Wisconsin Alzheimer's Disease Research Center

UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

The U-ARE Model: A Pragmatic Approach to Capacity Assessment

Spring ADC meeting
Boston
April 21, 2017

Carey E. Gleason, PhD, MS
Associate Professor (CHS)
Wisconsin Alzheimer's Disease Research Center
University of Wisconsin
School of Medicine and Public Health
Madison VA Geriatric Research, Education and Clinical Center

Acknowledgments

- No conflicts of interest
- Funding: NIA-NIH (P50 AG033514; R01 AG054059)
- Collaborators:
  - Sanjay Asthana, MD
  - Cynthia Carlsson, MD, MS
  - Sterling Johnson, PhD
  - Hanna Blazel, MS
  - Cynthia Phelan, PhD
  - Nichelle Cobb, PhD
  - Lisa Wilson, JD
  - Rachel Bencic Hamilton, MS

Outline

- Obtaining consent for research participation
  - Brief review of regulations and concepts
  - Research v Clinical assessments
- Assessment of Decisional capacity
  - U-ARE model
  - Adaptations (e-consent)
- When someone lacks decisional capacity
  - Legal standards
  - Legally authorized representatives
  - Research POAs

Informed Consent – History of Federal Regulation

- Historical abuses led to regulation
- Nuremberg Code (1946), Declaration of Helsinki (1964)
- Belmont Report: defined principles guiding research with human subjects (1978)
  - Respect for persons, Beneficence, Justice
- Common Rule (1991): Uniform set of rules for human subject research
- National Bioethics Advisory Commission (NBAC) (2001)

