

## 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

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## Acknowledgments

- No conflicts of interest
- Funding: NIA-NIH (P50 AG033514; R01 AG054059)
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## Outline

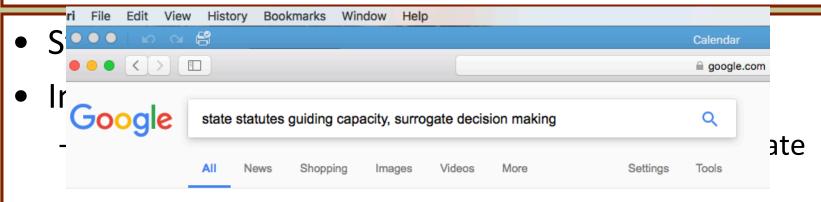
- Obtaining consent for research participation
  - Brief review of regulations and concepts
  - Research v Clinical assessments
- Assessment of Decisional capacity
  - U-ARE model
  - Adaptations (e-consent)
- When someone lacks decisional capacity
  - Legal standards
  - Legally authorized representatives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

### Informed Consent – History of Federal Regulation

- Historical abuses led to regulation
- Nuremberg Code (1946), Declaration of Helsinki (1964) Provide moral framework
- 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 Provides specific guidance
- National Bioethics Advisory Commission (NBAC) (2001)
  Provides specific guidance, especially

Provides specific guidance, especially for vulnerable populations

#### Informed Consent – State & Institutional Regulation



About 5,350,000 results (0.82 seconds)

#### Title 18-A, §5-805: Decisions by surrogate - Maine Legislature legislature.maine.gov/statutes/18-A/title18-Asec5-805.html -

A surrogate also is authorized to make any other health care decision for a patient ... to lack capacity and no agent or guardian exists, except that a surrogate may not ... all individuals having lower priority are disqualified from making the decision. ... Office of the Revisor of Statutes • 7 State House Station • State House Room ...

#### Section 5: Surrogate Decision-Making - Washington State Hospital ... www.wsha.org/our-members/projects/end.../section-5-surrogate-decision-making/ -

The Washington State statutes on guardianship and informed consent are included ... The surrogate decision-making statute specifies that a physician who is ... a guardian or other surrogate decision-maker is to be guided by the directive and ... (36) Finally, if at some point the resident regains decision-making capacity, the ...

#### 755 ILCS 40/ Health Care Surrogate Act. - Illinois General Assembly www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2111&ChapterID=60 -

Legislative **Guide** ... The enactment of **statutory** guidelines for private **decision making** will bring ... patients with decisional **capacity** and by **surrogate decision makers** on behalf ... "Health care provider" means a person that is licensed, certified, or otherwise authorized or permitted by the **law** of this **State** to administer health ...

## **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 decisionmaking capacity"
  - IRBs started to pay more attention to assessment of capacity
- Response to research practices with adults with mental illnesses

