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Ethical Issues in Conducting Research with Persons with Dementia

Melissa Aselage, MSN, RN, FNP-BC
2009-2011 John A. Hartford Foundation BAGNC Scholar
Doctoral Student, Medical University of South Carolina
Lecturer, University of North Carolina Wilmington
99 Jonathan Lucas Street
Charleston, SC 29425
aselagem@uncw.edu

Brian Conner, MSN, RN
Doctoral Student, Medical University of South Carolina
Nursing Instructor, Lander University
99 Jonathan Lucas Street
Charleston, SC 29425
bconner@lander.edu

Teresa Carnevale, MSN, RN
Doctoral Student, Medical University of South Carolina
Clinical Educator, Lenoir-Rhyne University
99 Jonathan Lucas Street
Charleston, SC 29425
carnevalet@lr.edu

Abstract

Conducting research with persons with dementia can be a daunting task for new and experienced researchers. A myriad of concepts related to the consent process need to be considered. Historically, efforts to provide federal guidelines for the consent process with persons with dementia have been unsuccessful. Since 1979, the Belmont Report has been the guide for individual Institutional Review Boards and researchers. Efforts are currently underway to develop federal guidelines, but considerable time is anticipated before approval and implementation would take place. Existing international guidelines for defining capacity and the process of consent are examined briefly for comparison. The purpose of this review is to provide historical background and an overview of current regulatory guidelines related to the consent process; examine the role of

legally authorized representatives; explore decision-making capacity, capacity, and competency as influencing factors in obtaining consent and assent both in the United States and internationally; and, to discuss methodological challenges and considerations. A dialogue among the present authors resulted in a synthesis of four exemplars as a “partnership of consent” and subsequently an algorithm was designed to assist future researchers.

Keywords: research, dementia, ethics, guidelines, regulations, aging, informed consent, assent

Introduction

Individuals with diminished decision-making capacity (cognitively impaired) are defined as individuals with mental retardation, some forms of mental illness, or dementia, whether temporary, progressive, or permanent, or as the result of trauma.[1] Of these cognitive impairments, dementia in the older adult warrants close attention due to the growing elderly population. Estimations are that 5.3 million Americans currently have been diagnosed with dementia and by mid-century this number will increase to 16 million.[2] Globally, in 2010, approximately 35 million persons will be living with dementia. The global rates are expected to double every 20 years to 115 million persons by the year 2050.[3] Given the estimates that rates of dementia will increase to alarming numbers, and no current treatment exists to cure the disease, research to support the needs of this vulnerable population will be critical.[4] It is a widely held belief that persons with dementia (PWD) should be included rather than excluded in studies that would benefit themselves or others.[5-7] The question of inclusion and how best to navigate the consent process is part of the ethical and methodological challenge that exists in dementia research.[8]

Federal guidelines for consent exist for researchers conducting studies with children and prisoners;[9] however, the literature indicates that research with the population of PWD is fraught with a lack of consensus for definitive guidelines to be used. Further, no clear international consistency exists for this population.[4,10-13] The responsibility lies with local Institutional Review Boards (IRB) to protect cognitively impaired persons with significant guidance by the Office of Human Research Protection. The Belmont Report lists the basic ethical principles by which researchers are guided; respect for persons, beneficence, and justice.[14] Examples of how these principles might be violated in research with PWD include not valuing the ability to make decisions in light of a cognitive impairment (respect for persons),[15] discussing the study with the legally authorized representative (LAR) without simultaneously obtaining the assent of the PWD (beneficence),[15] or exclusion of PWD on the basis of the cognitive impairment (justice).[8] Application of these principles is executed via informed consent, assessment of risk versus benefit, and selection of subjects.[14] The following discussion will focus on the application of informed consent.