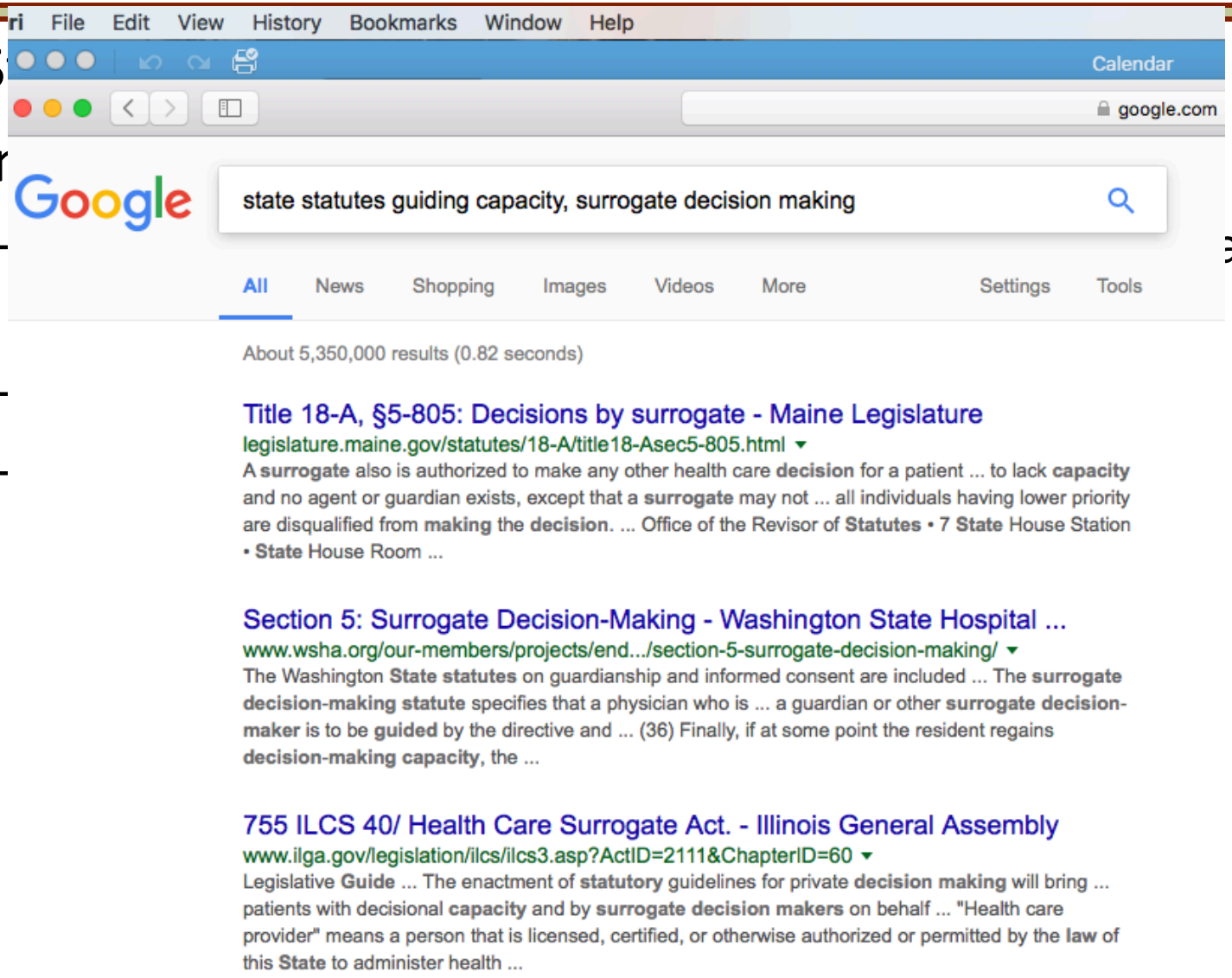
Provide moral framework

Provides specific guidance

Provides specific guidance, especially for vulnerable populations

Informed Consent – State & Institutional Regulation

- S
- Ir
  -
  -
  -



Obtaining Informed Consent

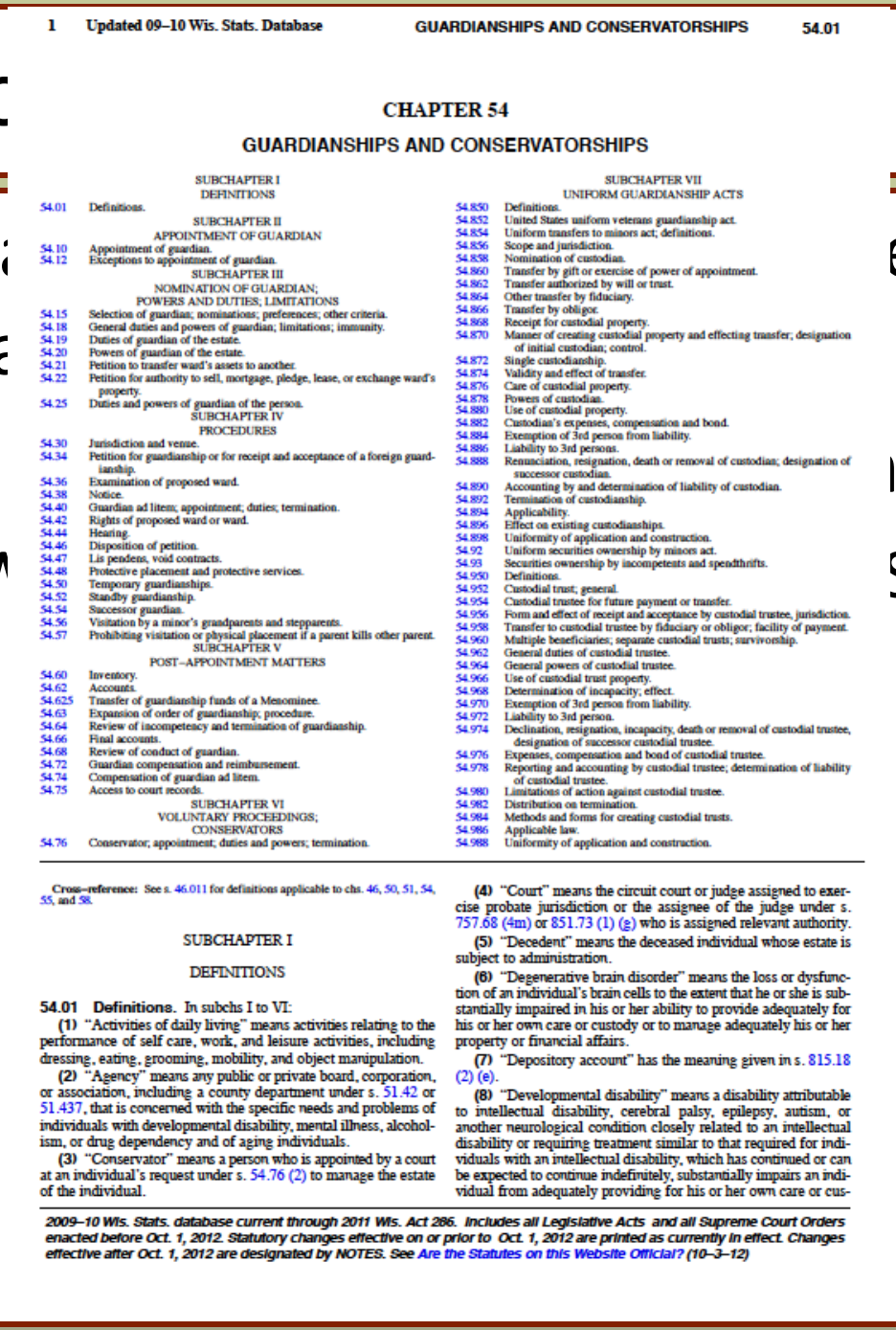
- Obtaining Informed consent is a conversation not a signature
- From Common Rule:
  - 12 basic elements: (examples)
    - Purposes of the research
    - Duration; Procedures
    - Risks/benefits
  - 6 additional elements if applicable
  - How to document informed consent
  - When it is reasonable to alter or waive some or all elements of consent

Obtaining Informed Consent

- NBAC: Commission established because
  - Common rule inconsistently applied
  - Common rule – confusing, difficult to interpret
  - Special attention to research involving "persons with mental disorders that may affect decision-making capacity"
  - IRBs started to pay more attention to assessment of capacity
- Response to research practices with adults with mental illnesses

A wc ssments

- Overla evel of regula
- State ıce
  - In W Statutes



CHAPTER 54

GUARDIANSHIPS AND CONSERVATORSHIPS

Cross–reference: See s. 46.011 for definitions applicable to chs. 46, 50, 51, 54, 55, and 58.

SUBCHAPTER I

DEFINITIONS

54.01 Definitions. In subchs I to VI:

(1) "Activities of daily living" means activities relating to the performance of self care, work, and leisure activities, including dressing, eating, grooming, mobility, and object manipulation.

(2) "Agency" means any public or private board, corporation, or association, including a county department under s. 51.42 or 51.437, that is concerned with the specific needs and problems of individuals with developmental disability, mental illness, alcoholism, or drug dependency and of aging individuals.

(3) "Conservator" means a person who is appointed by a court at an individual's request under s. 54.76 (2) to manage the estate of the individual.

(4) "Court" means the circuit court or judge assigned to exercise probate jurisdiction or the assignee of the judge under s. 757.68 (4m) or 851.73 (1) (g) who is assigned relevant authority.

(5) "Decedent" means the deceased individual whose estate is subject to administration.

