Evaluating an Informed Consent Process Designed to Improve Inclusion of Adults with Intellectual Disability in Research

Thesis

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By

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Abstract

Adults with intellectual disability (ID) are both underrepresented in research and enrolled in studies that they may not understand. Instead of facilitating research engagement, the informed consent process often fails to elucidate the very elements that are essential to informed consent. The primary goal of this pilot research was to evaluate whether a novel informed consent process was more effective than current practice at including adults with ID in research. N=21 adults with ID completed a novel iterative teaching process (ITP) for teaching and assessing informed consent. The ITP consisted of three distinct approaches (i.e., Conventional consent form, Easy Read, and Conversational) to teaching comprehension of each of the nine core domains deemed essential to informed consent. Following each teaching mode, participants were asked a series of open-ended questions to assess their attitudes toward, and their comprehension of, the ITP materials. The pilot found encouraging evidence for the efficacy and feasibility of the ITP. The ITP approach improved comprehension of the essential elements of consent. Results did not support a clear advantage of one mode of presentation over another; both the Easy Read and Conversational modes were effective in teaching the materials as well as being well liked by participants. Measures of verbal intelligence were the strongest predictors of capacity to consent in this sample. The design and findings of this project contribute to a growing literature by introducing a process for teaching and evaluating informed consent.

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Fields of Study

Major Field: Graduate program in psychology

Subfield: Intellectual and developmental disabilities psychology

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Chapter 1. Introduction

Research participation as a human right

The recruitment of inclusive, representative participant samples helps to ensure that the benefits of research are shared equally among all members of the population. In 1994, the National Institutes of Health (NIH) Revitalization Act required the inclusion of women, minority groups, and their subpopulations in NIH-funded clinical research (NIH, 1994). In 2014, the NIH enacted policies mandating a balance of male and female cells and animals in all future applications unless sex-specific inclusion was unwarranted (Clayton & Collins, 2014). These policy announcements represent reactions to a growing understanding of the benefits and urgency of balancing representation in research that goes beyond sex differences. In addition to gender equality in research, other groups of people require advocacy to achieve equality in this domain such as ethnic or racial minorities, the underprivileged or uneducated, and vulnerable populations such as pregnant women, children, and those with intellectual disability (ID). NIH guidelines ensure that all NIH-funded clinical research be carried out in a manner sufficient to elicit information about individuals of both sexes and diverse racial and ethnic groups to determine whether interventions affect subpopulations differently (NIH, 2017). There are no such guidelines ensuring equal inclusion for those with ID. People with ID face

barriers to active engagement in research from forces aimed at protecting them from abuse or exploitation.

Research rights and protections for adults with intellectual disability

Researchers in the field of ID are challenged to negotiate the ethical tension between the inherent risks of including adults with ID in research where they may be exploited and, on the other side, imposing stringent protections against exploitation that may result in exclusion from and loss of the potential benefits of research. Ethical guidelines have often failed to protect the human rights of people with ID and other vulnerable groups (Iacono & Carling-Jenkins, 2012). Nevertheless, many researchers have been discouraged by over-regulation from research ethics committees involving people with ID (Boxall & Ralph 2009; Masterton & Shah 2007; McDonald & Keys 2008; Mulhall et al., 2020; Scott et al. 2009). Despite the potential to limit beneficial and valuable research, the need for regulatory oversight to protect all research participants, and especially those most vulnerable populations, is unquestioned.

The infamous Willowbrook and Tuskegee studies illustrate the need for regulatory oversight. Researchers at the Willowbrook State School for children with ID deliberately injected children with hepatitis virus in order to track its progression. When accused of unethical conduct, these researchers argued that the children would have contracted the disease eventually and that, by administering a mild form under controlled conditions, the children were ensured good care (Fischer, 2006; Krugman, 1971). They also argued that the parents had given consent to their children's participation. Critics described the parental consent as obtained through coercion based on incomplete or

misinformation (Goldby, 1971; Pappworth, 1971). Similar atrocities against people with ID, as well as other vulnerable groups, include radiation experiments on children in the U.S. with ID in the 1940s through 1961 (Advisory Committee on Human Radiation Experiments, 1996), and the Tuskegee syphilis study involving low-income African American men from 1932 to 1972 (Freedman 2001). These cases trace the historical evolution and development of informed consent and research ethics to better understand the precarious balance between regulatory protection and autonomy for vulnerable populations in research.

The researchers at Willowbrook used the vulnerable children under their care as a matter of convenience and not because the medical research was intended to benefit this population directly (Fischer, 2006). This case calls attention to the issues of guardianship and proxy consent to research. While there is a need for guardians to make consequential and legal decisions for minors who may have limited decisional capacity, no person should be enrolled in a research study before all reasonable steps are taken to assist them in understanding the decision. Additionally, no person should ever enter a study that they have not had the opportunity to refuse.

The modern history of ethics in human research begins with the Nuremberg Code, issued by the Nuremberg Military Tribunal in 1947 following, and in direct response to, Nazi atrocities at the end of the Second World War. The code is a 10-point statement meant to prevent future abuse of human subjects (Annas & Grodin, 1992). It notably includes the requirement that all research participation must be voluntary. Following the Nuremberg trials, the declarations of Geneva (1949) and then Helsinki (1964) produced

the document, *Ethical Principles for Medical Research Involving Human Subjects.* Of particular note, section A of this document contains language to remind researchers that special populations involved in research must be closely monitored. Section B includes the statement that potential subjects should only give consent after being fully informed of the study's procedures, goals, and sources of funding, potential conflicts of interest; researcher affiliations, risks and benefits, and their right to withdraw. Subsequently, the 1979 Belmont Report concluded that the primary principles underlying ethical research with human beings are respect for persons, beneficence, and justice. These principles are brought to bear on the informed consent procedures, risk/benefit analysis, and the appropriate selection of participants. The report notes that there are special classes of potential subjects in whom comprehension may be limited, including what was then called the mentally disabled; and, to protect the interests of these vulnerable populations, a third party should give consent to the study. This third party should be someone ‘‘most likely to understand the incompetent subject's situation and to act in that person's best interest" (p. 6, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Finally, the regulations of what was then called the Department of Health Education and Welfare (DHEW) became a Common Rule for 16 federal agencies of the United States (Department of Health and Human Services, 2001). Certain terms are defined in the policy including the determination of minimal risk, the purpose and rules of Institutional Review Boards (IRBs), and the components of informed consent. Throughout history, legal protections for human research subjects expanded. Notwithstanding noble intent, these regulations and ethical guidelines have

inadvertently created obstacles to equal participation and benefits of research in special populations.

Excluding a particular group from empirical study deprives them of the potential benefits of research, perpetuating inequalities and healthcare disparities. This could be perceived as discriminatory and disempowering (Calvaley, 2012). Clinical trials commonly exclude individuals with multiple diagnoses or any medical complications beyond the single indication under investigation. As a result, therapeutic medication and interventions have been approved for use in the entire population including groups where no data has been gathered on potential adverse effects (Shepherd, 2020). A review of 300 randomized controlled trials published in high impact medical journals between 2007 and 2011 found that over 90% of these studies were designed to exclude individuals with ID from participating; the authors concluded that, with minor accommodations, people with ID could have participated in at least 70% of the studies without compromising research integrity (Feldman et al., 2014). Excluding a particular group from research deprives them of the potential benefits gained and creates the potential risk of inappropriately extrapolating results (Clayton & Collins, 2014). Specifically, there are limitations with drawing inferences from the data obtained from other groups and applying those findings to people with ID (Calvaley, 2012). Excluding individuals with ID from research relegates them to an insignificant and peripheral status while contributing to their broader exclusion from society (Hart et al., 2020; Taylor, 2018). Addressing the exclusion of those with ID from research is essential to develop and provide evidence-based care and to take steps toward greater health equity (Shepherd, 2020).

The inclusion of adults with ID as research participants requires researchers, and the institutions that support them, to consider three risks: 1) inappropriately treating adults as children by relying on a proxy decision-maker to consent, 2) excluding vulnerable people from beneficial research, and 3) including research participants who are not sufficiently informed (Cambridge & Forrester-Jones, 2003). The informed consent process is one of the most powerful tools to protect research participants; however, the effort to prevent inappropriate or coercive consent may inadvertently impede many adults with intellectual disability from research participation.

What is informed consent?

When a person provides their consent, they are granting permission for something to happen or agreeing to do something. To provide informed consent indicates that one has been presented with, and acknowledges comprehension of, the relevant information for making the decision to grant permission (Goldsmith, Skirton, & Webb, 2008). People are made safer by exercising agency and choice in their lives, and even more so when they possess pertinent information to make choices in their own best interest. As an abstract concept, consent has multiple interesting and consequential applications.

Up until the turn of the 21st century, consent for participation in research was rarely studied empirically (Arscott, Dagnan, & Kroese, 1997; Mann, 1994), and the study of research consent has developed separately from understanding consent to medical treatment (Appelbaum et al., 1987; High, 1992). Since 2000, there has been a wide expansion of international researchers discussing and examining issues relevant to informed consent to research (Cohn & Larson, 2007; Mulhall et al., 2020).

