Informed Consent in Two Alzheimer’s Disease Research Centers: Insights From Research Coordinators

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ABSTRACT

Background: Informed consent (IC) is critical to performing ethical research. Unfortunately, the IC process and supporting IC forms are frequently burdensome and do not necessarily meet the informational needs of participants. The intersecting legal and ethical challenges of obtaining IC from individuals with memory or cognitive deficits further exacerbate existing IC shortcomings. For this reason, study coordinators play a critical role in facilitating the IC process in Alzheimer’s disease (AD) research. To identify opportunities to improve how IC is obtained in AD research, we examined the IC process from the perspectives of study coordinators at two Alzheimer’s Disease Research Centers (ADRC).

Methods: We performed semi-structured interviews with 15 study coordinators from two ADRC sites detailing their experience obtaining IC. Interviews were conducted in private, recorded, transcribed, and independently coded using the constant comparative method of grounded theory. Key themes were explored as they emerged.

Results: Coordinators reported overall satisfaction with the IC process. However, many reported difficulties maintaining participant attention, explaining complex procedures, and addressing medical misinformation. Although the centers use site-specific consent forms, coordinators at both centers stressed that their IC is too long and the supporting IC forms are too complicated. Coordinators indicated modifying the IC process to the perceived needs of individual participants. Adaptations reported include altering the cadence and vocabulary they employ, using supplemental materials, varying the order of IC topics, and limiting the depth of information presented.

Conclusion: A qualitative analysis of interviews with study coordinators reveals opportunities to improve how we obtain IC in AD research. These insights will be used to create an electronic informed consent (eConsent) designed to boost engagement, enhance trust, and improve understanding by supporting participants’ direct agency in the IC process.

Background

Informed consent (IC) is fundamental to the ethical and lawful conduct of research. Individuals are entitled to receive information about the purpose, benefits, risks, and procedures, and make autonomous decisions regarding their participation in biomedical research (World Medical Association 2013). The IC process is designed to facilitate decision making, with IC forms supplying the written explanation about the research and documenting a participant’s decision to enroll.

Much has been written about the need to improve the IC process in general and the accompanying IC forms specifically (Thorogood et al. 2018; Kraft and Doerr 2018; Sachs, Greg A and AGS Ethics Committee 1998). Yet, a comparison of the quality of IC forms in clinical trials and in research studies over the past 30 years shows that they have nearly doubled in length, are more difficult to read, and often still lack key information (Malik and Cooper 2018; Albala, Doyle, and Appelbaum 2010). Recommendations for improving the IC process emphasize redesigning IC forms, including modifying the written language (avoiding legalese, writing at the middle school grade level or below), using pictures to help explain complicated concepts, presenting best case/worst case outcomes, storytelling, and focusing on the participants’ values or the perceived needs of a “reasonable person”...
Individuals with memory deficits or early dementia pose additional ethical and operational concerns to effective IC. The progressive memory and cognitive deficit of potential participants in AD research add challenges (Biros 2018; Dalpê, Thorogood, and Knoppers 2019). Researchers may need to assess current decision-making capacity and weigh possible future cognitive decline. Further, research teams may need to define the role of primary caregivers and/or legal representatives in IC. While regulations may allow a legally authorized representative (LAR) to provide proxy IC for people with diminished decision-making capacity (Saks et al. 2008; Office for Human Research Protections 2017; Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization 2017) a key barrier to enrolling research participants through a proxy is the proxy’s perception of logistical burden and/or the proxy’s own level of interest (Fields and Calvert 2015; Warren et al. 1986). Alternatively, researchers may promote the involvement in research of individuals with cognitive impairment through efforts to support the decisional autonomy of these individuals (Sachs, Greg A and AGS Ethics Committee 1998; Howe 2012).