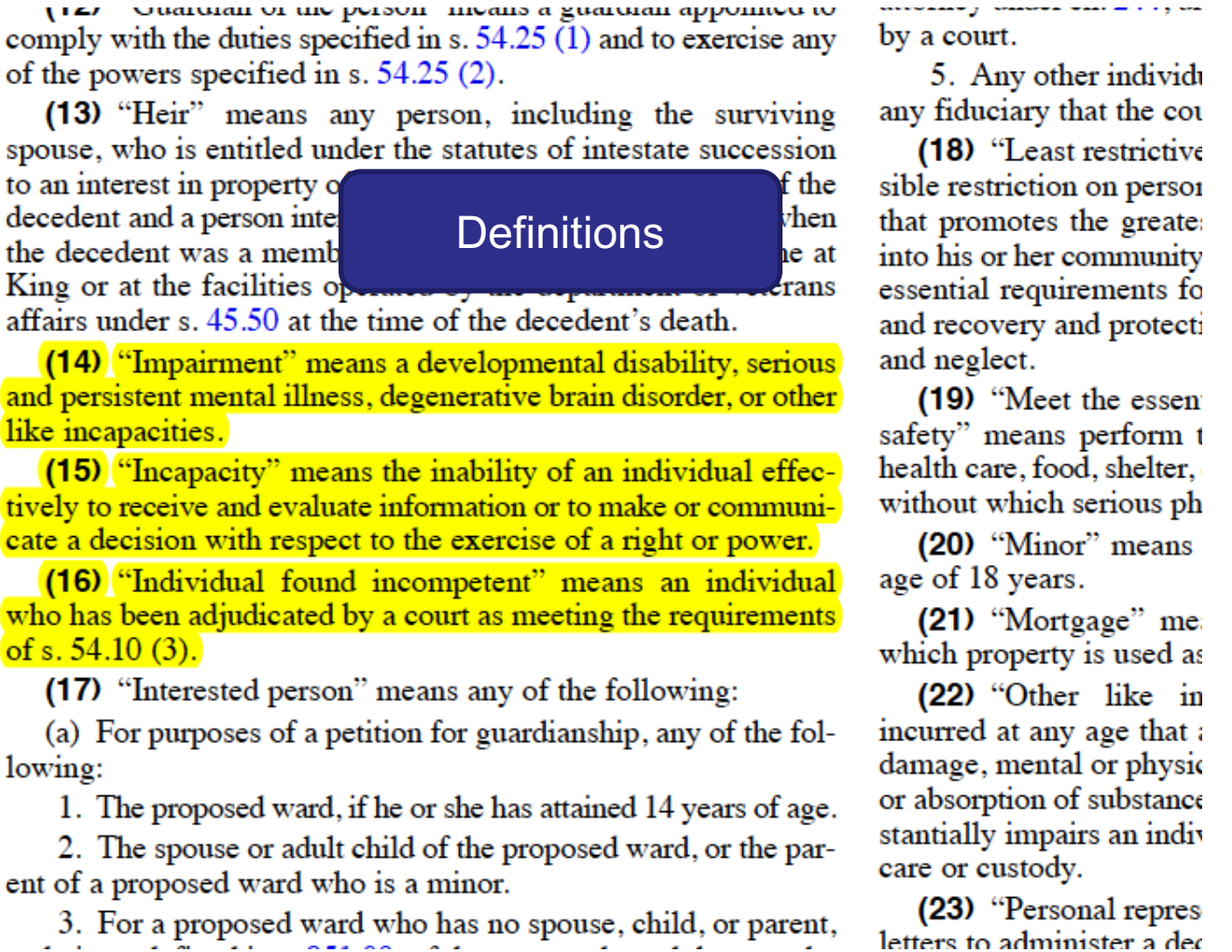
(6) "Degenerative brain disorder" means the loss or dysfunction of an individual's brain cells to the extent that he or she is substantially impaired in his or her ability to provide adequately for his or her own care or custody or to manage adequately his or her property or financial affairs.

(7) "Depository account" has the meaning given in s. 815.18 (2) (e).

(8) "Developmental disability" means a disability attributable to intellectual disability, cerebral palsy, epilepsy, autism, or another neurological condition closely related to an intellectual disability or requiring treatment similar to that required for individuals with an intellectual disability, which has continued or can be expected to continue indefinitely, substantially impairs an individual from adequately providing for his or her own care or cus-

A word about clinical assessments

- In Wisconsin: Chapter 54 of State Statutes



comply with the duties specified in s. 54.25 (1) and to exercise any of the powers specified in s. 54.25 (2).

(13) "Heir" means any person, including the surviving spouse, who is entitled under the statutes of intestate succession to an interest in property o f the decedent and a person inte hen the decedent was a memb e at King or at the facilities o erans affairs under s. 45.50 at the time of the decedent's death.

Definitions

(14) "Impairment" means a developmental disability, serious and persistent mental illness, degenerative brain disorder, or other like incapacities.

(15) "Incapacity" means the inability of an individual effectively to receive and evaluate information or to make or communicate a decision with respect to the exercise of a right or power.

(16) "Individual found incompetent" means an individual who has been adjudicated by a court as meeting the requirements of s. 54.10 (3).

(17) "Interested person" means any of the following:

(a) For purposes of a petition for guardianship, any of the following:

1. The proposed ward, if he or she has attained 14 years of age.

2. The spouse or adult child of the proposed ward, or the parent of a proposed ward who is a minor.

3. For a proposed ward who has no spouse, child, or parent,

by a court.

5. Any other individ any fiduciary that the co

(18) "Least restrictive sible restriction on perso that promotes the greate into his or her community essential requirements fo and recovery and protecti and neglect.

(19) "Meet the essen safety" means perform t health care, food, shelter, without which serious ph

(20) "Minor" means age of 18 years.

(21) "Mortgage" me which property is used as

(22) "Other like in incurred at any age that damage, mental or physi or absorption of substance stantially impairs an indiv care or custody.

(23) "Personal repres letters to administer a dec

A w…nts

– In…s

54.36 Examination of proposed ward. (1) Whenever it is proposed to appoint a guardian on the ground that a proposed ward allegedly has incompetency or is a spendthrift, a physician or psychologist, or both, shall examine the proposed ward and furnish a written report stating the physician's or psychologist's professional opinion regarding the presence and likely duration of any medical or other condition causing the proposed ward to have incapacity or to be a spendthrift. The privilege under s. 905.04 does not apply to th… of the report to the p… ian ad litem, and t… examination on which the report is based, the guardian ad litem, physician, or psychologist shall inform the proposed ward that statements made by the proposed ward may be used as a basis for a finding of incompetency or a finding that he or she is a spendthrift, that he or she has a right to refuse to participate in the examination, absent a court order, or speak to the physician or psychologist, and th… report to the court e… physician or psycho… proposed ward prior to each examination establishes a presumption that the proposed ward understands that he or she need not speak to the physician or psychologist. Nothing in this section prohibits the use of a report by a physician or psychologist that is based on an examination of the proposed ward by the physician or psychologist before filing the petition for appointment of a guardian, but the court wi… determining whether the… posed ward's current stat… given to the report.