Consent is an ethical requirement implemented to protect research participants as well as researchers and academic institutions. The primary aim of an informed consent process is to communicate and confirm adequate knowledge of the purpose, nature, potential benefits and risks, and participants' rights and responsibilities with respect to a research study in order to facilitate an informed decision of whether or not to participate (Dye, Hare, & Hendy, 2007). The capacity to consent indicates competence and the ability to meaningfully consider the implications of the relevant information presented (Dye, Hare, & Hendy, 2007). The general presumption of capacity assumes that every adult has the ability and understanding necessary to make decisions in their own interest and be supported to exercise this right unless there is reasonable evidence to question this presumption (Carey & Griffiths, 2017). By definition, minors do not have the legal right to consent themselves for participation in research. Minors are asked for their assent to participate and their legal guardian decides whether to consent on their behalf. This issue of proxy consent is relevant to adults with ID.

Adults with diminished decision-making abilities, by virtue of intellectual disability, neurocognitive disorders, or psychosis, may lack capacity to provide consent themselves. In such cases, a proxy decision maker is required to provide informed consent on behalf of the potential research participant in order to enter a research study. In the United States, state laws and institutional regulations dictate whether legal guardianship is required for proxy decision making. Assent is required, in combination with proxy consent, to protect vulnerable individuals from completely losing their agency. Assent can be viewed as the willingness of the vulnerable individual to go along

with, or not object to, a proposed study or intervention (Calvaley, 2012; Sachs et al., 1994). In practice, assent may reflect little more than the absence of clear dissent (Thomson, Roberts, & Bittles, 2014). Without an intentional and accessible consent process, many vulnerable individuals may not completely understand the research studies in which they participate. Ethical assent procedures should share all of the same elements as informed consent administered in a way that aligns with the cognitive and communicative abilities of each potential participant on a case-by-case basis (Hart et al., 2020). Thomson, Roberts, and Bittles (2014) caution that individuals with diminished cognitive and communication abilities do have the ability to signify assent and dissent by their physical actions, and these cues should be noted and respected in a research context, even if proxy consent has been supplied. In practice, researchers might consider a participant's reluctance or resistance as an informal indication of dissent, while a nonverbal expression of one's desire for engagement might strengthen a researcher's confidence in written assent (Cascio, Weiss, & Racine, 2021). Informed consent or assent may be more meaningfully framed as a continuous process rather than a one-off event (Carey & Griffiths, 2017), requiring constant monitoring, awareness, and communication between researchers, participants, and other persons involved.

Capacity to consent is an imperfectly defined construct. In practice, this ambiguity has led to a single dichotomous categorization, whereby individuals are assessed as either having or not having capacity to consent to a particular decision; with their legal guardianship status often as the sole distinguisher (Dye, Hare, & Hendy, 2007). Capacity is not static but can change over time or require distinct abilities

depending on the nature and complexity of the decision (Dye, Hare, & Hendy, 2007; Ho et al., 2018). It is therefore more appropriate and respectful of individuals' autonomy and self-determination to assist potential research participants in making a well-informed decision. Dye, Hare, and Hendy (2007) proposed that the seriousness of a study's risks or consequences should determine the level of capacity needed. This recommendation aims to balance the need for greater agency and inclusion whenever possible while safeguarding against potential harms. Respectful and well-designed consent should be a process that occurs in the context of a respectful and informative relationship.

Adults with intellectual disability

Intellectual disability is defined as significant limitations in both intellectual functioning and adaptive behavior that manifest before the age of 22 (Schalock, Luckasson, & Tassé, 2021). Adults with ID are a highly heterogeneous population without a common etiology for their disability. Due to communication impairment, cognitive impairment, and functional impairment that may include difficulty with activities of daily living, the decisional capacity of adults with ID is often questioned.

The consent process itself poses a barrier for individuals with ID to successfully enter and benefit from participation in research (Iacono, 2006). Some of these obstacles include: a lengthy consent process, jargon-laden consent forms that are difficult to understand, and a lack of engagement in the consent process related to guardianship status. Adults with ID frequently have impairments in receptive and expressive language, memory, and a tendency toward acquiescence or suggestibility compared to adults without ID (Arscott, Dagnan, & Kroese, 1999; Murphy & Clare, 1995). The future-

oriented cognitive demands required for effective decision making, such as attending to and retaining information and applying flexible thinking to determine and compare consequences, may exceed the cognitive abilities of many individuals with ID (Wheeler et al., 2020). Acquiescence to authority is learned, making informed decision making increasingly difficult when agreement and compliance with authority figures has been repeatedly rewarded throughout an individual's life (Cascio, Weiss, & Racine, 2021). The prevalence of communal or assisted living situations, coupled with a lack of necessary support networks, produce additional logistical obstacles such as coordinating transportation and the schedules and inclination of caregivers and guardians. Arscott, Dagnan, and Kroese (1999) suggest that problems abstracting from examples, difficulties processing complex sequences of information, and even limited decision-making opportunities contribute to making consequential decision making, such as in informed consent, even more problematic for adults with ID. It is incumbent upon researchers to mitigate these barriers to improve inclusion of adults with ID in their research studies.

The most prominent study designs to engage people with ID have been participatory action research (Nind & Vinha, 2012), where the focus is on empowering participants by deliberately sharing control over the content and direction of the study (Porter & Lacey, 2005). This emerging subfield is not without its challenges, researchers must continually weigh their ability to improve accessibility by simplifying information regarding consent, data, and potential harms to participants, with the relative risks of oversimplifying information to the extent that it is no longer accurate and may pose additional risk (Savage et al., 2015). Still, consensus exists that there is an obligation for

researchers to move toward conducting research with, rather than on, people with ID (Carey & Griffiths, 2017). More inclusive and participatory research will contribute to how people with ID are viewed as equal members of society who must be respected as active decision-makers (Carey & Griffiths, 2017).

Historically, adults with ID were viewed as objects and beneficiaries of research, rather than as colleagues or active participants with agency. Adults with ID perceive exclusion from research as harmful and report a greater interest in active participation than predicted by family, friends and researchers (McDonald et al., 2017). Crucially, McDonald et al., (2017) found that adults with ID have greater interest in participating in research than all other groups predicted they would, except when someone else made the decision about participation on their behalf. Supported decision-making (SDM) is a process of promoting autonomy by deliberately supporting people to make informed and critical decisions (Davidson et al., 2015). SDM supports individuals with ID using a wide range of methods such as person-centered planning, self-advocacy training, and assistive technology (Davidson et al., 2015). Person-centered supports have been shown to increase academic, employment, and quality of life outcomes among adults with ID (Wehmeyer et al., 2000; Wehmeyer & Schwarz, 1997; Wehmeyer & Schwarz, 1998). Convergent research findings clearly indicate that people with ID are capable of learning valuable skills and knowledge, thus improving their quality of life, when provided with the appropriate supportive environments (Iacono & Murray, 2003). It is the researchers' responsibility to create an accommodating, supportive, and inclusive research environment to lower barriers and promote equal participation for adults with ID.

Assessment of capacity to consent

The Electronic Code of Federal Regulations provides a checklist of eleven basic elements required for informed consent to research involving minimal risk in accordance with the common rule (Electronic Code of Federal Regulations, 2018). These basic elements are:

1) A statement that the study involves research
2) An explanation of the purpose of the study
3) The expected duration of the subject's participation
4) A description of the procedures to be followed
5) Identification of any procedures which are experimental
6) A description of any reasonably foreseeable risks or discomforts to the subject
7) A description of any benefits to the subject or to others which may reasonably be expected from the research
8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
9) A statement describing the extent, if any, to which confidentiality of records identify the subject will be maintained
10) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject
11) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

While informed consent forms must include these eleven elements, there is no consensus on how to evaluate understanding of the essential components of consent (Carey & Griffiths, 2017). Studies assessing capacity to consent have employed a wide

variety of criteria (Andre-Barron, Strydome, & Hassiotis, 2007; Arscat, Dagnan, & Kroese, 1997; Hurtado, Jones, & Burniston, 2014; Thomson, Roberts, & Bittles, 2014; Wheeler et al., 2020), none of which align perfectly with the eleven basic elements specified by the Electronic Code of Federal Regulations (2018). Institutional review boards are primarily concerned with protecting human subjects while complying with regulations imposed by the common rule, their institutions, as well as local and federal governments. Despite this ambiguity, it is essential for ongoing and future research on informed consent to use components of consent that are applicable to the criterion of IRBs and the regulations that govern them.