Study coordinators play a critical role in research involving people with memory deficits or early dementia, facilitating the recruitment, IC, and retention of research participants. They present the principles of the research study, explain the procedures, answer questions from potential participants, and often engage participants’ caregivers or LAR (Kohara et al. 2017). Coordinators are at the front lines, balancing advocacy for the research itself against protection of participants from undue influence (Davis et al. 2002). Therefore, it is critical to seek counsel from study coordinators when evaluating and refining an IC experience for persons with cognitive impairment.

The Alzheimer’s Disease Research Center (ADRC) network is a large initiative funded by the US National Institute of Aging. Its goals are to understand Alzheimer’s disease (AD) and related disorders, and to improve the diagnosis, management, and prevention of these conditions. A central component of all ADRCs is the recruitment and maintenance of a longitudinal cohort of participants who contribute to research by volunteering for intensive phenotyping. The majority of ADRCs enroll cognitively intact participants, people with mild cognitive impairments, and individuals with dementia in the intensive phenotyping cohort.

We explored the views of study coordinators about the IC process and supporting IC forms used at the University of Wisconsin and Emory University ADRCs. Both centers are conducting separate but analogous longitudinal studies of changes in memory and other cognitive skills with repeated assessments of physical and cognitive health every one to two years. In both studies, participants agree to answer health and lifestyle questionnaires, share their electronic medical records, complete cognitive assessments and neurological exams, give blood for biomarkers and genetic testing, have brain MRI and PET scans, and give cerebrospinal fluid through lumbar punctures. In addition, the Emory study analyzes participants’ gait. In this formative evaluation, we sought the study coordinators’ insights to improve the IC process.

**Methods**

**Informed consent forms**

We reviewed each center’s IC form for content and readability levels, using the Flesch-Kincaid Reading Ease (FRE) (Flesch 1948), the Flesch-Kincaid Grade Level (FKGL) (Kincaid et al. 1975) and the Gunning Fog score (GF) (Gunning 1968). FRE evaluates comprehension using word and sentence length on a 100 point scale. A higher FRE score indicates a more accessible text. FKGL considers sentence length and number of syllables per word. FKGL provides an equivalent US grade level as an indicator of the level of formal education needed to read and understand a text comfortably. The GF score uses the percentage of difficult words and sentence length to determine the reading ease. We performed the readability tests using MS Word tool and a readability calculator (Scott 2019).

**Interviews**

15 face-to-face semi-structured interviews were conducted with the study coordinators from two Alzheimer’s Disease Research Centers:
UW-Madison (WISC): Wisconsin Alzheimer’s Disease Research Center, 600 Highland Avenue, J5/1 Mezzanine, Madison, WI 53792
Emory University (EU): Goizueta Alzheimer’s Disease Research Center, 12 Executive Park Dr., NE, Atlanta, GA 30329

Interviews were voluntary. Coordinators agreed to be interviewed, audio recorded, and quoted anonymously in publication. The interviews were conducted in a private setting by a colleague without a direct supervisory role to the study coordinator but with similar educational background and professional experience. Coordinators were encouraged to share their opinions candidly and could stop the interview at any time for any reason.

The interview questions and semi-structured interview guide provided to the interviewer were developed to:

1. Identify the barriers and facilitators of consent from the coordinator’s point of view;
2. Identify the coordinator’s perceived informational needs and preferences of individuals contemplating participating in ADRC;
3. Compare the coordinator’s experience with a traditional or an expanded IC form; and
4. Inform the development of an eConsent experience that addresses identified needs and supports the interaction between the study coordinator and the potential study participant. The interview questions are available as an online Appendix.

Coordinators also had a hard copy of their institution’s ADRC IC form to refer to during the interview. During the interviews, the interviewer could reorder questions or ask follow up questions. Coordinators were asked to think critically about the IC process and were encouraged to give examples of successful/less successful experiences. Interviews were recorded and transcribed verbatim. Transcripts were reviewed and information identifying specific ADRC participants and/or coordinators was removed. To preserve interviewees’ privacy, transcripts were assigned a random code ending in A or B to designate their site.

This study was reviewed and approved by the respective Institutional Review Board for implementation at both institutions.