Who can legally make determinations

Right to refuse participation in eval

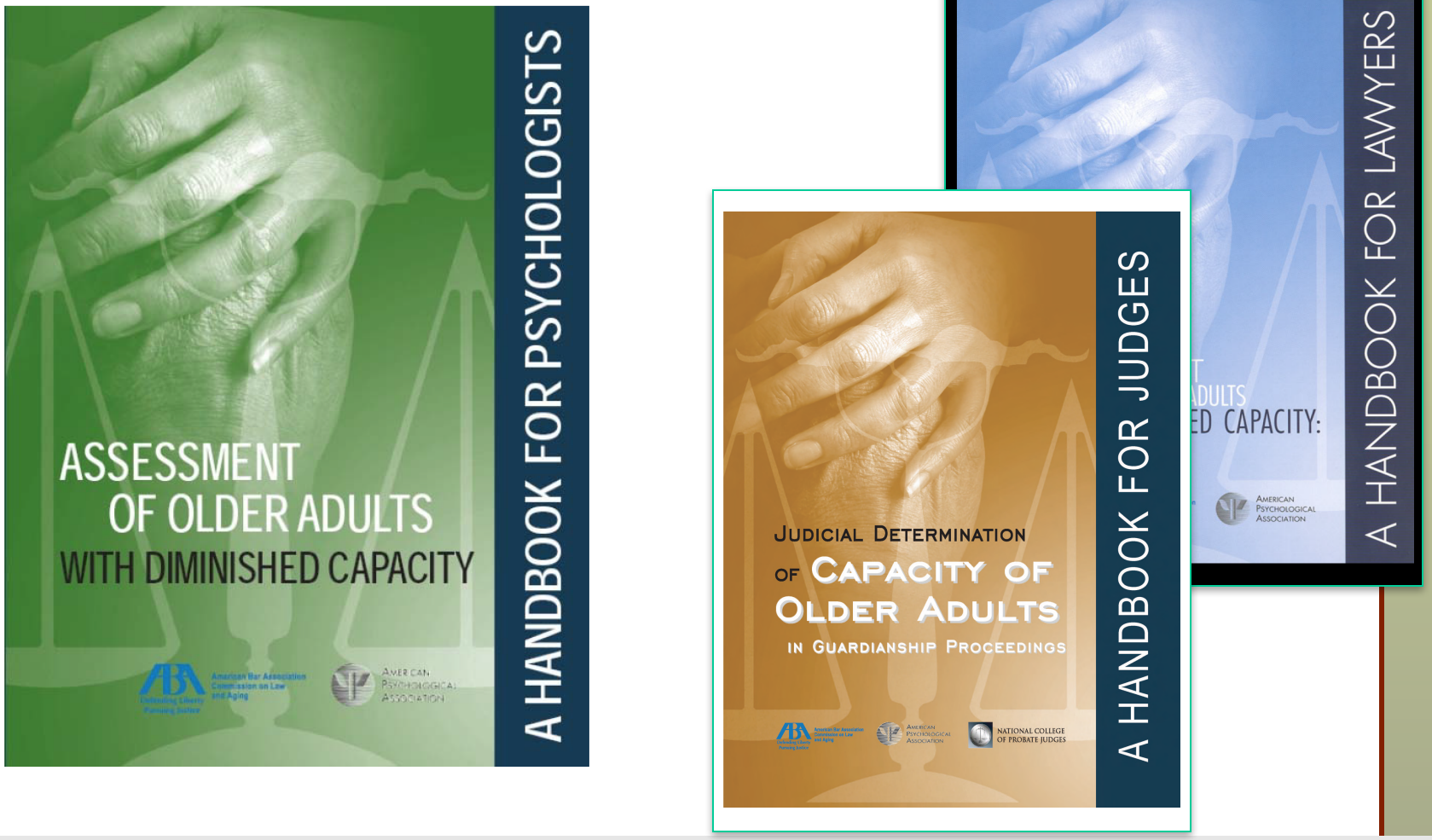
What data can be used to draw conclusions

2009–10 Wis. Stats. database current through 2011 Wis. Act 286. Inc…

Obtaining Informed Consent

- In the research setting – hybrid
  - Regulations may guide ***when*** you need to assess
  - Clinical disciplines guide ***how*** you assess
- Key concepts from clinical practice:
  - Global v. Specific capacities
  - Legal (competency) v. Clinical
  - Prospective v. Retrospective
  - Decisional v. Executional
  - Adults are presumed to have capacity unless reason to suspect otherwise

Obtaining Informed Consent



http://www.apa.org/pi/aging/programs/assessment/index.aspx

U-ARE Model

- When research program started in Wisconsin – 2001
  - IRB asked, “What is your approach to capacity assessment?”
- Goals:
  - Ensure we know ***who*** is providing informed consent
  - Provide consistent and accurate assessments
  - Reduce burden on participants

U-ARE Model

- Consistency improved by use of a model
  - Adopted Appelbaum and Grisso's model
- Elements of capacity:
  1. Understand
  2. Appreciate
  3. Reason
  4. Express a choice

Appelbaum. Assessment of Patients' Competence to consent to treatment NEJM 2007; 357:1834-40.

