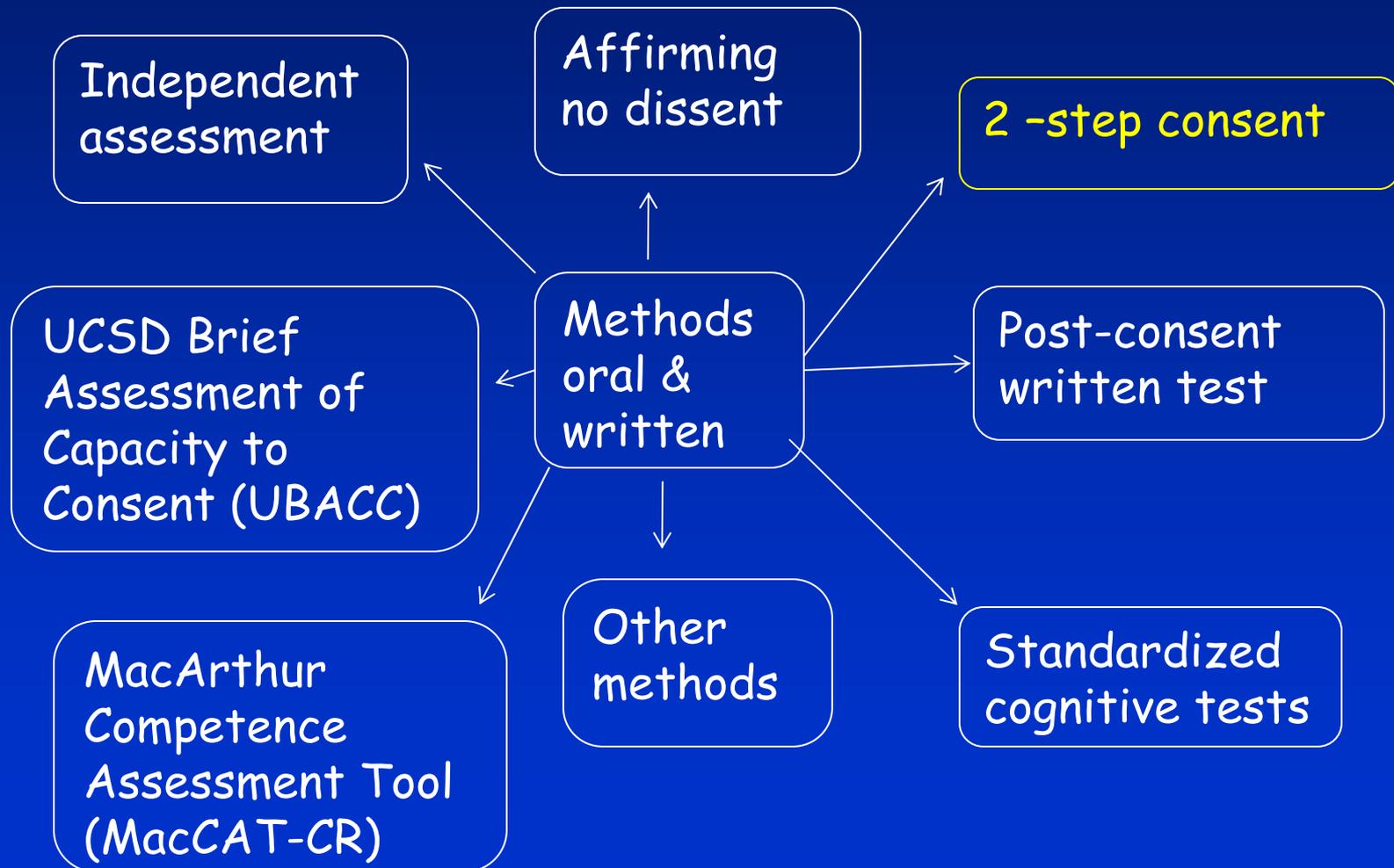
# Assessing Decision-Making Capacity



# Affirming no dissent

- Least comprehensive approach
- Usually a leading yes-no question
  - Do you have any questions?
- Presumes understanding