Analysis method

Three reviewers analyzed and coded the interviews without a priori assumptions using the constant comparative method of grounded theory (Holton and Walsh 2016; Ellis, Strauss, and Corbin 1992). The grounded theory was selected for its structured approach to data analysis. Reviewers started by independently examining each interview line by line and tagging ideas with descriptive words or codes. This emergent coding technique, also referred to as open coding, supports finding meaning in text without preconceptions while open to new findings. It is meant to reduce risks of bias when coding (El Hussein et al. 2014). Dedoose software was used to facilitate data coding and retrieval of themes (SocioCultural Research Consultants, LLC 2018). The coders discussed their coding scheme weekly, iteratively developing and refining a consensus codebook. When changes were made to the evolving coding scheme, reviewers re-coded previously coded transcripts for consistency. Reviewers grouped ideas into concepts and categories that formed the bases for understanding the coordinators’ view of informed consent, their concerns, and how they try to resolve them. For example, the quote “I change up my speed” was coded as Cadence with the concept of Adaptation and the category Facilitator of Consent. Themes were explored as they emerged.

Results

Demographics

Every study coordinator for these studies agreed to be interviewed. Eight study coordinators from UW-Madison (4 experienced and 4 novices with less than one year consenting experience), 4 experienced study coordinators from Emory, and 3 experienced outreach/recruitment specialists from UW-Madison were interviewed. One person switched position in the course of the study and was interviewed once as an outreach specialist and another time as a study coordinator. The study coordinators were mostly female (n = 10), two-third White (n = 9), one quarter African American (n = 4), almost all under 40 years old (n = 11), almost two-third under 30 (n = 8), and most had at least one year experience as a study coordinator for the ADRC studies (n = 10). Interviews were conducted in English in June and July 2017. Interviews lasted 25 to 45 minutes (average 30 minutes).

Readability of informed consent

The IC forms used by each center differed in length and style. The Emory IC form was 12 pages long, written in 11-point font, and included a single illustration. The UW-Madison form was 22 pages, written in 12-point font, with 13 illustrations. Both forms were...
written at a high school reading level, which is considered difficult to understand for more than half the US adults (Mamedova and Pawlowski 2019)

The followings are selected quotes from study coordinators grouped by key themes: First are quotes about the overall consent experience (Building rapport, positive experiences, metrics for success), second are the key challenges encountered by coordinators (barriers and frustrations), third are the coordinators’ recall of participant’s questions and last are quotes illustrating the coordinators’ choices of adaptations to address their perceived needs of study participants.

**Building rapport**

Coordinators put effort into knowing who the participants were, considering their informational wants and needs, and their concerns. Many coordinators stated they attempt to establish empathetic rapport with participants before beginning the IC process, with the goal of making participants feel comfortable, safe, and at ease. For example, one said that “right away you try to ease them [the participant] a little bit” (-C1B-). They also recognized the vulnerability of individuals considering enrolling in a memory study. As one coordinator noted, “they’re anxious that they’re, you know, they’re going to be told that there’s something wrong with them, to some degree” (-C14B-).

**Positive experiences**

Coordinators reported generally positive experiences with the IC process and believe that participants are satisfied with the IC process. They stated “I feel like all my consents go pretty well” (-C12A-), or, “I think most of the time, you know, I think we do a great job going through it … I think the way we conduct the consenting process is pretty efficient” (-C12A-).

Coordinators estimated that it takes them between 15 minutes to 1 hour to complete the IC process at Emory. Coordinators at UW-Madison estimated that it takes them between 30 minutes to 1 hour to complete the IC process.

**Metrics for success**

Coordinators’ metrics for success in both centers include objective and subjective criteria. As objective criteria to gauge success, coordinators verify the participant’s mastery of the material at the end of the IC process.

We do ask them some questions at the end just to make sure that we have covered everything and that they can then explain to us exactly like the main parts of the consent so that we can make sure that they have a complete understanding of what they’re being asked to do. -C12A-

Coordinators also rely on more subjective criteria, such as the participant’s attitude, to assess IC success and participant satisfaction with the IC process. Some coordinators identified participants who were actively engaged and asking many questions as a sign of the coordinator’s success with the IC process.