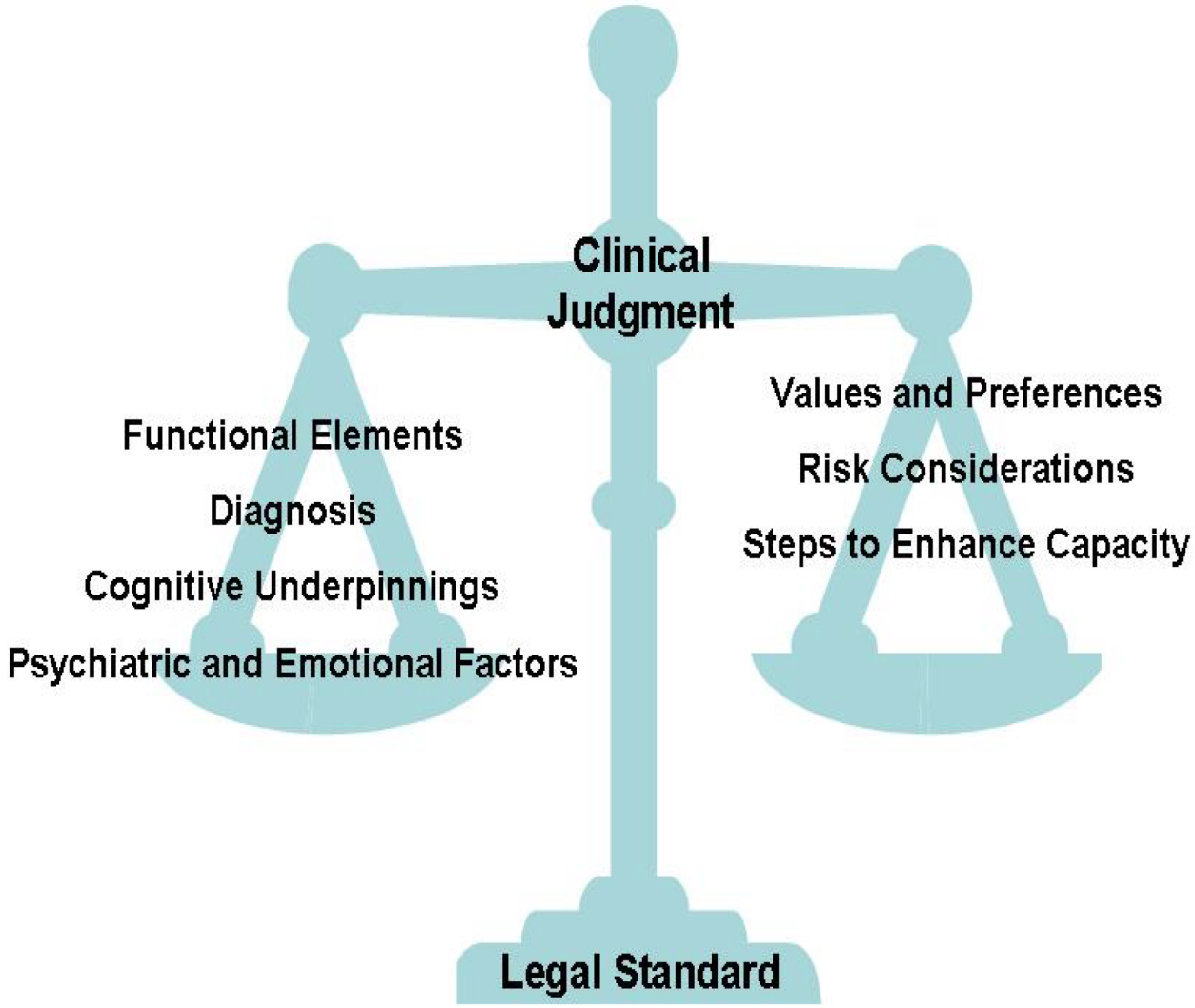
U-ARE Model

- Ask four questions to assess decisional ability
- Elements of capacity:
  1. Understand: This is a research study, do you have to participate?
  2. Appreciate: Review risks, remind participant that he/she is taking the research for science. Discuss their appreciation of risk/benefit ratio.
  3. Reason: What if you changed your mind?
  4. Express a choice: What do you want to do

U-ARE Model

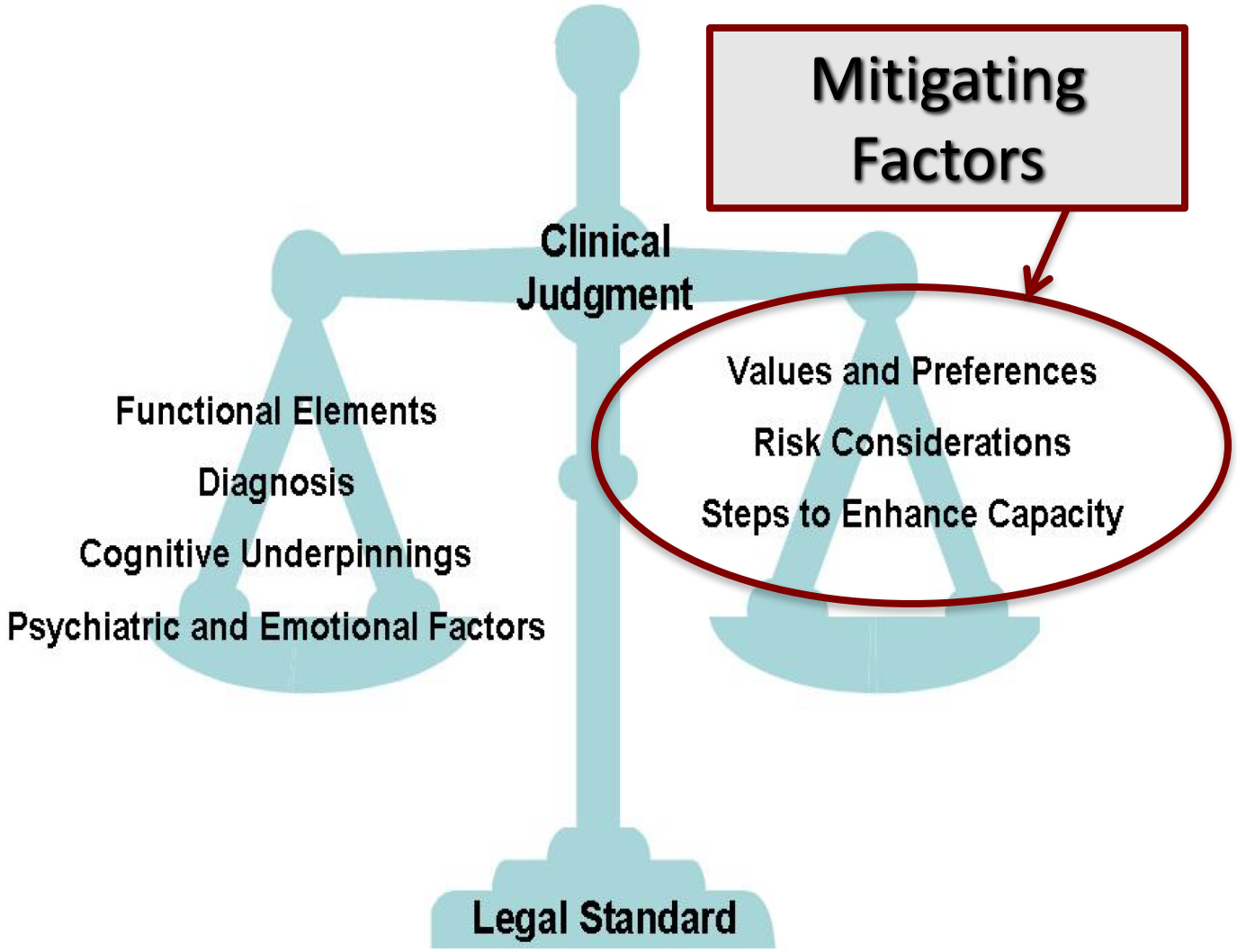
- Questions asked after consent document reviewed
- Consider
  - Values and Preferences
  - Cultural factors
  - Language
  - Communication style
  - Decision making style
  - Riskiness of behavior or decision
- Are there ways to enhance capacity?