		1	Updated 09-10 Wis. Stats. Database GUA	ARDIAN	ISHIPS AND CONSERVATORSHIPS 54.01	
	Awc		CHAPTER 54 GUARDIANSHIPS AND CONSERVATORSHIPS			ssments
1			SUBCHAPTER I DEFINITIONS		SUBCHAPTER VII UNIFORM GUARDIANSHIP ACTS	
•	Overla	54.01 54.10 54.12	Definitions. SUBCHAPTER II APPOINTMENT OF GUARDIAN Appointment of guardian. Exceptions to appointment of guardian. SUBCHAPTER III NOMINATION OF GUARDIAN; POWERS AND DUTTES, LIMITATIONS	54.850 54.852 54.854 54.856 54.858 54.860 54.862 54.864	Definitions. United States uniform veterans guardianship act. Uniform transfers to minors act, definitions. Scope and juriediction. Nomination of custodian. Transfer by gift or exercise of power of appointment. Transfer authorized by will or trast. Other transfer by fiduciany.	evel of
	rogula	54.15 54.18 54.19	Selection of guardian; nominations; preferences; other criteria. General duties and powers of guardian; limitations; immunity. Duties of guardian of the estate.	54.866 54.868 54.870	Transfer by obligor. Receipt for custodial property. Manner of creating custodial property and effecting transfer; designation	
	regula	54.20 54.21 54.22	Powers of guardian of the estate. Petition to transfer ward's assets to another. Petition for authority to sell, mortgage, pledge, lease, or exchange ward's	54.872 54.874	of initial custodian; control. Single custodianship. Validity and effect of transfer.	
	U	54.25	property. Duties and powers of guardian of the person. SUBCHAPTER IV	54.876 54.878 54.880	Care of custodial property. Powers of custodian. Use of custodial property.	
	C + a + a	54.30 54.34	PROCEDURES Jurisdiction and venue. Petition for guardianship or for receipt and acceptance of a foreign guard-	54.882 54.884 54.886 54.888	Custodian's expenses, compensation and bond. Exemption of 3rd persons from liability. Liability to 3rd persons.	
	State	54.36	ianship. Examination of proposed ward.	54,890	Renunciation, resignation, death or removal of custodian; designation of successor custodian. Accounting by and determination of liability of custodian.	ice
		54.38 54.40	Notice. Guardian ad litem; appointment; duties; termination.	54.890 54.892 54.894	Termination of custodianship. Applicability.	
		54.42 54.44	Rights of proposed ward or ward. Hearing.	54.896 54.898	Effect on existing custodianships. Uniformity of application and construction.	
		54.46 54.47	Disposition of petition. Lis pendens, void contracts.	54.92 54.93	Uniform securities ownership by minors act.	$\sim$ 1 1 1
	– In V	54.48 54.50	Protective placement and protective services. Temporary guardianships.	54.950	Securities ownership by incompetents and spendthrifts. Definitions.	Statutes
	111 V	54.52 54.54	Standby guardianship. Successor guardian.	54.952 54.954	Custodial trust; general. Custodial trustee for future payment or transfer.	Juluces
		54.56 54.57	Visitation by a minor's grandparents and stepparents. Prohibiting visitation or physical placement if a parent kills other parent.	54.956 54.958	Form and effect of receipt and acceptance by custodial trustee, jurisdiction. Transfer to custodial trustee by fiduciary or obligor; facility of payment.	
		34.37	SUBCHAPTER V	54.960 54.962	Multiple beneficiaries; separate custodial trusts; survivorship. General duties of custodial trustee.	
		54.60	POST-APPOINTMENT MAITTERS Inventory.	54.964 54.966	General powers of custodial trustee. Use of custodial trust property.	
		54.62 54.625	Accounts. Transfer of guardianship funds of a Menominee.	54.968 54.970	Determination of incapacity; effect. Exemption of 3rd person from liability.	
		54.63 54.64	Expansion of order of guardianship; procedure. Review of incompetency and termination of guardianship.	54.972	Liability to 3rd person.	
		54.66 54.68	Final accounts.	54.974	Declination, resignation, incapacity, death or removal of custodial trustee, designation of successor custodial trustee.	
		54.72	Review of conduct of guardian. Guardian compensation and reimbursement.	54.976 54.978	Expenses, compensation and bond of custodial trustee. Reporting and accounting by custodial trustee; determination of liability	
		54.74 54.75	Compensation of guardian ad litem. Access to court records.	54.980	of custodial trustee. Limitations of action against custodial trustee.	
			SUBCHAPTER VI VOLUNTARY PROCEEDINGS;	54.982 54.984	Distribution on termination. Methods and forms for creating custodial trusts.	
		54.76	CONSERVATORS Conservator, appointment, duties and powers; termination.	54.986 54.988	Applicable law. Uniformity of application and construction.	
		54.70	consecutors, advantant, once and lowers, reministor.	JAC 100	curvenus y or approximation and constructions.	
		Cro 55, and	ss-reference: See s. 46.011 for definitions applicable to chs. 46, 50, 51, 54, 1 58. SUBCHAPTER I	cise p 757.6	"Court" means the circuit court or judge assigned to exer- robate jurisdiction or the assignee of the judge under s. (4m) or $851.73$ (1) (g) who is assigned relevant authority. "Decedent" means the deceased individual whose extate is	

#### 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.

of the individual.

(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 indi-(3) "Conservator" means a person who is appointed by a court viduals with an intellectual disability, which has continued or can at an individual's request under s. 54.76 (2) to manage the estate be expected to continue indefinitely, substantially impairs an individual from adequately providing for his or her own care or cus-

2009-10 Wis, Stats, database current through 2011 Wis, Act 286, Includes all Legislative Acts and all Supreme Court Orders enacted before Oct. 1, 2012. Statutory changes effective on or prior to Oct. 1, 2012 are printed as currently in effect. Changes effective after Oct. 1, 2012 are designated by NOTES. See Are the Statutes on this Website Official? (10-3-12)

## 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 decedent and a person inter the decedent was a memb King or at the facilities op-

### Definitions

affairs under s. 45.50 at the time of the decedent's death.