Capacity to consent is not static but can change over time (Dye, Hare & Hendy, 2007; Ho et al., 2018). The question of whether capacity can be learned or taught has not been established in the research literature. To possess capacity, a person must be able to comprehend and retain information relevant to the decision at hand, they must then use this information in the decision-making process (Calvaley, 2012). Appelbaum (2007) proposed that decisional capacity includes four elements: (1) understanding, perceiving and retaining information; (2) appreciation, linking a decision to one's own situation; (3) reasoning, considering all the information and weighing the consequences; and (4) making and communicating a choice. While relative deficits in language, reading, attention, and memory may pose barriers to an individual's ability to comprehend, retain, and manipulate information, these difficulties may be ameliorated with deliberate supports. This leaves the question of how to meaningfully assess this abstract concept of capacity.

In a review of the various aspects of informed consent in people with ID, Iacono and Murray (2003) concluded that there was no clear indication of a measurable threshold of performance that signifies a capacity to consent. One could even argue that it is discriminatory to assess the competence of adults with ID, and potentially exclude them from research participation, when no such assessment is applied to the general population of potential participants (Dye, Hare, & Hendy, 2007). The very same procedures that were established to protect vulnerable populations from exploitation are potentially serving to limit the benefits these populations can glean from research participation. Nevertheless, several studies have examined whether capacity to consent can be objectively measured for adults with ID.

While there is growing attention to methods for determining individual's capacity to consent to research studies (Dye, Hare, & Hendy, 2007), there is no consensus or empirical guidelines to evaluate capacity in adults with ID (Carey & Griffiths, 2017). Studies that attempted to empirically measure capacity to consent followed a common approach; they presented information about a real or hypothetical study or procedure and then asked participants a series of questions that were scored to reflect their capacity to consent to that particular scenario at that time (Dye, Hare, & Hendy, 2007; Ho et al., 2018; Hurtado, Jones, & Burniston, 2014; McCormack et al., 2019; Wheeler et al., 2020).

A small number of established scales have been used to assess the capacity to consent to research. One such scale is the University of California, San Diego Brief Assessment of Capacity to Consent tool (UBACC; Jeste et al., 2007). The UBACC is a brief screening tool consisting of 10-items evaluating the domains of Understanding,

Appreciation, and Reasoning. Each item receives a score of 0, 1, or 2 with the intermediate score of 1 allowing for a more precise estimate of the individuals capacity and possibly the amount of effort that would be needed to improve it. To use the UBACC in a new study, researchers must examine the UBACC questions and determine which of the 10 are essential for consent to the specific protocol and prepare a list of answers for the specific study that will receive a score of 1 or 2 on each item. The UBACC is a potentially useful instrument for screening large numbers of subjects to identify those needing a more comprehensive decisional capacity assessment because it is considered easy to use and typically takes less than 5 minutes to administer and score (Jeste et al., 2007).

The MacArthur Competence Assessment Tool for clinical research (MacCAT-CR; Appelbaum, & Grisso, 2001), which was derived from the MacArthur Competence Assessment Tool for Treatment (MacCAT-T; T. Grisso and P. S. Appelbaum, 1998b), is a structured interview for assessing decision-making abilities relevant for judgments about subjects' competence to consent to research participation. The MacCAT-CR interview evaluates performance in four domains: Understanding, Appreciation, Reasoning, and Expressing a Choice. The measure consists of a total of 21 items, the number of items varies by domain, and each item is assigned a score of 0, 1, or 2. Both the MacCAT-CR and UBACC are often used to screen and exclude potentially vulnerable participants who are unable to demonstrate sufficient decisional capacity to a clinical trial. These measures are purely evaluative in nature and lack a teaching component.

The Ability to Consent Questionnaire (ACQ; Morris et al., 1993), and the Three-Item Decisional Questionnaire (IDQ; Palmer et al., 2005) have also been used to assess capacity to consent. The ACQ, originally used by Morris et al., (1993), was later adapted to improve comprehension (Arscott, Dagnan, & Kroese, 1999; Dye, Hare, & Hendy, 2007). The ACQ consists of three vignettes describing individuals being offered treatments requiring informed consent. Participants were asked five questions about each vignette designed to measure the abilities seen as important in consent by assessing their understanding of: 1) the presenting problem, 2) the nature of the proposed intervention, 3) the alternatives, risks and benefits, 4) their involvement in the decision-making process, their rights and the options available, and 5) their ability to express a clear decision with a rationale. Questions are asked in two parts in order to make them easier to comprehend. Dye, Hare, and Hendy (2007) note that their adaptation of the ACQ does not effectively differentiate recall from comprehension, which could be assessed by asking participants to paraphrase the consent information. The IDQ was originally used by Palmer et al., (2005) and then adapted by Ho et al., (2018). The IDQ consists of three questions, each scored as incapable, questionable, and capable. The questions are: what is the purpose of the study, what are the risks, and what are the benefits. A higher total score reflects a better understanding of the study. While the ACQ and IDQ use some similar questions for their assessment, there is no consensus on the questions, the score, or the threshold to objectively establish capacity to consent. We suggest that, by examining the essential elements of informed consent, one can identify concepts that are

most important to assessing capacity in a specific research context with consideration of risks, benefits, and content.

An accessible informed consent process

Several studies have attempted to modify the informed consent process in order to improve accessibility for people with ID. Hurtado, Jones and Burniston (2014) examined whether an Easy Read leaflet with or without pictures improved comprehension in adults with ID. Easy Read refers to guidelines for constructing information in a way that is easy to understand including simplifying vocabulary, content layout, and wording concepts to improve accessibility. While both experimental modalities improved knowledge, neither was significantly more effective at improving comprehension in the sample. This study was limited by the absence of auditory presentation or control conditions. Dye, Hare and Hendy (2007) randomized adults with ID to one of three informed consent conditions: the first (control) condition provided a written informed consent form, the second condition presented the same information broken into discrete sections, and a third where consent information was accompanied by color photographs. No significant difference in ability to consent was found between experimental conditions, leading the authors to conclude that providing additional information or reducing memory load are not themselves sufficient to enable adults with ID to attain capacity to consent. Wheeler et al., (2020) randomized adults with Fragile-X Syndrome, the most common inherited cause of ID, to one of two informed consent presentations. Half of the participants used a digital decision support tool, which included visual aids in addition to text and audio descriptions, to present the informed consent materials. The comparison group received informed consent

information provided through standard research practices of printed consent forms. Both groups had their decisional capacity assessed with the use of an adapted MacCAT-CR, though the experimental group completed the measure via the digital tool while the control group completed a paper measure. Wheeler et al. found that the use of the interactive decision support tool showed promise for individuals with no ID, mild ID, and higher levels of moderate ID, though there were no differences in any domain of decisional capacity between experimental groups for the sample as a whole. While all three of these studies developed promising methods and made valuable observations about the informed consent process, none successfully adapted the consent process to significantly increase adults with ID's participation in research. There is still no consensus on best practices for meaningfully including people with ID in the informed consent process.

The present study

The present study aimed to pilot a modified informed consent process to make research more accessible to adults with ID. Instead of viewing capacity to consent as a simple dichotomy, we propose a dynamic teaching process where the individual is taught the essential domains of informed consent so that they are better able to make a decision about whether to participate. The present study tested the efficacy of an iterative teaching process (ITP) to improve participants' competency in nine domains that we deemed essential for providing informed consent (see table 1 and study procedures).

Our Iterative Teaching Process incorporates the following educational elements gleaned from existing research: Easy Read documents (Department of Health, 2010;

Hurtado, Jones & Burniston, 2014), and conversational presentation of consent information (Dye, Hare & Hendy, 2007). We hypothesized that participants who lacked capacity to consent in one or more domains at baseline would attain capacity through the ITP. Capacity to consent is operationalized as a score of 9/9, demonstrating comprehension of all core domains.

This project was ultimately aimed at lowering barriers to enrollment and participation in research for adults with ID. If we successfully adapt the informed consent process, then more people with ID can more meaningfully participate in research. As more people with ID enter and contribute to research, our scientific understanding and ability to serve this population will be enhanced.

Chapter 2. Participant Sample and Methods

Participant sample

Twenty-one adults (N=21) with ID living in central Ohio (n=17) or the Hudson Valley region of New York (n=4) were recruited for the present study. Study visits took place at multiple locations including The Ohio State University Nisonger Center, participant homes, or their place of work. One participant withdrew from the study prior to completing the ARS due to a time conflict. Therefore, complete data was available for n=20 participants.

Inclusion and exclusion criteria

To be included in the study all participants were required to be adults (i.e., 18 years of age or older), have a diagnosis of intellectual disability, and be fluent in English. Potential participants were excluded from the study if they had complete hearing loss or deafness, or if they had no expressive or receptive language ability. There was an additional exclusion criterion for complete vision loss or blindness, which was later removed in order to expand the participant sample to include individuals with more diverse experiences and perspective.