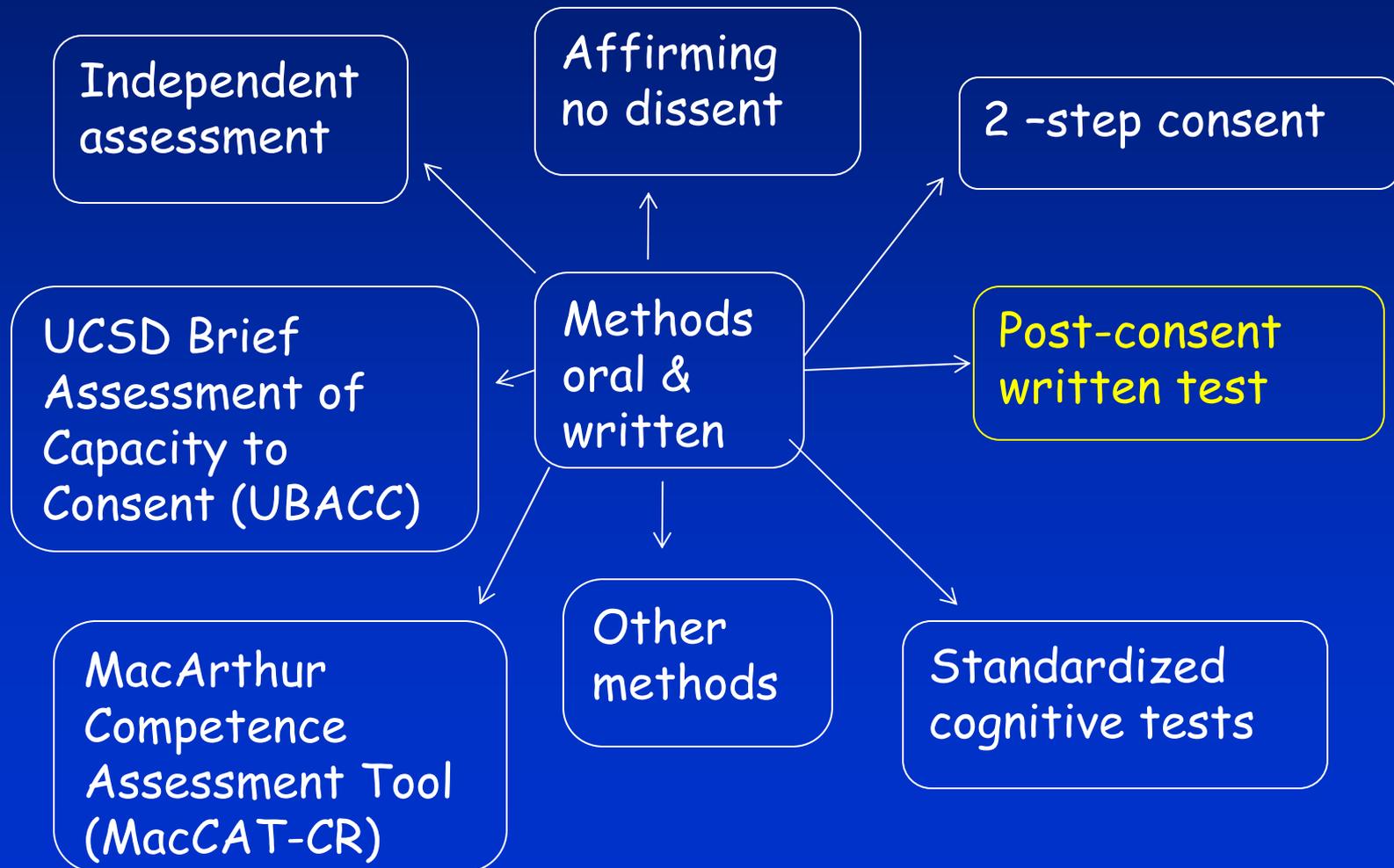
# Assessing Decision-Making Capacity



# 2 -step consent

- Adds time for potential subject:
  - to consider information
  - talk with family, friends, others
- Sets stage for "conversation" between potential subject and researcher