Persons with dementia, from mild to severe, and their LAR, must be able to understand the abstract concepts of equipoise, interventions, use of placebo, and randomization. Unfortunately, full comprehension of these concepts may not always be possible and researchers must take steps to minimize therapeutic miscommunication.[16,17] As overwhelming as the process may be for PWDs and their LARs, it is also a daunting task for researchers to consider all the facets related to ethically conducting research with PWD, and to meet all regulatory guidelines. A gap in the literature exists in a synthesis of the multiple ethical and regulatory facets researchers must consider in the consent process with PWD. The current literature often fragments concepts; all of which are important for researchers to acknowledge in order to adequately protect human subjects. PWD should be included in research as they continue to have value as individuals. Research is increasingly needed to provide insight as to how to preserve function and improve the quality of life for this vulnerable group.[16]

The purpose of this review is to provide a historical background and overview of current regulatory guidelines related to the consent process; examine the role of legally authorized representatives; to explore decision-making capacity, capacity, and competency as influencing factors in obtaining consent and assent; and to discuss methodological challenges and considerations. A dialogue among the present authors resulted in a synthesis of four exemplars as a "partnership of consent" and subsequently designed an algorithm to assist future researchers.

Methods

A computer database literature search was conducted from May through October of 2009 using the Cumulative Index to Nursing and Allied Health Literature (CINAHL) database, Medline, Ovid, Pubmed, and ProQuest. Key words used for this search strategy included: *dementia, ethics, research, informed consent, aging, guidelines, regulations,* and *consent*. Articles selected had a specific focus on research with older adults with dementia, and discussed relevant areas related to ethical considerations, regulatory guidelines, consent, assent, or methodological considerations for this population. A total of 25 articles were identified as relevant. Reviewed publications included articles from 1997 to 2009.

Secondarily, an online search was conducted. Websites for the countries identified in the articles were visited and a brief summary of how capacity to provide informed consent was included for comparison of international guidelines (Table 1). Intrigued by the discussion related to the role of individual IRB involvement, authors arbitrarily searched four research intensive university websites to determine how these organizations defined the issues of decision-making capacity, capacity, and competency websites for researchers. Universities were chosen from different parts of the United States and IRB guidelines reviewed to determine guidance available to researchers (Table 2). Federal agency websites were also investigated regarding guidelines related to this population as primary sources of information.

Regulatory Guidelines

Beginning in the 1970's, the National Commission for the Protection of Human Subjects recommended provisions for protecting PWD, yet to date, federal guidelines in the United States do not exist beyond taking "additional safeguards."[11,18,19] The responsibility of determination of "additional safeguards" are left to individual researchers and ultimately the IRB, which is directed by the Office for Human Research Protections.[12,20-22] In 1998, the National Bioethics Advisory Commission proposed new federal guidelines, but implementation of the recommended protections would make some research logistically impossible.[15,21] Two reasons for the continued debate are cited in the literature: 1) states are to determine their own definition of a LAR, with few states actually doing so; and, 2) there remains a lack of consensus of how much protection is needed for subjects enrolled in studies based on the LAR consent.[10,22] In 2000, the National Institutes of Health began to require protection of human subjects for all funding.[21]

The most recent development by federal agencies is that the Secretary's Advisory Committee on Human Research Protections (ADCHRP) has formed a Subcommittee for the Inclusion of Individuals with Impaired Decision-making in Research (SIIIDR). This subcommittee is presently drafting recommendations for changes in the federal regulations but this is expected to be a lengthy process.[16,23] The framework for the work of the subcommittee revolves around three questions:

1. "How do we define (and how do IRBs, investigators identify) the populations requiring additional protection?",
2. "How do we decide who may provide consent for those who are unable to consent for themselves?", and
3. "Approval criteria and what is a "reasonable" risk-benefit relationship when consent is provided by a LAR?"[23]

Until this work is complete, the Belmont Report asserts a respect-for-persons principle, and the federal policy for the Protection of Human Subjects (aka "Common Rule") does allow a LAR to sign informed consent for participation in research on behalf of individuals who cannot provide this because they are incapable of doing so on their own.[12,14,21,22] Some US states (e.g. California and Virginia) have determined the order of priority for potential research surrogates: those previously appointed as a research surrogate, legal conservators or guardians, spouses, domestic partners, adult children, custodial parents, adult siblings, and adult grandchildren.[22]

The general strategy researchers employ in the consent process is to provide information about the study and assess the person's decisional capacity and understanding as well as the persons' capacity to consent. There are no specific instruments or standards to guide researchers in this process. Additionally,

researchers must be able to identify a LAR to provide informed consent for those incapable of doing so, obtain assent and written consent.[19,21] Other recommendations take the consent process further by eliciting assent with each research encounter.[8,24]