Measures

The Iterative Teaching Process Assessment (**ITPA**; see appendix D) was created for this study. Rather than composing an exhaustive list of assessment items that may be

burdensome and discourage participation, a list of items deemed most relevant to participants' understanding and decision of whether to enroll in a sham research study was created. We developed a nine-domain practical distillation of the eleven basic elements specified by the Electronic Code of Federal Regulations. The ITPA was informed by the emphasized domains of the ACQ (Morris et al., 1993), and the IDQ (Palmer et al., 2005), while incorporating the recommendations of other researchers in this literature (Arscat, Dagnan, & Kroese, 1998; Hurtado, Jones, & Burniston, 2014; Thomson, Roberts, & Bittles, 2014).

The ITPA was developed to evaluate a novel informed consent process for minimal-risk, observational studies in the social sciences. In such a study, neither disclosing which aspects are experimental (item 5) nor alternative treatment options (item 8) are applicable. The fact that the study involves research (item 1) does not warrant independent assessment, as it is included in understanding other items. An explanation of who to contact for questions or in case of injury (item 10) will continue to be available on the informed consent document where it is more likely to be referenced than memorized. We concluded that these five items were not among the essential considerations a participant should be mentally manipulating and weighing in making their decision of whether to enroll in a study. As such, they were not assessed by ITPA, although this information was presented in the consent form.

Our list of nine recommended domains of informed consent intentionally presents voluntariness and the right to withdraw as two separate domains, though they are encompassed under one of the eleven points in the federal guidelines. These domains

were separated for effective assessment purposes so that each could consist of a single concise question. Additionally, we wanted to ensure that research participants understood that even if they do voluntarily enter a research study initially, they retain the right to withdraw at any time and are neither compelled to enter the study nor to remain a participant.

Table 1 presents the nine essential elements measured by ITPA as they align with the federal requirements for informed consent. The four elements that were not assessed by the ITPA are shaded in gray. The four omitted elements were included in the informed consent document to be retained for participants' records and reference. It should be noted that the Electronic Code of Federal Regulations stipulates eleven requirements for what should be included in the informed consent document. There are no requirements for what research participants must comprehend, and no mechanism in place to assess comprehension at all.

Table 1. Essential Elements of Informed Consent

Eleven elements specified by Electronic Code of Federal Regulations (2018) [a]	Nine elements used in the present study
1) A statement that the study involves research	
2) An explanation of the purpose of the study	1. Study purpose
3) The expected duration of the subject's participation	2. Study duration
4) A description of the procedures to be followed	3. Study procedures
5) Identification of any procedures which are experimental	
6) A description of any reasonably foreseeable risks or discomforts to the subject	4. Risks of participation
7) A description of any benefits to the subject or to others which may reasonably be expected from the research	5. Benefits of participation
8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	
9) A statement describing the extent, if any, to which confidentiality of records identify the subject will be maintained	6. Confidentiality
10) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject	7. Participation incentives [b]
11) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.	8. Voluntariness [c] 9. The right to withdraw [c]

[a] *Gray shading indicates four domains omitted from the list to be used in the present study*
[b] *Participation incentives element is additional, and not aligned with federal guidelines*
[c] *The original domain #11 is split into two separate domains for assessment purposes*

The ITPA consists of nine open-ended questions to assess comprehension of each of the nine essential domains of consent. Responses are scored as sufficient (1.0), partial (0.5), or insufficient (0.0) according to pre-determined criteria (see appendix E).

The Iterative Teaching Process Impressions Evaluation (**ITPIE**; see appendix F) consists of three open-ended questions to evaluate participants' impressions of the iterative teaching process modes. Questions were focused on participants' impressions of

whether the ITP was respectful and understandable. Participant responses were transcribed verbatim and later coded for qualitative analyses. This process is described in detail in the data analysis section.

Demographic Questionnaire (see appendix G). A questionnaire was developed for this study to measure sex, race, ethnicity, age, education, employment, guardianship status, etiology of ID, and history of research participation. Participants were queried as to how many research studies they had participated in, if any, as well as the approximate duration of these studies. Research staff administered the Demographic Questionnaire through an interview with research participants with assistance from a caregiver when one was present at the visit.

The Wechsler Abbreviated Scale of Intelligence Second Edition (**WASI-II**; Wechsler, 2011) verbal scale was administered to examine potential relationships between verbal intelligence and baseline capacity to consent as well as change in capacity to consent. The WASI-II was previously used in a study examining whether an Easy Read leaflet improved comprehension of health information in a sample of adults with ID (Hurtado, Jones, & Burniston, 2014).

The WASI-II has strong psychometric properties (Irby & Floyd, 2013). The FSIQ-4 demonstrated an average corrected split-half reliability coefficient of 0.97 across the adult sample. Indicating validity, the FSIQ-4 correlated 0.92 with the WAIS-IV FSIQ, a more extensive measure that is considered a gold standard in intelligence testing. The full-scale IQ (FSIQ-4) can range from 40 to 160. Thus, the WASI-II is capable of measuring intelligence at both extremes of functioning.

*The **Digit Span** subtest of the Wechsler Adult Intelligence Scale Fourth Edition* (WAIS-IV; Wechsler, 2008) was administered to examine potential relationships between attention to verbal stimuli or working memory, and baseline capacity to consent as well as change in capacity to consent. It comprises the 'Digits forward', that asks to repeat progressively longer sequences of random numbers, the 'Digits backwards', where participants have to repeat the numbers backwards, and the 'Digit Sequencing', which requires participants to sequentially order the numbers presented by the examiner. The digit span subtest measures auditory recall, short-term memory, and working memory. Hurtado, Jones, & Burniston (2014) used the digit-span subtest to assess attention to verbal stimuli in adults with ID.

The Schonell Reading Test (Schonell, 1971) was administered to examine potential relationships between reading ability and baseline capacity to consent as well as change in capacity to consent. The measure consists of 100 words. Grades in difficulty and scores can be converted into reading age in years and months – up to 12 years and 6 months. This measure was chosen over other adult reading tests because it is less demanding. Hurtado, Jones, & Burniston (2014) used the Schonell Reading Test in a study examining whether an Easy Read leaflet improved comprehension of health information in a sample of adults with ID.

A set of Matched Pairs of Logically Opposite Items (Winkler, Kanouse, & Ware, 1982; see appendix H) was administered to assess Acquiescence Response Set (ARS), the tendency to agree with questionnaire statements regardless of content. The tendency to acquiesce is prevalent in adults with ID (Arscat, Dagnan, & Kroese, 1997). To inform the

assessment of decisional capacity, ARS illuminates whether participants may have a tendency to agree to research participation independent of their understanding of content and the essential domains of informed consent. The scale includes 12 pairs of balanced worded, logically opposite items, with a possible score from 0 to 12 based on the number of logically opposite items endorsed. Winkler, Kanouse, and Ware (1982) found satisfactory test-retest reliability of the ARS scale (Chronbach's alpha = 0.56). As expected, higher ARS scores were found among respondents who were older and less educated. The original set of 12 pairs (24 items) was modified for administration as three sets of eight items for this study. The scale was administered in three sets to temporally separate matched pairs from each other and to minimize participant confusion. The first eight items were administered after the WASI-II, the second set after the digit span subtest, and the third and final set after the Schonell reading test.

Pause due to global public health emergency

Data collection and all in-person research activities were paused from March to September of 2020 due to the COVID-19 global pandemic. The study team determined that a transition to data collection via video conferencing technology was not feasible and would represent a separate study whose data should not be combined with what had been gathered prior to March 2020 for analyses. It was reasoned that the present pilot study was evaluating a novel in-person informed consent process and that a remote informed consent process requiring materials to be reviewed electronically would be nonequivalent in multiple ways.

When the Ohio State University Wexner Medical Center (OSUWMC) policies allowed for the resumption of in-person research, a detailed safety procedures plan was submitted to, and approved by, a member of the medical center administration prior to new study visits being scheduled. Data collected in the resumption period between October 2020 and January 2021 was completed using social distancing and personal protective equipment that required minimal changes to study procedures and that were not believed to significantly influence the data collected. A total of five of the 21 participants who completed the study protocol did so under these additional safety procedures.

Procedures

Development of Iterative Teaching Process (ITP) materials. The ITP utilizes three distinct presentations of informed consent materials that were developed by study investigators. These materials were reviewed by a panel of adults with intellectual and developmental disabilities (the DEEP) on May 10, 2019. Materials were modified based on DEEP feedback. This panel functions as a research advisory committee for the Rehabilitation Research and Training Center (RRTC) on Health and Function for People with Intellectual and Developmental Disabilities directed by Susan Havercamp, Ph.D. Collaboration with the DEEP strengthened the study by helping to maximize the accessibility of study materials and procedures for adults with ID.

ITPA Training. As part of their training, research assistants (RAs) administered the ITPA by completing simulations with the principal investigator (PI) in which they had to score an ITPA for a practice participant. The scoring reliability criterion was set at

85% agreement with the PI. After the first three participants completed the study, all RAs completed reliability scoring by listening to audio recordings of study participants completing the ITPA while they independently scored the measure. RAs needed to achieve greater than 85% agreement with the study PI prior to participating in study visits and administering the ITPA to participants. Interrater reliability of the ITPA was satisfactory (kappa .93-.76, $p<.001$). More information about ITPA interrater reliability can be found in the results section and table 3.