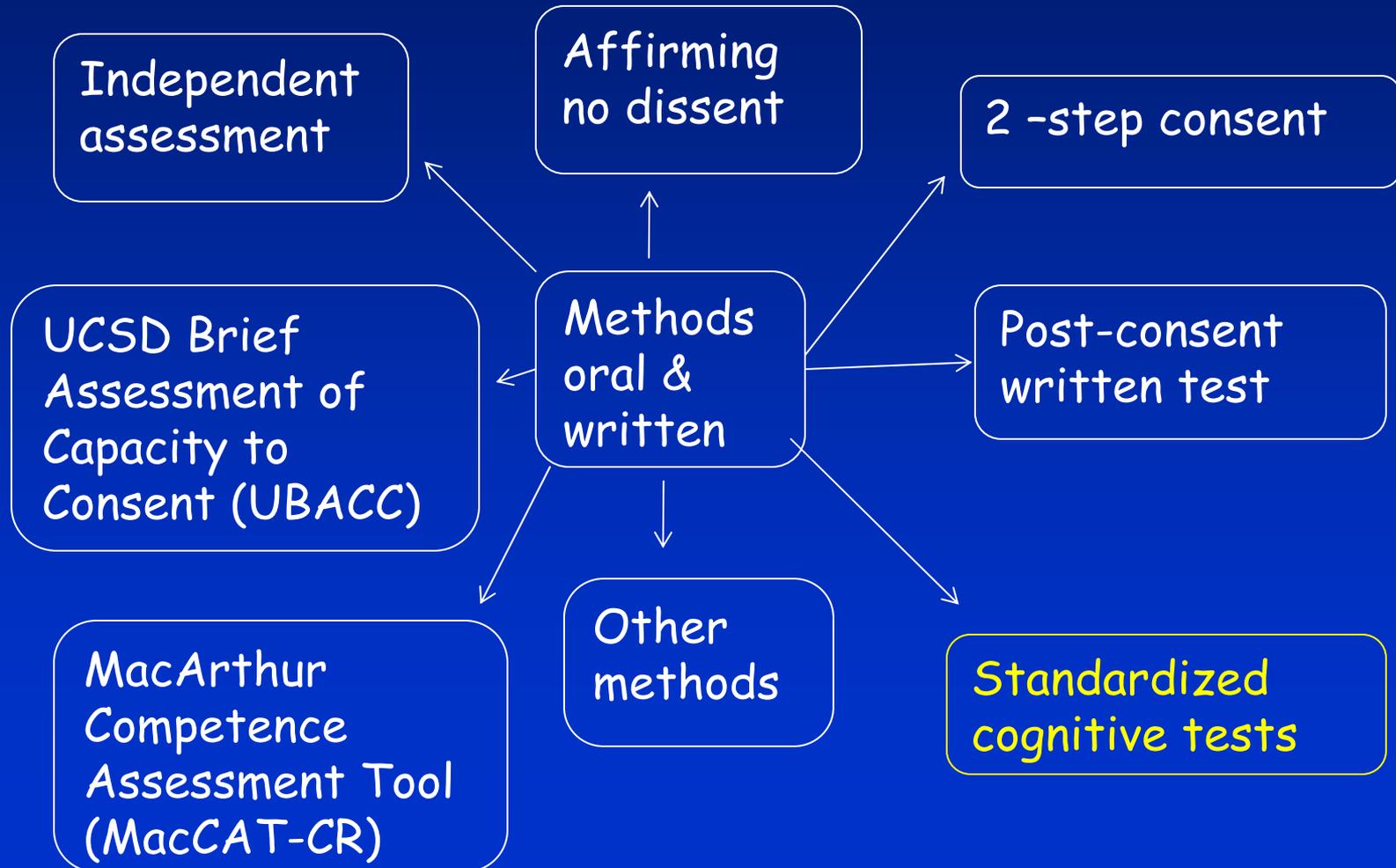
# Assessing Decision-Making Capacity



# Post-consent written test

- Be sure test questions actually tests understanding and not reading skills
- Can be intimidating - especially if no "conversation" included
- Criteria for "passing" - or failing
- "Over coaching"