Persons with dementia and legally authorized representatives

Dementia is a disease that results in a progressive loss of cognitive function, therefore rendering the person more vulnerable as the disease progresses and cognitive function declines. PWD may be involved in all types of research with varying levels of risk and would require some level of "additional safeguards."[9] Determining how much protection is needed for this population appears to be one of the key elements involved in resolving the issue of federal guidelines for researchers using this population.[13] Defining "additional safeguards" is left to IRBs and varies from state to state, and institution to institution.[9,11]

The only federal requirement for researchers is that PWD should have a LAR available to sign informed consent before participating in any research study.[25] LARs are referred to by many terms in the literature (e.g. research surrogate, proxy, substitute decision makers) and are people such as family members, close friends, or a legally appointed guardian.[11,13,15,26] Defining who may serve as the LAR is left to individual states, and many states have not clearly defined qualifying LAR policies.[13] In addition, lack of availability of a LAR is often a reason to exclude the person from the study.

Decision-making capacity, Capacity, and Competency

As dementia progresses, persons demonstrate increasing loss of *capacity, decision-making*, and *competency* over time. *Decision-making capacity* is generally held to be present when one possesses the ability to understand relevant information, appreciate the nature of the situation and its consequences, reason by manipulating information, and express a choice.[27] The ability to make day-to-day decisions (e.g. what clothes to wear, where to sit, etc.) often remains intact in mild to moderate dementia, but the person may lack the capacity to consent to research.[19] This differentiation becomes critical when researchers obtain informed consent from a LAR, but still promote the autonomy of the PWD by allowing an opportunity for make a decision regarding assent.

Capacity differs from decision-making capacity in that the person must be able to express understanding of consequences. Capacity can diminish over time, in that a person can possess capacity in the earlier stages of dementia but during longitudinal research may lose capacity.[26] Capacity has been defined as performance on measures of the ability to make decisions.[28] Some IRBs have taken the initiative to differentiate these concepts for researchers.[24,29-31] (Table 1)

There are also no clear guidelines for any one particular method to assess capacity; however, one article found that drug studies tended to do a better job of assessing capacity than non-drug studies.[19] In this study, over 84% of informed consent representatives (ICR) did not attempt to determine if the LAR or the PWD possessed the capacity to make the decision of informed consent. The 16% who did assess capacity queried if the LAR "understood" the study as it had been explained (Do you understand what I mean? Is that clear?) or asked an open-ended question of comprehension (What are we asking you to do?).[19] Assessment of capacity only occurred in the seven drug studies examined, and this was assessed by physicians. The basis of this determination was either on prior clinical assessments or responses by the LAR during the informed consent process. No standardized method or instrument was used in any determination of capacity.[32] This complicates the picture further considering researchers are called to assess and reassess capacity at each stage of research.[15,33,34] Federal guidelines leave a gap in setting standards for decision-making capacity, and many IRBs do not have specific requirements for determining capacity.[21,22] Persons with a medical diagnosis of dementia may lack the capacity to make decisions regarding informed consent, therefore the LAR is designated this responsibility. However, the lack of capacity in the PWD does not override the PWD's ability to continue to make decisions related to participation and therefore continued assessment for assent should be pursued.[16]

Competency is a legal term, and one's level of competency is assessed by court proceeding to determine a declaration of competence or incompetence.[35] The concept of competency has been linked with that of self-awareness, and the problem with assessing cognitively impaired individuals is that cognitive function may be sporadic, fluctuating, and context-dependent.[36] Thus, an individual may be deemed legally incompetent yet still demonstrate periods of lucidity and awareness of self and surroundings which would allow them to participate in decision-making.