Randomization. Participants were randomized into one of two groups. The two groups differed only in the order of experimental conditions (ABC or ACB). A randomization table was created using blocks of four to ensure that the second researcher, who administered the ITPIE and ITPA, remained blind to ITP condition.

Pause to assess procedures. Study investigators scheduled a brief pause in data collection after the first 3 participants. During the pause, the research team reviewed the preliminary data and participant feedback. There were no significant changes to the study protocol as a result of the scheduled pause. Minor revisions to the ITP sham consent materials were made to improve readability.

Recruitment and consent procedures. Potential research participants were recruited through the Ohio State University Nisonger Center and community organizations serving adults with ID. Recruitment efforts included posting flyers throughout the Ohio State University Nisonger Center, circulating flyers to professionals in the ID field, and study researchers giving brief presentations to adults with ID who were part of community organizations. Interested participants contacted researchers who

informed potential participants, and their legal guardians, about the research purpose and procedures. Inclusion and exclusion criteria were screened over the phone or by email. Interested participants who met screening criteria were scheduled for a single study session.

A member of the research team reviewed the study informed consent form with all potential research participants and their legal guardian, if applicable. Participants who were their own legal guardians provided written informed consent if they chose to participate in the research study. For those participants with a legal guardian, consent was obtained from the guardian first and the participant then provided written informed assent to participate in the research study. Participants were encouraged to have a caregiver present at the study visit to consult with them during the informed consent process. Participants were compensated $30.00 for their participation as well as up to $20.00 of reimbursement for travel to and from the study visits.

Data collection procedures. All study procedures were approved by the Ohio State University Behavioral and Social Sciences Institutional Review Board. All participants, caregivers and legal guardians were informed that the present study was intended to assess understanding of the informed consent process for a sham (i.e., hypothetical) research study that did not exist. They were told that the procedures, risks, benefits, etc. described in the sham consent process would not actually occur for any participants of the present study. Participants completed the demographics and research experience questionnaire with research staff and with the aid of their caregiver or guardian, if desired. At the completion of the demographic questionnaire, caregivers and

guardians were asked to leave the assessment room for the remainder of the protocol unless the participant requested that they stay.

Iterative Teaching Process. The ITP consisted of three distinct approaches (see appendices A, B, and C) to teaching comprehension of each of the nine core domains essential to informed consent. Teaching modes were offered until a) the participant demonstrated mastery of the content, or b) the participant exhausted the three available modes. Throughout the process, participants were encouraged to ask questions about the sham study and the consent process. With each subsequent ITP mode presented, participants were only presented with, and assessed on, information from those domains that they had not yet mastered. Written materials for the three modes were printed on paper of different colors to make the distinction between modes more salient. The sequence of modes B and C was counterbalanced across participants.

Mode A: Sham Consent Form. Consistent with common IRB-recommended practices for research in social and behavioral sciences (Electronic code of federal regulations, 2018; The Ohio State University IRB, 2013), participants were given a copy of the informed consent form for the sham study. Research staff read the consent form aloud verbatim and answered any questions that were asked.

Mode B: Easy Read. The sham informed consent form was re-written according to guidelines for creating Easy Read materials (Department of Health, 2010). Participants were given a copy of the Easy Read text for each domain and research staff read the text aloud and answered any questions that were asked.

Mode C: Conversational. The informed consent form was presented as an oral script and broken into discrete sections for each of the 9 core domains. The oral script was read to the participant and discussed conversationally. The researcher administering the ITP encouraged participants to generate their own examples and make connections between the informed consent information being discussed and their own lives. Participants were asked to explain each core domain during the Conversational mode before moving on to the next procedure.

Following each mode, participants completed the ITPIE via interview. The evaluative questions were asked before the comprehension assessment to avoid the influence of performance on reported attitudes. Following the evaluative questions, participants completed the ITPA via interview to assess their comprehension of the essential elements they had not previously mastered. Participants' ITPA score following ITP mode A represented their baseline measurement of capacity. Participants receiving a perfect score on all 9 domains of this baseline assessment would not proceed to modes B or C, as they would already have sufficient comprehension. If the participant demonstrated mastery of all 9 essential elements at any point, the ITP ended regardless of the number of modes presented. A second researcher who was blind to ITP condition administered the ITPIE and ITPA to limit the influence of the study hypotheses and demand characteristics of the participant on these assessments. Following the third assessment, the ITP ended.

Finally, participants completed the following assessments: Wechsler abbreviated scale of intelligence (WASI-II verbal scale), Wechsler Adult Intelligence Scale (WAIS IV) Digit Span subtest (attention to and memory of verbal stimuli), the Schonell Reading

Test (reading ability), and a set of matched pairs of logically opposite items (Winkler, Kanouse & Ware, 1982). The study protocol was completed in 2 to 3 hours for the majority of participants.

Data Analysis

Four primary research aims guided this work: 1.) to assess change in capacity to consent associated with a novel ITP of the essential elements of informed consent; 2.) to explore which mode of the ITP, Easy Read or Conversational, was more effective in increasing capacity to provide informed consent among adults with ID; 3.) to explore participants' preferences for one mode of the ITP over the others as well as their views on the relative strengths and weaknesses of each approach; and 4.) to identify predictors of participants' comprehension of consent materials as measured by the ITPA. We hypothesized that participants who lacked capacity to consent in one or more domains at baseline would attain capacity through the ITP. Capacity to consent is operationalized as a score of 9/9, demonstrating comprehension of all core domains. Data were analyzed by using SPSS Statistics for Mac, Version 27.0 (IBM SPSS Statistics for Macintosh, Version 27.0. Armonk, NY: IBM Corp) and RStudio: Integrated Development Environment for R, Version 1.3.1073 (RStudio 2020, Version 1.31073, PBC, Boston, MA: RStudio Team).

To answer the first research question, we first assessed whether the ITP was successful in facilitating capacity to consent. We reported on sample scores for the ITPA at each wave, including the percentages of participants who achieved a degree of comprehension indicating capacity to consent (i.e., a score of 9/9). To assess the degree

to which the ITP increased comprehension of the informed consent materials, paired-sample t-tests were performed to compare participant ITPA scores across the three waves of the ITP. To assess the degree of change in comprehension in each of the 9 essential components of informed consent, two-tailed one-sample z-tests were performed to determine whether significantly greater than half of participants achieved an ITPA item score indicating sufficient comprehension of the consent material by wave 3.

To evaluate the second research question, whether the Easy Read or Conversational modes of presenting consent materials differed in their efficacy of teaching comprehension of the informed consent materials, independent samples t-tests of ITPA change scores for participants' performance between waves 1 and 2, grouped by the order of ITP mode presentation (i.e., ABC vs. ACB) were performed.

To evaluate the third research question, to explore participants' preferences for one mode of the ITP over the others as well as their views on the relative strengths and weaknesses of each approach, we used a Grounded theory approach to qualitatively analyze the Iterative Teaching Process Impressions Evaluation (ITPIE) data. Three independent raters who were blind to ITP condition each reviewed verbatim transcripts from the ITPIE to identify themes. The raters then each created a unique coding theme, met to compare coding, and came to a consensus on the coding themes. Each rater then coded transcripts for ITP modes A, B and C using the consensus coding themes. These data were analyzed to calculate frequencies and percentages of coding themes to determine the relative satisfaction with the three presentations of the consent material.

To address the fourth aim, to identify predictors of participants' comprehension of consent materials, a median split of ITPA scores was used to compare demographics (e.g., gender, age, education, etc.) and secondary measures (e.g., IQ, working memory, reading, etc.) in high vs. low ITPA score groups.

Chapter 3. Results

Sample demographics

Participants in this study were 21 adults with ID. One participant withdrew from the study prior to completing the ARS due to a time conflict. Therefore, complete data was available for n=20 participants. The sample was disproportionately female (n=15) with a mean age of 39.24 (*SD*= 17.88; range 18-72). The sample was mostly Caucasian (n=17) and single (n=15). The mean WASI-II full-scale IQ score was 62.86 (*SD*=14.60; range 41-93) for the entire sample. Approximately half of the sample (n=10, 47.6%) reported that they had ever consented to medical procedure, while one third of the sample (n=7, 33.4%) reported that they had ever participated in a research study before.

Regarding the two experimental conditions, which represent different orders of presenting ITP consent materials (i.e., ABC v. ACB), the groups are relatively balanced on most, but not all, demographic characteristics. The groups differ in their proportions of males and females with the ABC group being relatively balanced (5 males, 6 female) and the ACB group consisting disproportionately of females (1 male, 9 females). Notably, an independent samples *t*-test indicated that IQ score was significantly lower in the ABC group (*M*=56.91, *SD*=12.69) than in the ACB group (*M*=69.40, *SD*=14.28), $t\ (19) = -2.12$, $p = .047$, two tailed. See table 2 for more details about the sample.