Framework



Assessment of Older Adults with Diminished Capacity: A handbook for Psychologists

Framework

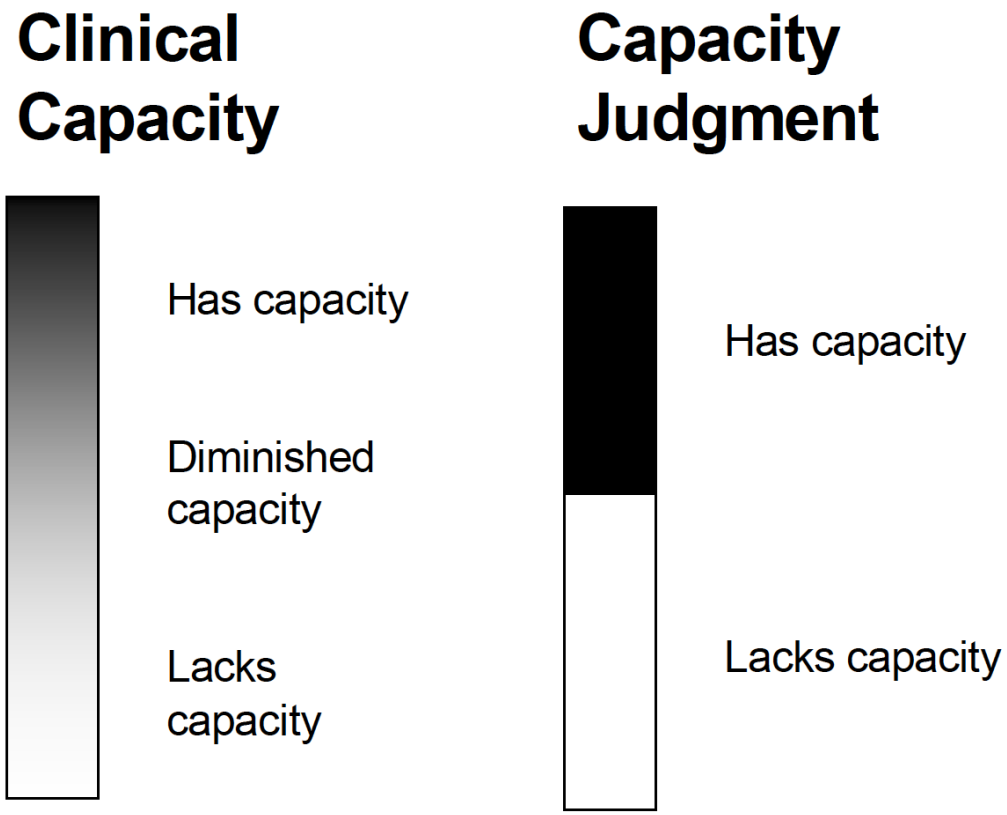


Assessment of Older Adults with Diminished Capacity: A handbook for Psychologists