Several countries have guidelines publicly available for researchers related to the issue of defining capacity and the consent process (See Table 2).[8,10,15,37] For example the Tri-County Policy Statement sets the ethical standard for Canada,[15,37] Australia is directed by the National Health Medical and Research Council,[38] Scotland passed the Adults with Incapacity (Scotland) Act in 2000,[39] and the UK has the Mental Capacity Act 2005.[10,40]

Informed consent by self and proxy, Assent, Dissent

Informed consent has been a requirement when conducting research since the introduction of the Nuremberg Code after World War II.[14] However, while informed consent is legally required for all research participants, assent is only legally required when the research population is considered vulnerable, as in persons with cognitive impairment.[15] Researchers do not agree on how to define or assess assent capacity in the cognitively impaired.[27] Assent generally is

believed to be obtained in dementia when the participant expresses affirmative initial and ongoing willingness to participate. In contrast, dissent is the refusal to participate, even in the presence of a willing informed consent by self or proxy.[14,15,33] Researchers are generally encouraged to consider the nature of the research, nature of dissent, and nature of decisional capacity (fluctuating, limited, or incomplete capacity) and to attend to the underlying feelings exhibited in assent or dissent situations, seeing all of these components as complexities within the research process.[8,14,15]

Current federal guidelines leave a gap in setting standards for assent and dissent, but the National Commission for Protection of Human Subjects research recognizes assent as an authorization by a person, who remains functional, but whose capacity to understand and judge is somewhat impaired by illness or institutionalization.[14,22,27] A common parameter to determine a person with dementia in conjunction with the medical diagnosis of dementia along with the subsequent need for proxy informed consent or assent, is to use the Mini-Mental State Examination (MMSE).[17,27,41] The MMSE was intended as a screening instrument for cognition, and is not always the best marker of capacity in the person with dementia as capacity varies along the disease trajectory.[8,11,15]

Methodological challenges and considerations

Many nursing researchers conduct descriptive or exploratory studies of disease experiences or interventional studies.[16] When conducting longitudinal studies with PWD in the early stages of the disease, issues may arise as to the impact of time on the cognitive ability of the PWD. It is recommended to work closely with the IRB to create clear protocols of the recruitment and informed consent process, and IRBs will be able to help with protocol specific guidance.[16]

Researchers may use the MMSE to determine cognitive abilities, yet the practice is increasingly cited as inadequate and does not take into consideration the abilities of the person with dementia to expressly talk about his or her life, needs, and experiences.[8] The MMSE does not\ consider any life experiences which require any long-term memory, but rather a very present moment snapshot of the ability to recall or manipulate facts.[8]

Obtaining informed consent is often considered a *one-time event* and Hellstrom, et al. (2007) pose a shift in thinking should occur and this be viewed as a *process* of consent and assent and would be appropriate for repeated measurement studies. Further, the importance of establishing rapport before, during, and after a research interaction creates a positive perception/ feeling for the person with dementia.[8] Researchers must be aware of verbalizations and distressing behaviors (e. g. shrieking, agitation, repetitive verbalizations) in the PWD that may be interpreted as a sign of distress or a sign of agreement, as well as consideration of non-verbal cues (e. g. facial grimacing, hand-wringing, rocking movements).[8,36] Dewing (2007) describes this as part of the '*process consent*

method' that can be used with research participants with dementia.[26] In this method, capacity is further acknowledged as situational, which can be strengthened and invigorated with the use of the process that includes watching for verbal and non-verbal cues and the utilization of caring relationships.[26]

Hellstrom et al. (2007) also urged researchers to consider the influence of gatekeepers on the person with dementia, as gatekeepers may use their influence to sway situations within the context of the study. The examples provided by Hellstrom et al. (2007) describe an incident whereby a spouse (LAR) refused to allow a person with dementia to participate in a study, when the person with dementia indicates a willingness or interest. Another incidence may describe the spouse (LAR) of a person with dementia attempting to quell anxieties of the impending research interaction because of the perceived benefit of the study to spouse (LAR).

Guidance for Researchers

Many scientists have published guidelines for the process of obtaining informed consent, assent and/or dissent when conducting research with older adults with dementia. Four articles presented similar ideas that the current authors considered to be the exemplars.[7,8,15] The general theme that emerged was viewed by the current authors as a "partnership of consent".

The first part of the process involves the researcher partnering with the LAR and the PWD at the initial point of obtaining informed consent and assent to participate in the study. Emphasis is placed on developing a relationship with the PWD to show interest in them as an individual rather than a "hit and run" approach.[8,42] After enrollment, as dialogue and interaction ensues, continual assent or dissent by the PWD is assessed by the researcher at each contact point along the research continuum.