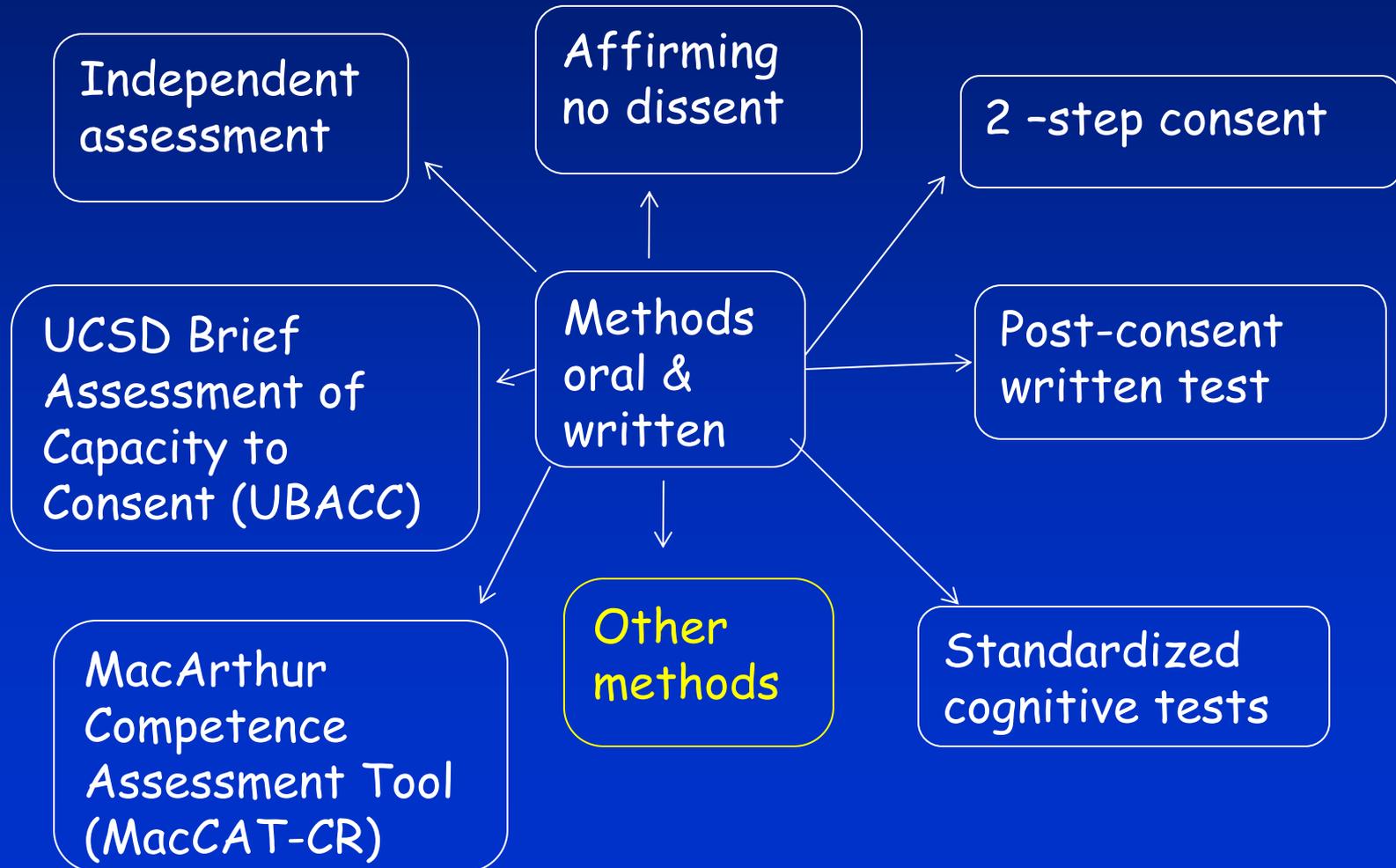
# Assessing Decision-Making Capacity



# Standardized cognitive tests

- Mini—Mental State Examination (MMSE), BECK Depression scales, etc.
- Tests for specific populations or individuals, or purposes
- Supplement screening or assessment