Ultimately – a clinical decision

Clinical Capacity v. Legal Capacity

- Continuum v. Category



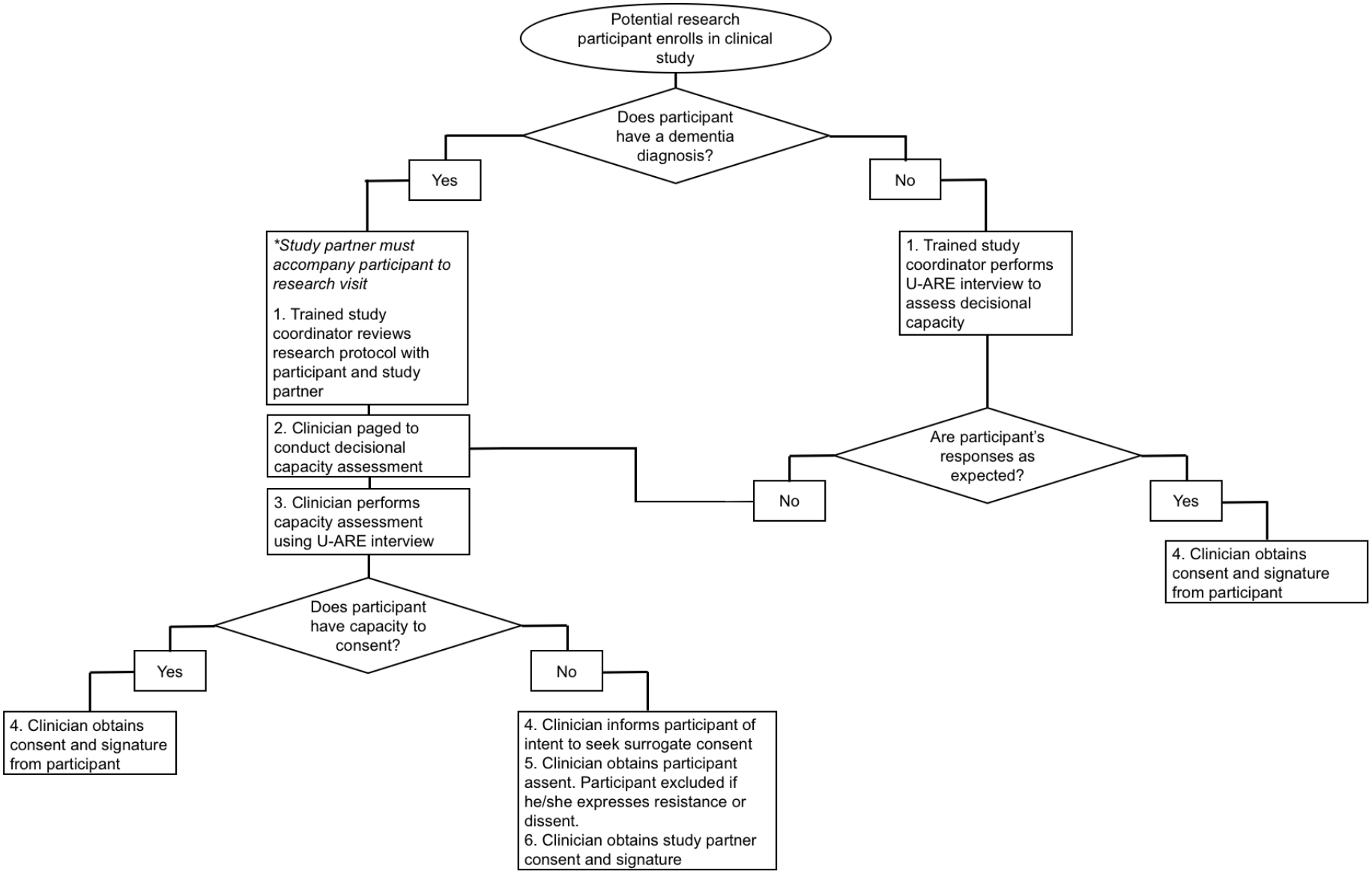
Ultimately – a clinical decision

- Using a Framework improves consistency
- Know your biases
- Assessment usually
  - Focused in specific type of capacity
  - Occurs within a context

Practicalities

- Made the case that assessment of capacity not triggered by diagnosis of MCI alone
- Need to be able to reach a clinician
  - In Wisconsin psychologist or physician (Chapter 54, WI State Statutes)
- Incorporate directives if participant as loses capacity after enrolling
- Clinical core has sub-studies with varying risk and “prospect for benefit”
- Genetic language – added complexity
- Not eligible if lack capacity at Baseline

U-ARE Model - applied



E-Consent

- Already incorporate elements:
  - Pictures
  - Descriptions separated out in text boxes
  - Stopping points to have participant engage
- E-consent add-ons
  - Using tablets
  - can incorporate video
  - Pop-text boxes
- Goal: increase interaction

Wisconsin Alzheimer's Disease Research Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Inspiring Hope for the Future

Main Consent Form
and
Authorization to Use and/or Disclose Identifiable Health Information for Research

When participant lacks consent

- Considerations for Research Involving Subjects Lacking Capacity UW-guidelines
- Risks and benefits must fall into one of the following categories:
  - Minimal risk;
  - More than minimal risk but the prospect of direct benefit;
  - More than minimal risk and no prospect of direct benefit but likely to yield important generalizable knowledge about participant's condition

UW-Madison Human Research Protection Program

- The IRB determines that the research cannot be performed solely with persons who possess decision-making capacity and:
  - The focus of the research is the disorder leading to the participant's lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated or
  - The focus of the research is not directly related to the participant's lack of decision-making capacity but the investigator has presented a compelling argument for including such subjects.

UW-Madison Human Research Protection Program

- A subject's preference not to participate in research = veto
- Should involve subjects in decision making to extent they can participate (e.g. assent)
- Contingency plan for disputes among possible representatives
- May need to exclude subject from participation
- Not necessary to solicit opinions of every possible representative

Who can provide informed consent

- UW-Madison's guidance
- Legally Authorized Representatives
  - Subject with Capacity
  - Research POA
  - Guardian
  - Healthcare POA
  - Next of Kin

Subject with capacity

- Must be consulted regardless of whether she has a research agent, guardian, or healthcare agent
  - Capacity is presumed to exist absent evidence
  - Subjects who have regained capacity should have guardianship terminated or power of attorney de-activated

Research Power of Attorney

Research Power of Attorney

- Agent's decision may not be inconsistent with the wishes and preferences of the potential subject as expressed in the power of attorney instrument
- Check POA document for subject's preference re: risk level of research
- POA is activated if appropriate member of research team (as defined by policy) finds that subject is unable to receive and evaluate information or effectively communicate decisions

Guardian

- Guardian “of the person”, not “of the estate” or “ad litem”
- Under Chapter 54 Court must appoint healthcare POA unless not in best interest of ward
- Must be a power awarded to guardian in court order