(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.

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5. Any other individu any fiduciary that the cou

(18) "Least restrictive sible restriction on person 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 a damage, mental or physic or absorption of substance stantially impairs an indiv care or custody.

(23) "Personal repres letters to administer a dec

Aw	<b>54.36</b> 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 fur-
– In	nish a written report stating the physician's or psychologist's pro- fessional opinion regarding the presence and likely duration of any medical or other condition causing the proposed ward to have on tl
	incapacity or to be a spendthrift. The privilege under s. 905.04 must does not apply to the of the report to the p ian ad litem, and the Who can legally make determinations
	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 spend-
	thrift, that he or she has a right to refuse to participate in the sough examination, absent a court order, or speak to the physician or sough
	psychologist, and the report to the court even Right to refuse participation in eval
	proposed ward prior to each examination establishes a presump- tion that the proposed ward understands that he or she need not (2)
	tion that the proposed ward understands that he or she need not (2) ( speak to the physician or psychologist. Nothing in this section by the
	prohibits the use of a report by a physician or psychologist that is acts
	based on an examination of the proposed ward by the physician eign
	or psychologist before filing the petition for appointment of a 1 guardian, but the court with the theory of the second s
	determining whether the What data can be used to draw
	posed ward's current stat given to the report.

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

- 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

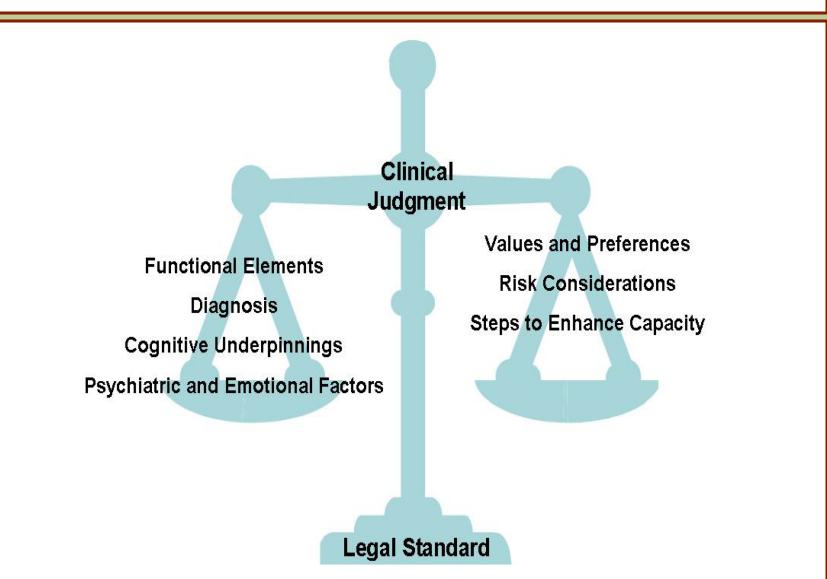
- Consistency improved by use of a model
  - Adopted Appelbaum and Grisso's model
- Elements of capacity:
  - 1. Understand
  - 2. Appreciate
  - 3. Reason
  - 4. Express a choice

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

- Ask four questions to assess decisional ability
- Elements of capacity:
  - 1. Understand: This is a research study, do you have to participate?
  - 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

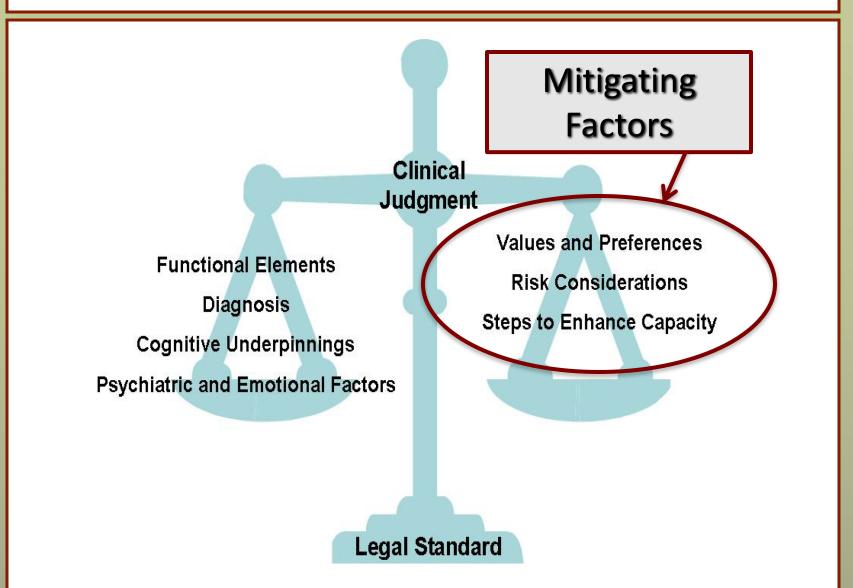
- Questions asked after consent document reviewed
- Consider
  - Values and Preferences
  - Cultural factors
  - Language
  - Communication style
  - Decision making style
  - Riskiness of behavior or decision
- Are there ways to enhance capacity?