When conducting research with PWD, the researcher would first make contact with the LAR of the person with dementia through "gatekeepers". Gatekeepers may be persons who are working directly with the PWD (in any healthcare setting) and are able to identify the LAR for the PWD. The LAR may be a named agent or guardian, or the person the gatekeeper would ordinarily be contacted for medical treatment or care needs consent.[8,15] This person can legally give consent to the initiation of formal contact with the participant and should be included in the negotiation to participate in the study.[7,8,15] An initial informed consent discussion would occur between the researcher, LAR, and the PWD. The LAR and PWD would then indicate consent/ assent and the LAR would sign the informed consent and the PWD would be enrolled in the study - or decline to participate.

As the research begins with the PWD, the researcher would ask permission in order to proceed with the intervention monitoring for cues of continued assent.

The researcher should interpret verbalizations or distressed behaviors (e. g. shrieking, agitation, repetitive verbalizations) and/ or non-verbal behavior (e. g. facial grimacing, hand-wringing, rocking movements) as a lack of adequate assent.[8,15]

If the PWD says “yes”, the intervention would occur. If the PWD says “no”, then the researcher could spend time with the PWD in an attempt to create a more conducive environment and check with the gatekeeper (and LAR, if necessary) to see if this is a difficult day for the PWD, or identify any other factors that may contribute to the negative assent. A second approach could be attempted after resolution of any underlying issues, or on another day. If the PWD declines assent a second time, they would be excluded from the study.[8,15] Repeated attempts to obtain assent are not recommended, and dialogue between the researcher and LAR should continue to best protect the PWD.[15,16]

These guidelines are considered a partnership of consent and are diagrammed as an algorithm. Dependent on the design of the research study, this process may occur more than one time, but the algorithm poses only one cycle. Using the algorithm, a researcher would be able to clearly and easily indicate the human protection in place to the IRB for use in a research study.

Conclusions

At this point in our nation’s history, we have been unable to agree on clear guidelines for the process of informed consent with PWD, though work is currently in progress towards this goal. Presently, the majority of responsibility falls on the individual researchers, states and IRBs. This review provides a basic outline for considerations researchers need to be aware of when obtaining consent for research with this population. The lack of consistency for the consent process shifts responsibility to researchers to know the appropriate individual IRB guidelines, and to work closely with IRBs to create clear protocols to protect human subjects. Researchers are called to be aware that PWD are individuals, and have value to offer to the research arena. Respect for persons and beneficence can be achieved through promoting autonomy in the consent and assent process, and inclusion promotes justice. Each of these ethical principles and a partnership of consent approach promote thoughtful and respectful consideration for the person behind the cognitive impairment.

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Table 1

International Agency Guidelines related to defining competency and consent process

Canada **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**[37]	Tri-Council is composed of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This document stipulates that regardless of whether or not a person is incompetent to consent for themselves, they should not be excluded from research. These individuals are still unique individuals and deserve the same inclusiveness as competent individuals.
Scotland **Adults with Incompetency (Scotland) Act 2000**[39]	Research must be approved by the Ethics Committee composed of Scottish Ministers. If guardianship is recognized by Scottish law, this person may sign consent on half of the incapacitated person. “incapable” means incapable of— (a) acting; or (b) making decisions; or (c) communicating decisions; or (d) understanding decisions; or (e) retaining the memory of decisions.
Australia **National Statement on Ethical Conduct in Human Research**[38]	Position statement created jointly by the National Health and Medical Research Council, the Australian Research Council, and the Australian Vice-Chancellors’ Committee. Persons with cognitive impairment should be included in research, when appropriate. Consent should be sought from the person with the cognitive impairment, and a guardian if the person does not have the

	capacity to grant consent. Respect should be given if the person with the cognitive impairment is reluctant or refuses to participate in the study.
UK **Mental Capacity Act 2005**[40]	Guidelines available through the Office of Public Sector Information. A person is unable to make a decision for himself if he is unable— (a) to understand the information relevant to the decision, (b) to retain that information, (c) to use or weigh that information as part of the process of making the decision, or (d) to communicate his decision (whether by talking, using sign language or any other means).