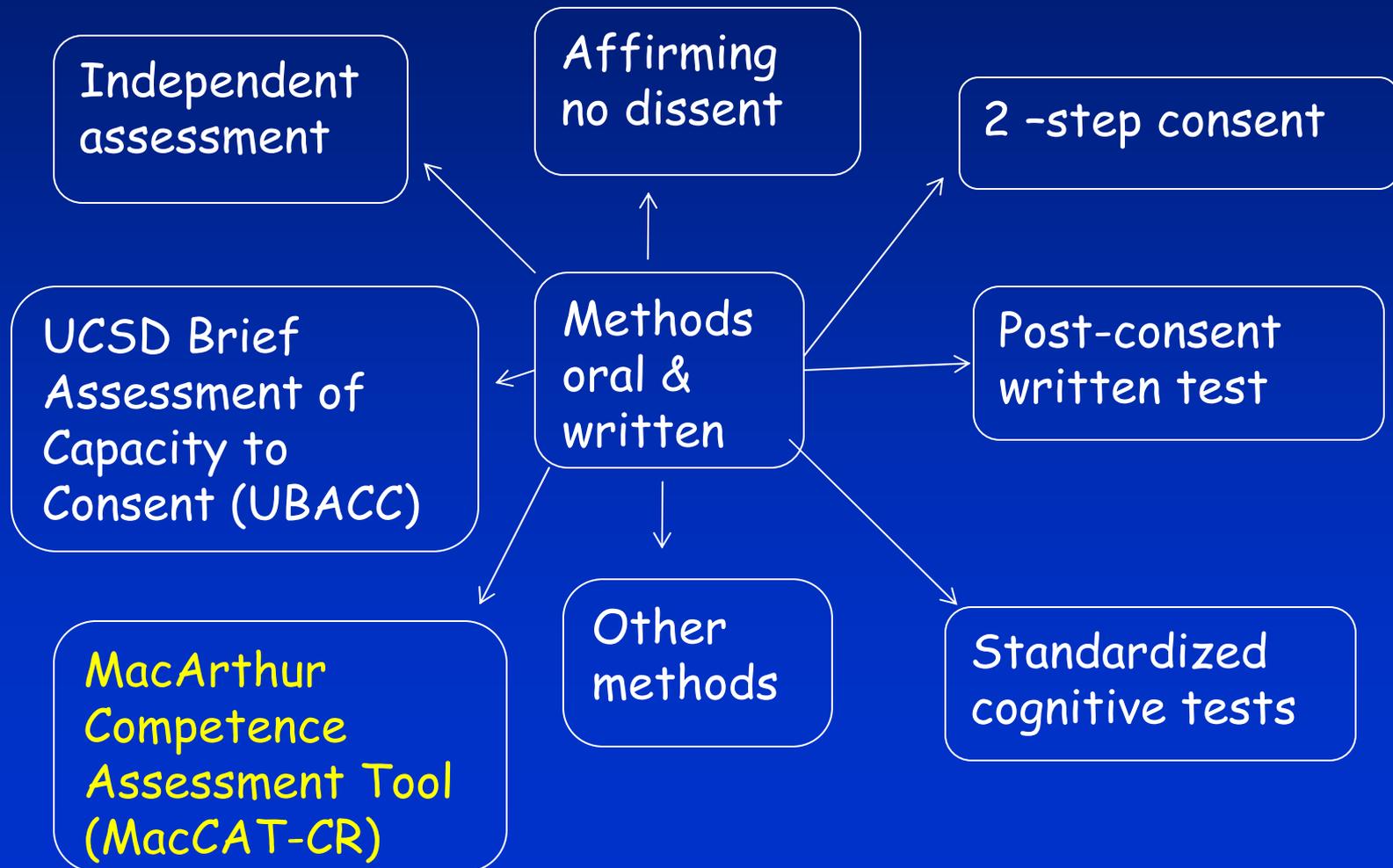
# Assessing Decision-Making Capacity



# Other methods

- Researcher-initiated alternatives
- Novel approaches

# Assessing Decision-Making Capacity

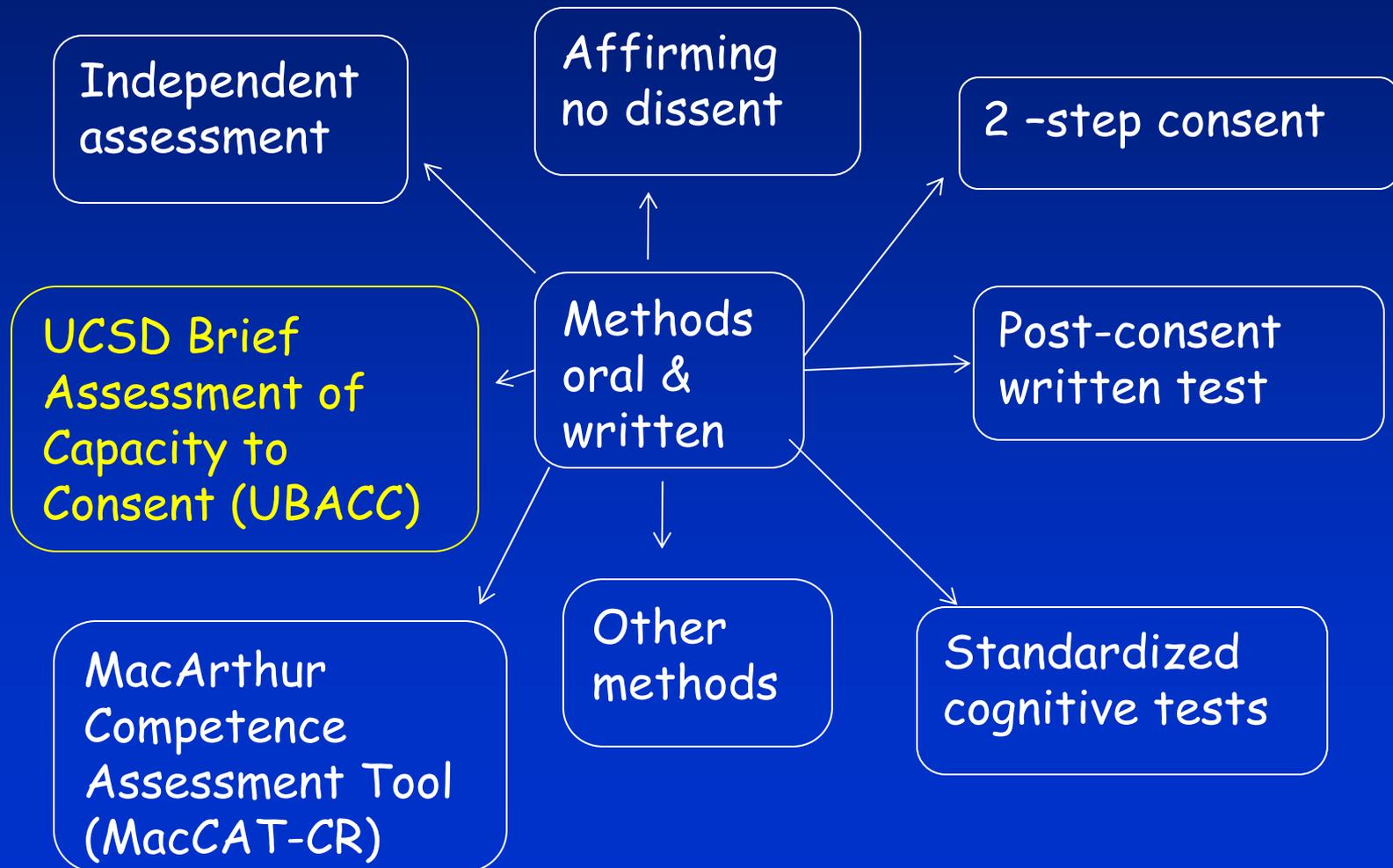


# MacArthur Competence Assessment Tool (MacCAT-CR)

- Standardized and validated
- Can be tailored to research protocol
- Takes about 15 - 20 minutes to administer
- Requires trained personnel
- Good general choice