They [IC processes] go well when, you know, the people are receptive, they’re asking questions, they’re asking really good questions. Or they go well even when people don’t ask questions, and you ask, do you have any questions, and they say, no, this is all straightforward. -C10B-

Other coordinators indicated that they saw a participant not asking questions as a sign of a successful IC process.

It goes pretty smoothly. And by smoothly I feel like I go through it [IC process] and they don’t have any questions. So I usually take that to mean that they understand what is involved… So I kind of take it that when things go well, people don’t have any questions because everything seemed to make sense to them. -C1B-

**Barriers and frustrations**

When prompted to recall issues they encounter or describe moments that did not go well, coordinators identified several barriers or frustrations with the IC process that cluster into the following themes:

1. Participant inattention, including the duration of the IC process and boredom
2. Complexity of the study procedures, visit schedule, and consent materials
3. Prior knowledge, including confusion about the scientific process, misinformation, and therapeutic misconception

**Cluster 1: Participant inattention—Duration of consent process and boredom**

Coordinators from both centers, experienced and novice alike, indicated their difficulty keeping participants focused during the IC process: “A lot of people, it seems like they tune us out sometime” (-C2B-). Coordinators listed boredom, the length of the IC form, and the duration of the IC process as contributors.
So I understand why we need more time to consent, but I've also experienced consenting here at the ADRC where it can take up to an hour and a half. And I feel like during that time, we lose our participants. I think we get them, at the beginning, they're paying attention, and then I'm pretty sure there's a period where they zone out, and then I feel like at the end, they try to catch up again. So there's something about that length of time where it's difficult to hold the participants' attention for the whole thing. -C4B-

Some coordinators reported that participants lost focus after the description of the study procedures or about 15 to 20 minutes into the IC process. One coordinator remarked, “I honestly think that everyone zone[s] out around confidentiality” (-C9A-). Another pointed out that: “Surprisingly, people tune out during the risks... like risks of memory tests and thinking tests, because they don’t think it’s a risk, or the questionnaires and interviews” (-C2B-).

Coordinators also noted that the participant's caregiver might be more engaged than the participant. Especially for participants affected by AD: “...the study partner is the one that's like really into the consent form, and the AD person is kind of just like, okay, you know, that's cool” (-C2B-).

### Cluster 2: Complexity of the study procedures, visit schedule, and consent materials

While coordinators reported feeling at ease with the IC process, they wrestled with uncertain or incomplete knowledge of the study procedures. When asked whether some sections of the IC form are difficult to explain, several coordinators identified explaining the study procedures in lay language was difficult. Coordinators also indicated difficulty with explaining technical content like research regulations and genetics.

I mean, it's good to be very thorough and that we're doing everything we can to protect your confidentiality, but it gets confusing when you name all the different certificates and all the different acts that we're abiding by. -C15A-

It took me a while to get used to there's a whole page on the DNA section. And that's a little bit technical, so I don't go too much detail on that one. I keep that one very brief, because I want to try to keep it simple for everybody else. -C10B-

Some coordinators singled out the lumbar puncture as a complicated procedure to explain: “The lumbar puncture was tricky because there were a lot of things to remember about where the needle goes in your back” (-C1B). Both centers included at least one illustration of the lumbar puncture in the IC form. They noted that this procedure raises anxiety for many participants. Coordinators appreciated having visual support to supplement the written explanation: “Adding that picture of the lumbar puncture actually really helps... before the picture, I honestly didn’t really know where the needle went” (-C2B-). One coordinator was disappointed by the absence of readily available supporting materials.

Other than that, we don't have anything really in place, you know, to explain the MRI and lumbar puncture. I, honestly, a video for the lumbar puncture would be helpful just, I don't know, maybe explaining further the procedure, something that explains it further and maybe helps us get the point across more to them that, you know, it's not as scary as it sounds. -C9A-

Coordinators expressed that they felt they needed to be better prepared. They recognized that their lack of practical training on study procedures might limit their effectiveness in explaining them during the IC process. Some coordinators wished for more study-specific training and to be able to observe the study procedures to improve their understanding. They also requested training on specific topics such as data privacy. Coordinators supported adding training and education materials to help both themselves and the participants.