Table 2

Comparison of IRB definitions

IRB	Capacity	Decision-making	Competence	Cognitively impaired
Oregon Health and Science University[30p1]	The IRB does not prescribe standardized measures for PIs to use when assessing a prospective subject's capacity. However, such persons may be assessed based upon their abilities to understand and to express a reasoned choice concerning the: -Nature of the research and the information	Limited decision-making capacity or decisional impairment used to refer to adults who may have one or more of four types of limitations as defined by NBAC. These include: 1. Fluctuating decisional impairment - e.g. schizophrenia, bipolar disorders, depressive disorders, and delirium; 2. Progressive decisional impairment - e.g. persons for whom		

	relevant to his/her participation; - Consequences of participation for the subject's own situation, especially concerning the subject's health condition; - Consequences of the alternatives to participation; - Potential risks involved in the study; and - Procedures to follow if he/she experience discomfort or wishes to withdraw. The capacity to understand all of these concepts may not be necessary in order to self-consent to participate in a particular research protocol. However, greater capacity will be required for higher-risk protocols, as determined by the IRB. Cognitive testing may be	decision-making deficits can be predicted due to the course of their disease or the nature of their treatment. Although these individuals may be decisionally capable in the early stages of the disease progression, such as in Alzheimer's disease or other forms of dementia, they have prospective incapacity; 3. Limited decisional impairment - e.g. persons with limited capacity but who are still able to object or assent to research, as in the case of stroke, more advanced Alzheimer's disease, or developmental disability resulting in cognitive impairment; and 4. Complete decisional impairment - e.g. persons who have lost the ability to make decisions that involve significant reflection, as in		

	required by the IRB to inform capacity assessment, but will not always be required.	the later stages of Alzheimer's disease or unconsciousness due to trauma.		
University of Illinois at Chicago[20p1-2]		Decisional Capacity: In Illinois, "the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment or forgoing life-sustaining treatment and the ability to reach and communicate an informed decision in the matter as determined by the attending physician." (755 ILCS 40/10).	Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See terms Incompetence, Incapacity) Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As	Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill

			a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions (e.g., writing a will) should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations. (Penslar RL, Porter JP. Institutional Review Board Guidebook, Chapter 6: Special Classes of Subjects, OHRP, 1993).	patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. (Penslar RL, Porter JP. Institutional Review Board Guidebook, Chapter 6: Special Classes of Subjects, OHRP, 1993).
Johns Hopkins Bloomberg School of	Incapacity: Refers to a person's mental status.	Decision making capacity: Often defined in state statutes –	Technically, a legal term used to denote capacity to act	Having a psychiatric disorder (e.g., psychosis,

Public Health[31p3]	It is the inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.	generally understood as the ability to understand the choice(s) presented, to appreciate the implications of choosing one alternative rather than another, and to make and communicate a choice.	on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Competence may fluctuate as a function of the natural course of a physical or mental illness, response to treatment, effects of medication, and general physical condition.	neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, seriously or terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best

				interests.
Yale Institutional Review Board[29]	Independent assessment of capacity to consent: Assessment by an individual who has no interest or affiliation to the study or to the sponsors of the study. The method of assessing capacity to consent ranges from an informal investigator peer evaluation to an independent health care professional utilizing formal instruments of assessment (e.g. dementia rating scales).			Decisionally impaired: An individual who has a compromised capacity to understand information and make a reasoned decision about participation in research. Such incapacity may be either temporary, permanent or may fluctuate. Decisionally impaired individuals may include women in active labor, individuals under the influence of drugs or alcohol, individuals under extreme emotional distress (i.e., experiencing pain, hearing of a newly diagnosed life threatening or terminal illness for self or loved one, being in the preoccupied condition of anticipating imminent major

				surgery) or individuals suffering from cognitive disorders. Decisional impairment as defined throughout this policy is distinct from legal incompetence. The latter refers to a designation of status that has been adjudicated in a court proceeding. Usually it refers to an inability to manage one or more significant areas of life such as business or monetary affairs. An individual may be decisionally impaired yet legally competent. An individual who is legally designated as incompetent probably will be decisionally impaired in terms of consenting to research.

Figure 1

Partnership of Consent

Based on work by Hellstrom, et al.(2007); Grout (2004); Slaughter, et al. (2007); Beattie (2009)