Table 2. Sample Demographics

	Full Sample N=21 Mean (SD)	Males n=6 Mean (SD)	Females n=15 Mean (SD)	ABC Group n=11 Mean (SD)	ACB Group n=10 Mean (SD)
Age	39.24 (17.88)	33.50 (14.17)	41.53 (19.11)	36.73 (16.24)	42.00 (20.02)
IQ	62.86 (14.60)	65.00 (12.44)	62.00 (15.70)	56.91 (12.69)	69.40 (14.28)
Years of education	11.90 (2.64)	13.67 (2.25)	11.20 (2.51)	12.64 (2.42)	11.10 (2.77)
	n (%)	n (%)	n (%)	n (%)	n (%)
Male	6 (28.6)	6 (100)	0 (0)	5 (45.5)	1 (10)
Female	15 (71.4)	0 (0)	15 (100)	6 (54.5)	9 (90)
Race/ethnicity					
Non-Hispanic Black or African American	3 (14.3)	0 (0)	3 (20)	2 (18.2)	1(10)
Non-Hispanic White or Caucasian	17 (81.0)	6 (100)	11 (73.3)	9 (81.8)	8 (80)
Prefer not to answer	1 (4.8)	0 (0)	1 (6.7)	0 (0)	1 (10)
Developmental Disabilities/Cause of ID					
Autism Spectrum Disorder	4 (19.0)	1 (16.7)	3 (20)	1 (9.1)	3 (30)
Down Syndrome	3 (14.3)	1 (16.7)	2 (13.3)	2 (18.2)	1 (1)
Cerebral Palsy	2 (9.5)	1 (16.7)	1 (6.7)	1 (9.1)	1 (10)
Perinatal Trauma	2 (9.5)	2 (33.3)	0 (0)	1 (9.1)	1 (10)
Postnatal Trauma	1 (4.8)	0 (0)	0 (0)	1 (9.1)	0 (0)
Epilepsy	1 (4.8)	0 (0)	1 (6.7)	1 (9.1)	0 (0)
Not specified or known	11 (52.4)	3 (50)	8 (53.3)	6 (54.5)	5 (50)
Highest Degree Earned					
No degree or certificate	4 (19)	0 (0)	4 (26.7)	1 (9.1)	3 (30)
High school certificate	7 (33.3)	2 (33.3)	5 (33.3)	5 (45.5)	2 (20)
High school diploma	9 (42.9)	3 (50)	6 (40)	4 (36.4)	5 (50)
Associate’s degree	1 (4.8)	1 (16.7)	0 (0)	1 (9.1)	0 (0)

Continued

Table 2 Continued

Marital status					
Single	15 (71.4)	5 (83.3)	10 (66.7)	8 (72.7)	7 (70)
In a romantic relationship but not married	5 (23.8)	1 (16.7)	4 (26.7)	2 (18.2)	3 (30)
Widowed	1 (4.8)	0 (0)	1 (6.7)	1 (9.1)	0 (0)
Living situation					
Independent with roommates	1 (4.8)	0 (0)	1 (6.7)	1 (9.1)	0 (0)
With romantic partner	1 (4.8)	0 (0)	1 (6.7)	0 (0)	1(10)
With family	7 (33.3)	3 (50)	4 (26.7)	5 (45.5)	2 (20)
Alone with less than 24-hour support staff	6 (28.6)	0 (0)	6 (40)	2 (18.2)	4 (40)
Supported living	5 (23.8)	2 (33.3)	3 (20)	3 (27.3)	2 (20)
Adult foster care	1 (4.8)	1 (16.7)	0 (0)	0 (0)	1 (10)
Paid work					
Yes – part time (less than 40 hours per week)	7 (33.3)	3 (50)	4 (26.7)	4 (36.4)	3 (30)
No – volunteer/unpaid position	6 (28.6)	2 (33.3)	4 (26.7)	2 (18.2)	4 (40)
No – have had paid work in the past	5 (23.8)	0 (0)	5 (33.3)	2 (18.2)	3 (30)
No – have never been employed	3 (14.3)	1 (16.7)	2 (13.3)	3 (27.3)	0 (0)
Ever consented to a medical procedure					
Yes	10 (47.6)	1 (16.7)	9 (60)	5 (45.5)	5 (50)
No	10 (47.6)	4 (66.7)	6 (40)	5 (45.5)	5 (50)
Unsure	1 (4.8)	1 (16.7)	0 (0)	1 (9.1)	0 (0)
Have participated in a research study					
None	14 (66.7)	5 (83.3)	9 (60)	8 (72.7)	6 (60)
Behavioral and social science	3 (14.3)	0 (0)	3 (20)	2 (18.2)	1 (10)
Biomedical/Clinical trial	1 (4.8)	0 (0)	1 (6.7)	0 (0)	1 (10)
Simple interview or questionnaire	2 (9.5)	1 (16.7)	1 (6.7)	1 (9.1)	1 (10)
Cannot recall study type	1 (4.8)	0 (0)	1 (6.7)	0 (0)	1 (10)

Interrater reliability

The ITPA consisted of 9 open-ended questions, asked up to 3 times each, assessing participant comprehension of the essential elements of informed consent. Each of the 9 questions were scored as 0, indicating an incorrect response, 0.5, indicating a partially correct response, or a 1 indicating a correct response, based on predetermined criteria developed by study investigators (appendix E). Each study participant (N=21) completed the ITPA with a researcher who scored the measure during the visit. In addition to those original scores, additional members of the research team listened to audio recordings of the ITPA to score each item independently and determine the overall interrater reliability of the measure. Six (n=6) participants were randomly selected to be rated for reliability. Fleiss' multi-rater kappa (Fleiss, 1971) was run to determine if there was agreement between researchers on ratings of participant responses on the ITPA. Fleiss' kappa values are reported in table 3.

Table 3. ITPA interrater agreement for 6 randomly selected participants

	# of raters	κ	*z*	*p*	Confidence Interval (95%)
1.	4	.93	13.42	<.001***	.79 – 1.06
2.	4	.88	14.55	<.001***	.76 – 1.00
3.	4	.78	12.89	<.001***	.66 - .90
4.	4	.78	10.94	<.001***	.64 - .92
5.	4	.84	13.73	<.001***	.72 - .96
6.	2	.76	5.37	<.001***	.48 – 1.04

Note. ***$p < .001$. κ = Fleiss' kappa of multi-rater agreement.

Fleiss' kappa ranged from .76 - .93 for this study, indicating that there was good (.61< κ <.8) or very good (.81< κ <1) agreement between researchers' ratings of the ITPA, according to guidelines for interpreting Cohen's kappa coefficient of interrater

reliability (Altman, 1999). The obtained kappa values were significantly different from 0, as confirmed by *z*-tests that produced statistically significant *p*-values, and 95% confidence intervals that did not include 0, indicating that interrater reliability of the primary outcome variable significantly exceed that which would occur by chance.

Capacity to consent

As expected, few participants demonstrated capacity to consent, defined as an ITPA score of 9 out of 9, following ITP mode A, which is the equivalent of how consent materials are conventionally presented. Only 4.8% (1 out of 21) of study participants achieved an ITPA score of 9 out of 9 following mode A. The mean ITPA score following mode A was *M*=3.74 (approximately 41.5% of the maximum score), *SD*=2.39. Participants' ITPA scores following the presentation of mode A materials served as their baseline capacity from which to compare their performance on the experimental conditions.

The ITP, which included up to three waves of teaching informed consent materials in three unique modes of presentation, led to relatively few participants demonstrating capacity to consent. Only 9.5% (2 out of 21) of study participants achieved an ITPA score of 9/9 by completion of the ITP. Only 1 of the 20 participants who did not demonstrate capacity to consent at baseline (i.e., following mode A) achieved it by the end of the process (i.e., wave 3). The mean ITPA score following mode A, which is the first time the assessment was given, was *M*=3.74 (or 41.5% of the maximum score), *SD*=2.39; *M*=5.24 (58.2% score), *SD*=2.41 following the second wave of consent

materials, and M=5.93 (65.87% score), SD=2.12 following the third and final wave of consent materials. In addition to those 2 participants who achieved an ITPA score of 9 at or before wave 3, 2 participants achieved a score of 8.5 out of 9, and 1 achieved a score of 8 out of 9. A one-sample z-test confirmed that significantly fewer than half of participants (i.e., a proportion of 0.5) achieved capacity to consent by wave 3 (.095 or 2 of 21), $z = -3.71$, $p < .001$. Our hypothesis that a greater number of participants would achieve complete comprehension of consent materials (i.e., a score of 9) indicating capacity to consent through completion of the ITP was not confirmed.