Yeah, I think early on, biomarkers were probably the hardest part, especially because I hadn't observed them yet at that point, because I had been here for years before I ever observed a biomarker. And that was always kind of weird to me that I was kind of selling people on something I hadn't observed. -C13B-

In addition to the complex study procedures, coordinators commented on the confusing schedule of study visits and the delay between IC and many study procedures. They wondered how much detail to provide at the time of IC versus at the visit when the procedure was being done: “So you don't want to leave too much out, but you don't want to overwhelm the participant, especially since they're not getting it [the procedure] for, what, three to six months later. So that's probably the most difficult part to explain” (-C2B-).

Coordinators found the organization of the IC form was confusing to participants. The IC forms are organized according to traditional IRB-approved templates describing every procedure before listing all potential risks and benefits of participating. Some coordinators would have preferred presenting the potential risks and benefits of each procedure when describing the procedure. One coordinator noted,

I think within this consent form we jump around a lot between like the meat and potatoes of just a regular study visit and then the biomarker procedures. So it's like we touch on the biomarkers,
and then we talk about other stuff, come back to the biomarkers, talk about other stuff, and then do it like a couple times... And then they're like asking questions prior to getting to the specific details of the procedures. And I'm like, well, I'll get to that. And so it's just kind of like a little scrambled. -C7B-

Furthermore, coordinators reported that study “add-ons” further complicate the IC process. For instance, after reviewing the information about joining the ADRC study, participants are asked to consider brain donation. This lengthens the IC process and can be unsettling for some participants.

Another point of frustration coordinators reported is keeping up with protocol changes. Because this research is an ongoing effort, the protocols at both centers have evolved, requiring coordinators to adapt to changes and stay on top of updates. In addition to shorter and updated IC forms, coordinators want cogent and updated IC narratives that are linked with protocol updates. As it stands now, some procedures listed in the IC forms from each site are not currently included or are optional for some sub-cohorts. This requires coordinators to select which parts of the IC form are relevant to the participant and cross out inapplicable sections in real time. One coordinator indicated how confusing this process is for both them and the participant:

We always have to reiterate that multiple times just to say, we could ask you for these things, but, hey, right now we’re not asking you for these things, but we might call you and ask you for these things, but you don’t have to say yes. -C15A-

Sometimes, this leads to mistrust. “People are always worried that, you know, something will be done with these procedures that was not shared upfront.” (-C4B-).

**Cluster 3: Prior knowledge, assumptions, and misinformation/correcting therapeutic misconception**

Coordinators were prompted to identify sources of confusion and misunderstanding by explaining why some sections of the consent form or some procedures are more challenging to understand. Coordinators indicated that the primary source of misunderstanding for participants comes from participants’ own prior experience and external sources of (mis)information.

I very frequently get comments, well, my daughter or my friend or my son or so and-so is a nurse, and they said I shouldn’t do a lumbar puncture, because you’re going to paralyze me. So that’s something we end up spending a lot of time discussing about how, well, we're actually too low, that's not really a problem, but, so really explaining that portion. -C13B-

...she thought that there was definitely a way that doctors can interpret CSF results and can like definitely tell you whether your family is at risk of Alzheimer’s or your children have that same risk... and she got in her mind that a doctor had told her this... -C1B-

Coordinators also indicated that participants do not readily distinguish research from clinical care. This therapeutic misconception is illustrated in multiple ways, from simple logistical questions about using information or biospecimens gathered during a clinical encounter to the expectation that the study provides a diagnosis. Participants ask whether they can contribute existing data to the research like existing blood samples, recent MRI results, or direct-to-consumer genetic testing results: “if they’ve already done an MRI, [the participant will ask] if they need to do it again, or (...) if they’ve recently got a blood draw, can they just use that same blood for this visit?” (-C7B-). Coordinators believe that participants may expect to receive more personalized care if they participate in the research. Participants appear to assume that the study will return results to them or will share their research data with their care provider.