Healthcare Power of Attorney

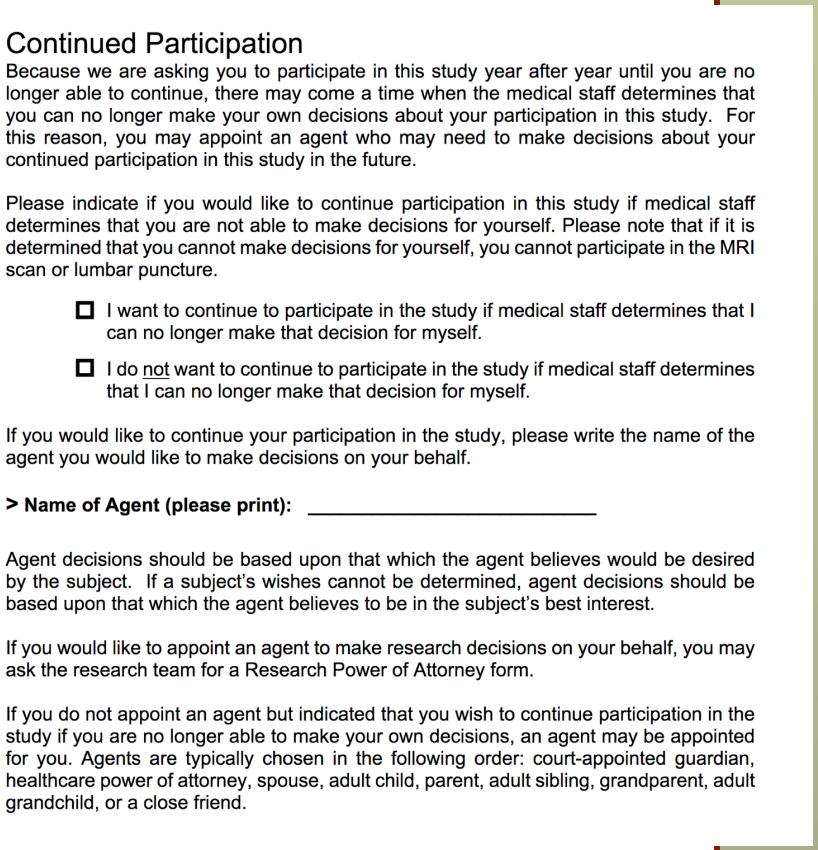
- Consult healthcare POA only if no guardian
- Under WI law, activation is by 2 physicians or 1 physician and 1 licensed psychologist
  - Signed statement that subject cannot receive and evaluate information or communicate decisions

Next-of-Kin

- Order of priority: spouse or domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, close friend
- Attempt consensus by all individuals within the class
- May be times when order of priority should not be followed (consult legal office)
- Next of kin should be someone who is actively involved in subject's care

Research Power of Attorney

- With UW Office of Administrative Legal Services, developed document
- Incorporate elements in consent document
  - Simplest
  - Addresses conversion
- Can download a version



Continued Participation

Because we are asking you to participate in this study year after year until you are no longer able to continue, there may come a time when the medical staff determines that you can no longer make your own decisions about your participation in this study. For this reason, you may appoint an agent who may need to make decisions about your continued participation in this study in the future.

Please indicate if you would like to continue participation in this study if medical staff determines that you are not able to make decisions for yourself. Please note that if it is determined that you cannot make decisions for yourself, you cannot participate in the MRI scan or lumbar puncture.

☐ I want to continue to participate in the study if medical staff determines that I can no longer make that decision for myself.

☐ I do not want to continue to participate in the study if medical staff determines that I can no longer make that decision for myself.

If you would like to continue your participation in the study, please write the name of the agent you would like to make decisions on your behalf.

> Name of Agent (please print): _____

Agent decisions should be based upon that which the agent believes would be desired by the subject. If a subject's wishes cannot be determined, agent decisions should be based upon that which the agent believes to be in the subject's best interest.

If you would like to appoint an agent to make research decisions on your behalf, you may ask the research team for a Research Power of Attorney form.

If you do not appoint an agent but indicated that you wish to continue participation in the study if you are no longer able to make your own decisions, an agent may be appointed for you. Agents are typically chosen in the following order: court-appointed guardian, healthcare power of attorney, spouse, adult child, parent, adult sibling, grandparent, adult grandchild, or a close friend.

https://kb.wisc.edu/gsadminkb/page.php?id=34102

Research Power of Attorney

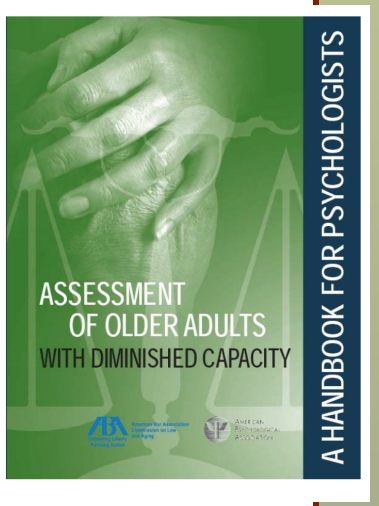
- Note: not yet widely used
- Must have capacity to designate Research POA
- Not legally tested

Documentation

- Capacity assessment
- Combined with
- Consent document
- A word about written documentation of informed consent
- Document decision process

Summary

- Recommend using a model to guide assessment
- Clinical decision nested in regulatory process
- Protocol can guide response to regulations
- Interface of clinical and legal worlds
- Most cases will NOT be adjudicated



Wisconsin Alzheimer's Disease Research Center

UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Thank you for your attention

Questions and Comments?

ceg@medicine.wisc.edu

Additional References

1. Appelbaum. Assessment of Patients' Competence to consent to treatment NEJM 2007; 357:1834-40.
2. Dunn et al. Assessing Decisional Capacity for Clinical Research or Treatment: A review of instruments Am. J. Psychiatry 2006; 163:1323-1334.
3. Palmer & Salva. The association of specific neuropsychological deficits with capacity to consent to research or treatment. J. of Intern Neuropsychological Society 2007; 13: 1047-1059.