Table 4. Cumulative ITPA Score Frequencies by Wave (N=21)

ITPA Score	Wave 1 Frequencies (%)	Wave 2 Frequencies (%)	Wave 3 Frequencies (%)
9.0	1 (4.8)	1 (4.8)	2 (9.5)
8.5	0 (0)	1 (4.8)	2 (9.5)
8.0	0 (0)	2 (9.5)	1 (4.8)
7.5	0 (0)	2 (9.5)	3 (14.3)
7.0	0 (0)	2 (9.5)	1 (4.8)
6.5	2 (9.5)	1 (4.8)	1 (4.8)
6.0	2 (9.5)	0 (0)	0 (0)
5.5	1 (4.8)	0 (0)	0 (0)
5.0	1 (4.8)	2 (9.5)	2 (9.5)
4.5	3 (14.3)	2 (9.5)	5 (23.8)
4.0	1 (4.8)	1 (4.8)	2 (9.5)
3.5	1 (4.8)	2 (9.5)	1 (4.8)
3.0	1 (4.8)	2 (9.5)	0 (0)
2.5	0 (0)	1 (4.8)	0 (0)
2.0	3 (14.3)	0 (0)	0 (0)
1.5	1 (4.8)	1 (4.8)	1 (4.8)
1.0	2 (9.5)	1 (4.8)	0 (0)
0.5	1 (4.8)	0 (0)	0 (0)
0	1 (4.8)	0 (0)	0 (0)
M (*SD*)	3.74 (2.39)	5.24 (2.41)	5.93 (2.12)

Note. The ITPA consists of 9 open-ended questions to assess comprehension of each of the 9 essential domains of consent. Responses are scored as sufficient (1.0), partial (0.5), or insufficient (0.0) according to pre-determined criteria (appendix E). Therefore, ITPA scores can range from 0 to 9.

Comprehension of consent materials

To assess the degree of change in capacity to consent participant ITPA scores were compared across the three waves of the ITP. The change in mean ITPA scores from wave 1 or baseline (*M*=3.74, *SD*=2.39) to wave 2 (*M*=5.24, *SD*=2.41) represents an approximately 40% increase in ITPA score for the entire sample. The change in mean ITPA scores from wave 2 (*M*=5.24, *SD*=2.41) to wave 3 (*M*=5.93, *SD*=2.12) represents an approximately 13% increase in ITPA score for the entire sample. While the change in mean ITPA scores from wave 1 (*M*=3.74, *SD*=2.39) to wave 3, or the completion of the ITP, (*M*=5.93, *SD*=2.12) represents an approximately 59% increase in ITPA score for the entire sample.

Paired-sample *t*-tests showed that wave 1 scores (*M*=3.74, *SD*=2.39) were statistically significantly lower than wave 2 scores (*M*=5.24, *SD*=2.41), t (20) = -6.874, $p < .001$, $d = 1.50$. Wave 1 scores were statistically significantly lower than wave 3 scores (*M*=5.93, *SD*=2.12), t (20) = -8.23, $p<.001$, $d = 1.80$. And wave 2 scores were statistically significantly lower than wave 3 scores, t (20) = -3.51, $p = .002$, $d = .75$. The effect sizes for the comparisons between waves 1 and 2 (*d*=1.50) and waves 1 and 3 (*d*=1.80) each exceed Cohen's (1988) convention for large effects in the social sciences (i.e., $d = 0.80$), while the comparison between waves 2 and 3 (*d*=.75) represent a medium effect size. These analyses indicate that there is a statistically significant improvement in ITPA performance with each subsequent wave of the ITP. However, these analyses do not separate the effects of the mode of presenting consent materials, nor do they control for

the potential effects of being taught the same material a second and even a third time while being asked the same questions to evaluate comprehension.

To assess the degree of change in comprehension in each of the 9 essential components of informed consent, two-tailed one-sample z-tests were performed to determine whether significantly greater than half (i.e., a proportion of 0.5) of participants achieved an ITPA item score indicating sufficient understanding of the consent material by wave 3 (see table 5). These analyses indicate that significantly greater than half of participants achieved comprehension on questions (2) Study Duration, (7) Participation Incentives, (8) Voluntariness, and (9) The Right to Withdraw. Significantly fewer than half of participants achieved comprehension on questions (1) Study Purpose and (3) Study Procedures. These findings suggest that not all of the ITPA questions assessing comprehension of the key domains of consent were equally difficult, with study purpose and procedures being particularly difficult for adults with ID to comprehend.

Table 5. Proportions of Participants Demonstrating Comprehension by ITPA Question

ITPA question	*P*	*SD*	*z*	*p*
1. *Study Purpose:* What is the purpose of the study?	0.24	0.43	-2.38	.02*
2. *Study Duration:* How long will you be in the study?	0.86	0.35	-3.30	<.001***
3. *Study Procedures:* What will happen in the study?	0.19	0.39	-2.84	.004**
4. *Benefits of Participation*: What are the risks of being in the study?	0.48	0.50	-.18	0.85
5. *Risks of Participation:* What are the risks of being in the study?	0.38	0.49	-1.10	.27
6. *Confidentiality:* What does confidentiality mean in this study	0.67	0.47	1.56	.12
7. *Participation Incentives:* Can you be paid for being in the study?	1.0	0.00	4.58	<.001***
8. *Voluntariness:* Do you have to be in the study?	0.76	0.43	2.38	.02*
9. *The Right to Withdraw:* If you decide to start the study and then change your mind, what can you do?	0.86	0.35	3.30	<.001***

Note. *$p < .05$. **$p < .01$. ***$p < .001$. One-sample z-tests are comparing the proportions (*P*) represented above against a proportion representing half (0.5) of participants achieved comprehension on a given ITPA question by wave 3.

Mode of presenting consent materials

Multiple approaches were used to assess how well each mode of presenting consent materials taught the essential components of informed consent. Independent

samples *t*-tests were completed to compare the modes of presenting consent materials at each wave of the ITP. An independent samples *t*-test found that baseline (wave 1) ITPA scores were lower in the ABC presentation group (*M*=2.73, *SD*=1.98) than in the ACB group (*M*=4.85, *SD*=2.38), *t* (19) = -2.30, *p*=.038, *d*=.97. ITPA scores at wave 2 were again lower in the ABC group (*M*=4.00, *SD*=2.20) than the ACB group (*M*=6.60, *SD*=1.90), *t* (19) = 2.88, *p*=.01, *d*=1.26. Interestingly, while final ITPA scores (wave 3) were lower in the ABC group (*M*=5.18, *SD*=2.12) than the ACB group (*M*=6.75, *SD*=1.89), this difference was not statistically significant, *t* (19) = -1.78, *p*=.091, *d*=.78.

The two groups (i.e., ABC v. ACB) were not expected to differ on baseline ITPA scores. Despite randomly assigning participants to the different orders of presenting ITP materials, a two-tailed independent samples t-test indicated that IQ scores were significantly lower in the ABC group (*M*=56.91, *SD*=12.69) than in the ACB group (*M*=69.40, *SD*=14.28), *t* (19) = -2.12, *p* = .047. A One-way Analysis of Covariance (ANCOVA) controlling for IQ found that there was not a significant effect of group (i.e., ABC v. ACB) on baseline ITPA change score, *F* (1,19) = 2.02, *p* =.38, η_p^2 =.04, while there was a significant effect of IQ, *F* (1,19) = 18.19, *p*<.001, η_p^2 =.50. This finding indicated that the significant difference observed between groups ABC and ACB on baseline ITPA scores is better explained by the group differences in IQ.

Due to unexpected group differences in baseline ITPA scores, and the observed group differences in wave 2 ITPA scores, we performed an ANCOVA to determine whether the wave 2 group differences were best explained by the mode of presenting consent materials (i.e., mode B v. C), by IQ, or by the baseline scores. An ANCOVA to