I go over the difference between clinical care and research study, because there have been enough people who come to us thinking that we will be able to give them, I don’t know, like their biomarker profile or help them figure out their risk level. And I really try to explain to them that we don’t do that because we’re investigators, we’re not treating anybody. -C6B-

[Participants] get in their minds that, you know, they can access any results that we have, that we will share anything, especially if they just ask for it. And if we can’t, then they kind of feel like we’re deliberately withholding information from them. -C1B-

Coordinators described challenges in attempting to dismantle general participant misconceptions, including misconceptions around disclosure of their results. One coordinator admitted, “I don’t really know how to tackle that yet, but I feel like it’s common enough that maybe it’s something to explore in the future” (-C4B-).

A common suggestion to alleviate this challenge was to provide information to potential participants earlier: “Making sure that we can get that [IC form to participants] ahead of time would be helpful” (-C7B-).

**Questions raised by participants**

To understand the coordinator’s perceptions of participant’s concerns with the research, we asked them which sections of the consent elicit questions and/or concerns from participants. Most coordinators recalled
being asked questions about the biomarker procedures (n = 14) and visit logistics (n = 12):

The study participants are generally more concerned about the procedures, and I think the partners are more concerned about the practical nature of transportation and what their involvement will be, how long they’ll be needed for. (-C14B-)

Coordinators at both sites indicated that participants had more questions about the lumbar puncture than about the MRI regardless of the number of illustrations provided in the IC form: “People just want to know more detail about exactly how long the procedure takes, who will be doing the procedure, if it’s, you know, if it’s a physician or one of our trained nurse practitioners” (-C12A-). Coordinators attributed this difference to participant familiarity with the MRI procedure and anxiety about lumbar puncture. Two-thirds of the coordinators indicated getting questions about physical pain, with all the coordinators using the less-illustrated IC form reporting getting questions about physical pain, versus half of the coordinators using the more heavily illustrated IC form.

In addition to the study procedures, coordinators recalled participants’ concerns about being injured or being diagnosed with cognitive decline or AD. More than half the coordinators stated that participants wanted to access their results: “So one of the most frequent questions I get is what sorts of results am I going to get? A lot of participants, you know, want results” (-C9A-), and some get confused or angry when told that research results may not be returned to them (see misconceptions about research and clinical care discussed above).

Only one coordinator had gotten questions about the cost of participating in the study, and coordinators reported getting a few questions about privacy and confidentiality.

I don’t get a whole lot of questions when it comes to privacy and confidentiality, so I’m always concerned that maybe they’re, you know, they just think it’s typical sort of legal mumbo-jumbo and they’re not always paying attention during those sections. -C5A-

However, coordinators noted that participants with AD and mild cognitive impairment (MCI) were more likely to ask questions about diagnosis and privacy. Participants ask, “who all is going to see their information, what, how their privacy is protected” (-C3B-).

I get questions about so like what information we release to their insurance companies, like what are like the repercussions if anybody were to like, you know, see that they had an AD diagnosis or something like that. -C7B-

A coordinator indicated that participants with AD could be indecisive, asking about what other participants were doing. They sought advice from their caregiver or appeared to want to please the study coordinator: “AD and MCI…they ask about like what other participants do?” (-C7B-).

Coordinator adaptation

Using their professional expertise and personal touches, universally coordinators adapt the consent experience to what they perceived are the preferences and needs of the study participants. This extends to reordering or modifying the materials, changing the cadence, adapting vocabulary, and prioritizing information in real-time based on the participant’s attitude. They sometimes supplement the information with homegrown materials to aid understanding.

Although undertaken with the best of intentions, coordinators expressed self-doubt that their adaptations were helpful to participants.