(Appelbaum and Grisso, 1995 & 2001)

# Assessing Decision-Making Capacity



# UCSD Brief Assessment of Capacity to Consent (UBACC)

- 10 item scale
- About 5 minutes to administer
- Easy to use and score
- Identify subjects who may have questionable decision-making capacity
- Can be tailored to research protocol

# UCSD Brief Assessment of Capacity to Consent (UBACC)

The 10 questions assess:

- **understanding** of protocol procedures
  - What is the purpose of the research...
  - Describe some of the risks or discomforts..

# UCSD Brief Assessment of Capacity to Consent (UBACC)

The 10 questions assess:

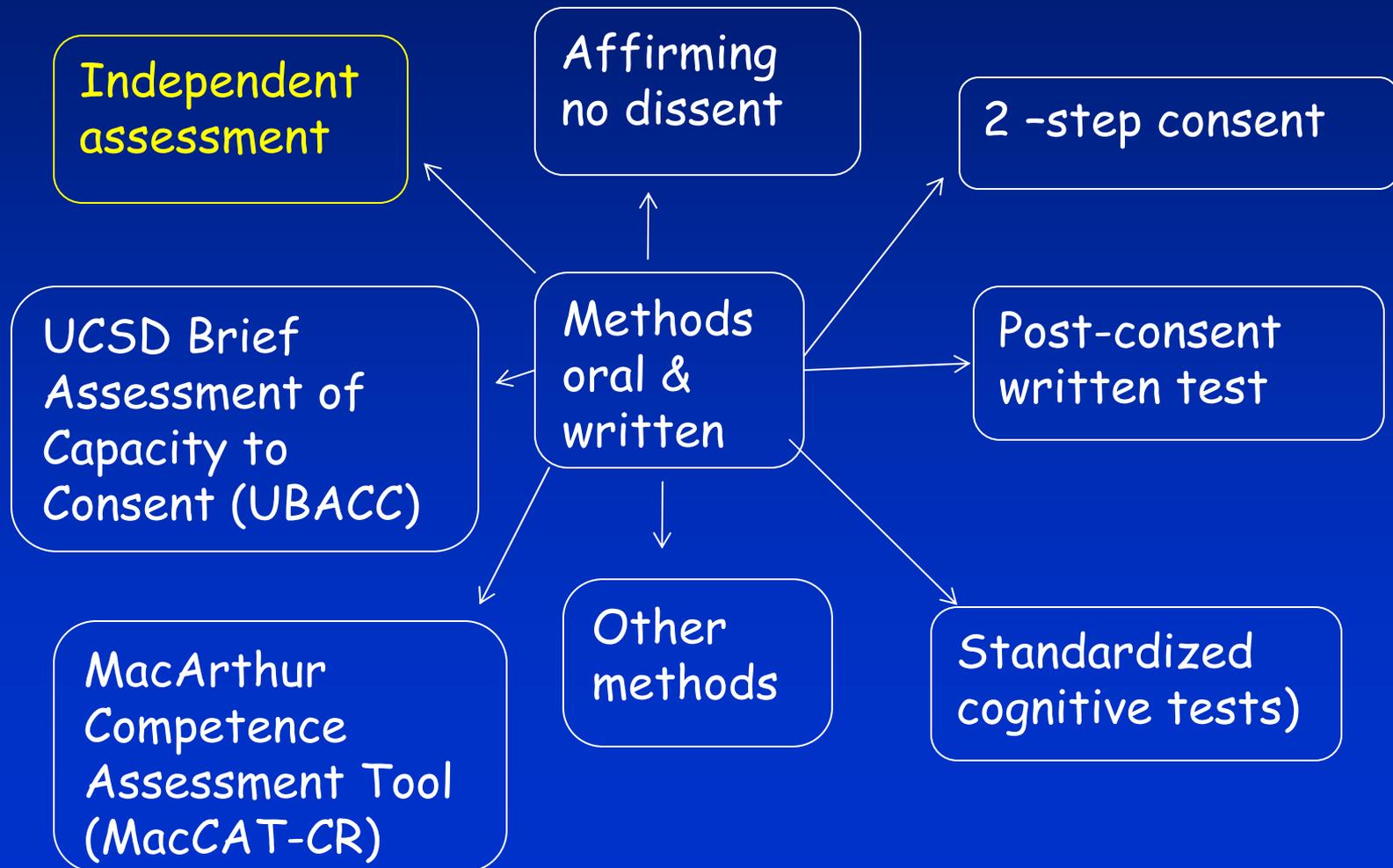
- **appreciation** of significance of the risks
  - Do you have to be in this study if you do not want to?
  - Is it possible that being in this study will not have any benefit to you?
  - Who will pay for medical care if you are injured....?