## Framework



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

## Framework



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

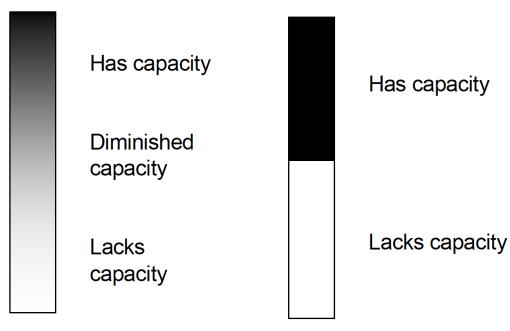
## Ultimately – a clinical decision



• Continuum v. Category

Clinical Capacity

### Capacity Judgment



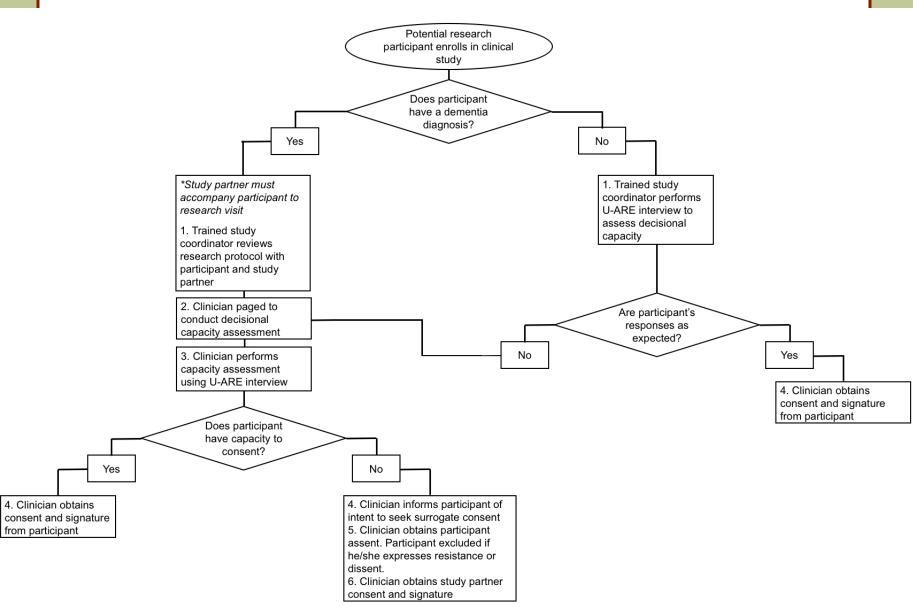
## Ultimately – a clinical decision

- 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



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#### 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 <u>not</u> 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**

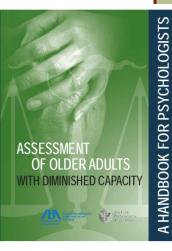
- Note: not yet widely used
- Must have capacity to designate Research POA
- Not legally tested

### Documentation

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

## Summary

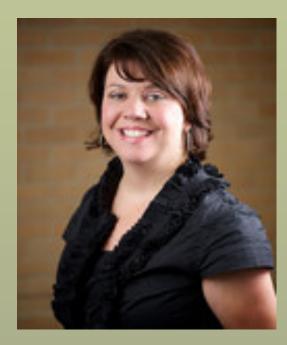
- Recommend using a model to guide assessment
- Clinical decision nested in regulatory process
- Protocol can guide response to regulations
- Interface of clinical and legal worlds
- Most cases will NOT be adjudicated





### Wisconsin Alzheimer's Disease Research Center

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# Thank you for your attention Questions and Comments?



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## **Additional References**

- Appelbaum. Assessment of Patients' Competence to consent to treatment NEJM 2007; 357:1834-40.
- Dunn et al. Assessing Decisional Capacity for Clinical Research or Treatment: A review of instruments Am. J. Psychiatry 2006; 163:1323-1334.
- 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.