Because I’m never quite sure if I’m saying enough, because I only say like two main aspects of this whole page, and then I move on… just because there’s a lot of words, and I thought about like, I thought is this second paragraph even necessary… Those are the main two points, but I would just be, like I say, like people want to know like why there’s so much writing in here, then why did you say two things and then just go to the next page? -C3B-

When asked what they wish they could do differently, a coordinator suggested customizing the consent: “But if we had the option that people, if they wanted more information, they can explore further, that probably would be beneficial” (-C1B). The same coordinator explained, “I try to make it fun” (-C1B). Another suggested that “more patience [from the coordinator] and simpler words are required” (-C8B-).

Discussion

The findings of this study contribute to our knowledge about how research coordinators navigate informed consent discussions with subjects with AD considering enrollment in research. Whether they have done it for many years or a few months, coordinators appreciate their role as educators and advocates for AD research, having to balance advocacy for the research and protection of participants. The progressive memory and cognitive deficit of potential participants in AD research add challenges (Biros 2018; Dalpé, Thorogood, and Knoppers 2019).
Coordinators identified several barriers and frustrations with the consent process and materials. The three main concerns identified as common across centers and both novice and experienced coordinators, are (1) the duration of the IC process and length of the form, (2) the complexity of the study procedures and schedule of visits, (3) and participant misconceptions. All of these concerns are not unique to AD research but may be heightened when consenting participants in AD research (Grady 2015).

Coordinators must communicate complex concepts and describe possibly distressing procedures, guided by the IC form. Although the two ADRC centers use different IC forms, coordinators at both sites reported needing to adapt the IC process and materials to address the needs and circumstances of the participants and their caregivers.

Coordinators do not have information about the potential participant’s diagnoses before the initial informed consent process. However, they may presume that individuals referred by clinicians may have signs of diminished memory or other cognitive deficits. Since this is a longitudinal study, coordinators re-consent participants yearly or every other year and have information about past diagnosis at the time of re-consent. Knowing or presuming the participant’s diagnosis may impact the coordinator’s approach to the consent process and the adaptations they chose to implement.

Coordinators compensated for shortcomings of the IC forms and other documents with variable success. The adaptations they described were developed through experience and trial and error. They were not the result of targeted training on engaging participants with memory or other cognitive deficits. Understanding the social, religious, and cultural context is essential to obtaining IC (Palazzani et al. 2019; Ekmekci and Arda 2017). Understanding the specific needs of participants with possible memory challenges, other cognitive deficits, or dementia is also critical to building the coordinator’s confidence and improving the IC process in AD research.

Cognitive, emotional, and environmental influences, as well as prior experience, affect how people understand and retain knowledge (Martins and Meyer 2012). Too many details may overwhelm the participant’s ability to make a conscious and informed decision. On the other hand, too little information may be misleading (Nilsson 2017). Study coordinators at both sites usually read aloud the ADRC study consent forms to prospective participants. One drawback is that participants become passive listeners and not active learners. Creating an active learning environment (Freeman et al. 2014) that allows for self-directed and self-paced learning may reduce the risk of boredom and inattention, especially among participants with memory and cognitive decline. Further, providing access to IC forms before meeting with a coordinator might allow potential participants time and space to review at their own pace and come with questions.

Therapeutic misconception is a well-documented challenge in IC (Henderson et al. 2007). Coordinators face culturally heterogeneous individuals with diverse views of medical procedures and understanding of the distinction between scientific research methods versus health care. Adding supporting materials to supplement the IC form and providing training and strategies to strengthen the communication skills of coordinators should be supported. This is particularly important for improving the representativeness of those participating in research. Further, conveying study details using plain language and multi-modal communication methods may reduce ambiguity and draw a more definite line between clinical care and medical research.