# UCSD Brief Assessment of Capacity to Consent (UBACC)

The 10 questions assess:

- reasoning
  - What makes you want to consider participating ....?

# Assessing Decision-Making Capacity



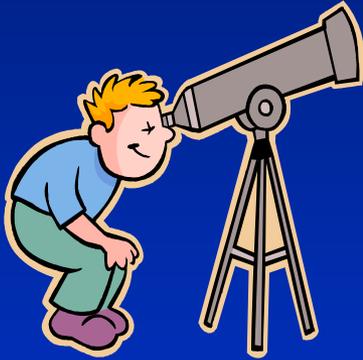
# Independent assessment

Some one outside the research team

- Research personnel
- Clinical personnel
- IRB Chair or member
- Research Subject Advocate

Focus on:

the process, not the  
document



understanding, not the  
signature

# Think outside the box.. to enhance decision-making capacity

"Adult Assent" (AA)

"A picture is worth a 1,000 words..."

"Do the Timeline" (children become adults)

"Informed Consent Check up"

"Guardian Angels"

Closing thought....

April 2001

Ellen Roche - 24 year old technician/healthy volunteer working at a JHU research center - volunteers for research project to study induced airway relaxation by inhalation of hexamethonium, a ganglionic blocker

One day after inhalation, Ellen develops cough and then respiratory distress. She is the third subject to do so.

Ellen died June 2, 2001



# Would the following have changed Ellen's decision to volunteer....?

## Information, Understanding, and Choice

- Hexamethonium is a chemical, not a "medication" and not FDA-approved
- Known toxic effects on humans not found on 'google' search (literature review)
- Problems with prior subjects not reported or disclosed to new subjects
- Possible undue influence

# For more information

*Jeste, et al., Arch Gen Psychiatry. 2007;64(8):996-974*

*UCSD Procedures for Determination of Decisional Capacity in Persons  
Participating in Research Protocols - January 7, 2003*

*Secretary Advisory Committee on Human Research Protections -  
Subcommittee of Inclusion of Individual with Impaired Decision-making  
in Research (SIIIDR) Report - October 29, 2007*

# In appreciation

.....to volunteer human research subjects who give of themselves.

... to IRB members who work diligently without recognition other than self-satisfaction...

...to researchers who respect and protect subjects who volunteer for research...

... to my colleagues for sharing their knowledge, insight, and friendship:

Paul Braunschweiger, Gary Chadwick, Jeff Cohen, Ed Gabriele, Dale Hammerschmidt, Karen Hansen, Mark Hochhauser, Dan Nelson, Susan Rose, and many others.