In addition, coordinators noted a power differential between the coordinator, participant, and caregivers. Although a general challenge for IC, participants exhibiting cognitive deficits demonstrated a greater reliance on the opinions of those around them – potentially exacerbating this point. Coordinators alluded to the influence they and the caregiver have on the participant’s questions about the study and decision to join. Participants in AD research include the elderly or people at risk of developing AD and therefore may be more vulnerable to pressure. They may be embarrassed to ask questions, worried to disappoint the coordinator or their caregiver, or they may fear the consequences of refusing to participate. Coordinators also highlighted the anxiety that some participants exhibit when enrolling in AD research. Some people may experience the IC process like a competency test, and indeed, the coordinators must determine whether the participant is eligible and competent to provide IC or should have their decisional capacity assessed by a clinician. This highlights the importance of conducting the IC process in a context of a trusted relationship, especially when participants are asked to consent in the presence of their caregiver.

Traditionally in these ADRC studies, at the end of the IC process, coordinators verify understanding by asking a series of questions before the prospective participant commits to joining the study. Both centers expect individuals to recall the purpose of the study and the principal risks/benefits of participating before
being allowed to sign the IC form. This is particularly challenging for participants with diminished memory. As others have suggested, an alternative could be to consider the genuine preference of the prospective participant throughout the long IC process instead of their accurate recall of study information afterwards (Kim 2011). In that way, coordinators could establish the authenticity of the participant’s decision and the conformity of participation with the participant’s expressed values.

Limitations

This study has several strengths, including the input of frontline study coordinators, the semi-structured interview approach, and the iterative coding process used to analyze the data. However, several limitations should be noted. First, we interviewed a small number of study coordinators. Thus the findings may not represent the diversity of experiences and perspectives from a broader group of coordinators who consent participants for AD research.

Second, the relationship between the coordinator and the interviewer may have affected the responses. Coordinators may have been cautious or guarded in answering the colleague who was interviewing them, even though the interviewer had no direct supervisory role. While the open conversation elements in the interviews were designed to give sufficient freedom to the coordinators to raise concerns or discuss issues important to them, answers may have been more candid if the interviews were conducted anonymously.

Conclusion

Obtaining IC in AD research is challenging. Populations with progressive memory deficit or diminished cognitive capacity require special care and additional considerations to support their autonomy in making decisions regarding research participation. The traditional paper-based consent isn’t particularly adapted to the needs of vulnerable participants with memory deficit. Consent forms are often too long and complicated, making it difficult to stay engaged. In addition, although the forms contain important information meant to support participant’s decision, the information presented isn’t always relevant to participants in longitudinal AD research. In response, study coordinators reported spontaneously modifying the process and the amount of information presented. These findings suggest that flexible approaches to IC could be better suited. Electronic consent (eConsent), which can integrate multimedia instructional supports, is an attractive option to facilitate self-directed and self-paced understanding of study details. Many of the recommendations for improvement of the IC process suggested by coordinators could be easily and effectively integrated into an eConsent.

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Author contributions

All authors contributed to the concept and design of the work, the analysis and interpretation of data, and approved the final manuscript.

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Conflicts of interest

Authors have no conflict of interest to declare

Ethical approval

This study was approved by the institutional review board(s) at the University of Wisconsin-Madison and Emory University.

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Appendix–Coordinators interview questions

1. Tell us a little bit about yourself and your experience as an ADRC coordinator.
2. How long have you worked with ADRC?
3. Do you have any experience being a coordinator for other projects, and if so, how does this experience differ?
4. Walk me through how the ADRC informed consent process works for you? Works for your participants?
5. What research procedures/activities described in the main consent form are the most difficult to explain and why?
6. Are there tools you currently use or that would help you better explain these procedures/activities?
7. (If they do not provide details, follow up) Walk me through a moment that went well. Walk me through a moment that did not go well.
8. Have you noted any differences in understanding different sections? If so, what differences? Please walk me through an example.
9. Have you noticed any differences in participants’ attention of different Informed Consent sections? If so, what differences? Please walk me through an example.
10. How, if at all, does the understanding of each section vary with different cohorts?
11. (If not already addressed through other responses) What are examples of questions participants frequently ask when you are going through the consent?
12. What if we were to give different information? Suggestions?
13. What do you do differently to make the process easier and efficient?