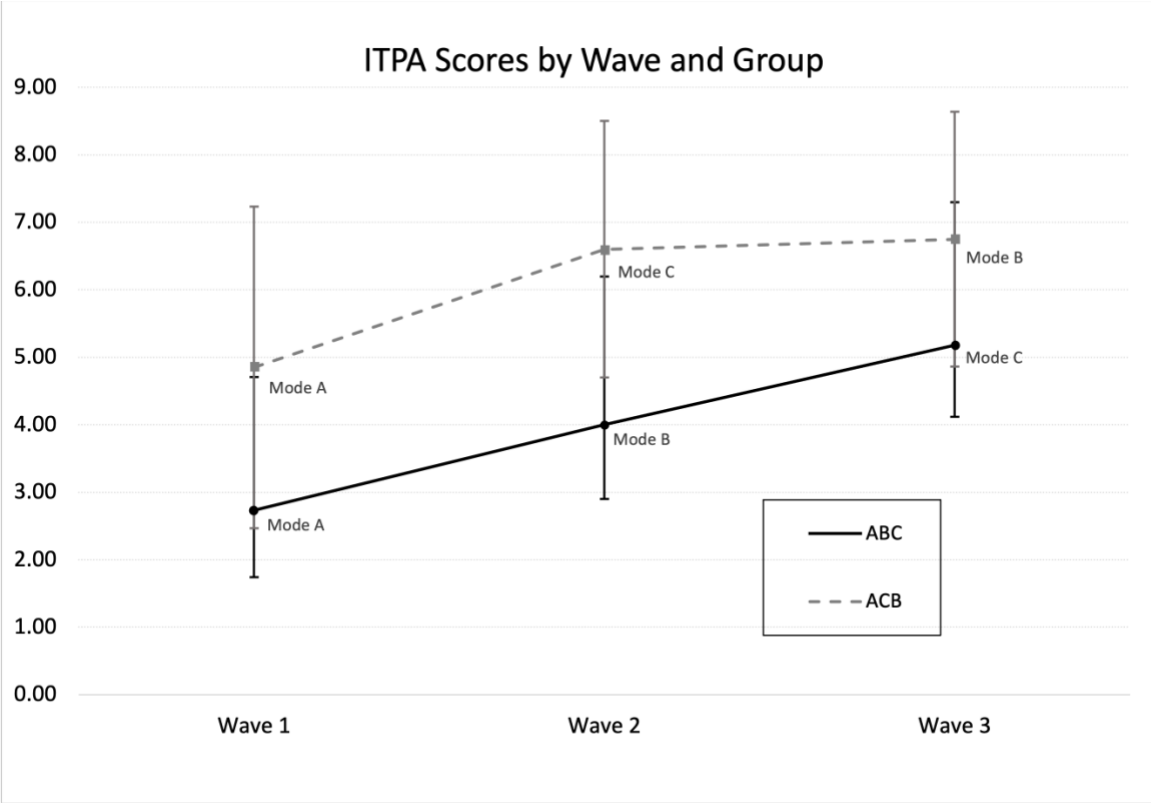
examine group differences in wave 2 scores controlling for IQ and baseline ITPA score found that there was not a significant effect of group F (1,18) = 2.4, p=.14, η_p^2 =.12, nor for IQ, F (1,18) = .78, p=.39, η_p^2 = .044; however, the effect of baseline ITPA score was statistically significant, F (1,18) = 27.281, p<.001, η_p^2 =.62. This finding indicates that the significant differences observed between groups ABC and ACB on wave 2 ITPA scores were best explained by the difference in baseline ITPA performance.

To evaluate whether ITP mode B, Easy Read, or mode C, Conversational, was superior for teaching the essential elements for capacity to consent, we conducted an independent samples *t*-test of ITPA change scores for participants' performance between waves 1 and 2, grouped by the order of ITP mode presentation (i.e., ABC v. ACB). This test was not statistically significant, t (19) = .56, p = .29, d = .48. This finding is not surprising given our finding that wave 2 ITPA scores are best explained by baseline ITPA. An independent samples *t*-test of ITPA change scores from participants' performance between waves 2 and 3, grouped by order of ITP mode presentation, was also conducted. ITPA change scores for those participants who completed mode B, Easy Read (n=10, M=.15, SD=.34) in wave 3 (group ACB) were significantly smaller than for those who completed mode C, Conversational (n=11, M=1.18, SD=.98), t (19) = 3.15, p = .005, d = 1.38. This finding is interesting because the groups did not differ in wave 3 ITPA scores after having significant differences in waves 1 and 2. Group ABC, which was exposed to mode C (Conversational) in ITPA wave 3, appears to close the statistically significant gap between the groups in wave 3. While this finding suggests that that mode C, Conversational, is superior to mode B, Easy Read, for improving

comprehension of the informed consent materials, it is difficult to interpret. Wave 1 ITPA scores are strongly correlated with scores in wave 2, r (19) = .91, $p < .001$; and wave 3, r (19) = .86, $p < .001$, respectively; wave 2 and wave 3 scores are also strongly correlated, r (19) = .93, $p < .001$. Therefore, it is difficult to attribute this statistically significant finding to the strength of mode C in wave 3 when it may also be influenced by the relative weakness of mode B in wave 2 for the ABC group. Alternatively, this difference may have been a result of a ceiling effect for the ACB group in that they had already correctly answered most of the questions they were capable of comprehending when assessed in waves 1 and 2. The associations between ITPA score, ITP wave, and mode are displayed in figure 1.

As previously noted, the ABC group had significantly lower IQ scores than the ACB group. An ANCOVA was conducted to control for IQ in testing the order effect on ITPA change scores from waves 2 to 3. There was a significant effect of ITP mode on ITPA change scores from waves 2 to 3 after controlling for IQ, F (1, 19) = 5.51, p = .031, η_p^2 = .23. This finding indicates that the significant effect found between the order of presenting ITP material on ITPA change scores from waves 2 to 3, F (1, 19) = 9.94, p = .005, η_p^2 = .34, remains when controlling for the effect of IQ. The ITP mode explains approximately 34% of the variance in ITPA change score from waves 1 to 2 without a covariate. This drops to explaining approximately 23% of the variance when controlling for IQ, which has a η_p^2 = .07, explaining 7% of the variance in ITPA change score in this model.

Figure 1. ITPA Scores by Wave and Group



Note. Group ITPA score means are displayed. Error bars represent standard deviations. All participants are presented with ITP mode A at wave 1. Group ABC was presented with mode B (Easy Read) at wave 2 and mode C (Conversational) at wave 3. Group ACB was presented with mode C at wave 2 and mode B at wave 3.

To evaluate the possible differences in ITP mode at the level of ITPA questions, we conducted two-proportion *z*-tests comparing modes B and C on the proportions of wave 2 ITPA scores demonstrating full comprehension (score of 1.0) in that particular wave, which excludes cases where a full comprehension score was achieved in wave 1. The proportions used in the test were calculated by dividing the number of full

comprehension scores achieved on each question in wave 2 by the number of questions asked in wave 2. The number of questions asked per wave varied by participant because participants are only asked questions in waves 2 and 3 that they had not previously mastered. Only 2 of the 9 ITPA questions produced statistically significant *z*-tests for these analyses. For wave 2, question 6 (confidentiality), a significantly lower proportion of participants exposed to mode B (P_B=0, n=11) received a full comprehension score than did those participants exposed to mode C (P_C=.83, n=6), z = -2.92, p = .004, two tailed. For wave 2, question 9 (the right to withdraw), a significantly lower proportion of participants exposed to mode B (P_B=.17, n=6) received a full comprehension score than did those participants exposed to mode C (P_C=1, n=2), z = -2.10, p = 0.04, two tailed. It is notable that the proportions of full comprehension scores were larger for mode C than mode B for all 9 of the ITPA questions in wave 2.

Table 6. Wave 2 Proportions of Participants Demonstrating Comprehension by ITPA Question

ITPA question	Mode B		Mode C			
	P_B	*n*	P_C	*n*	*z*	*p*
1. *Study Purpose*	0	11	0.22	9	-1.65	.10
2. *Study Duration*	0.29	7	0.75	4	-1.49	.14
3. *Study Procedures*	0.09	11	0.11	9	-0.15	.88
4. *Benefits of Participation*	0.22	9	0.33	6	-.47	.64
5. *Risks of Participation*	0	9	0.29	7	-1.73	.08
6. *Confidentiality*	0	11	0.83	6	-2.92	.004**
7. *Participation Incentives*	0.60	5	1	1	-0.77	.44
8. *Voluntariness*	0.25	8	0.33	3	-0.27	.79
9. *The Right to Withdraw*	0.17	6	1	2	-2.10	.04*

Note. *$p < .05$. **$p < .01$. Two-proportion z-tests are comparing the proportions (*P*) of modes B and C for participants who achieved comprehension on a given ITPA question during wave 2, which excludes those who previously achieved comprehension during wave 1. Additionally, n=11 participants were presented with mode B materials, while only n=9 were presented with mode C materials in wave 2.

Participant impressions and ITP acceptability

Both qualitative and quantitative analyses of response data to the iterative teaching process impressions evaluation (ITPIE) were used in a mixed methodological approach to assess whether participants prefer one ITP mode over the other and to learn

about the relative strengths and weaknesses of the three presentations of the consent material. Three independent raters who were blind to ITP condition each coded verbatim transcripts of participants' responses to ITPIE-Part A using a consensus coding scheme. All transcripts were coded and a total of 28 themes were identified across all 3 ITPIE questions. Table 7 presents the frequencies and percentages of each of the 9 themes identified, by mode, for question 1, "Did you find this information understandable?".

Table 7. ITPIE Question 1 Theme Frequencies by Mode

Theme	Mode A (n=21) Frequency (%)	Mode B (n=20) Frequency (%)	Mode C (n=20) Frequency (%)
1. Understandable	17 (81)	18 (90)	18 (90)
2. Confusing	2 (9.5)	0 (0)	0 (0)
3. Learned something	1 (4.8)	0 (0)	0 (0)
4. Somewhat clear	2 (9.5)	1 (5)	1 (5)
5. Hard	1 (4.8)	0 (0)	0 (0)
6. I remember	1 (4.8)	0 (0)	0 (0)
7. Improving understanding	0 (0)	2 (10)	0 (0)
8. Enthusiastic	0 (0)	3 (15)	0 (0)
9. I don't know	0 (0)	1 (5)	1(5)

Note. ITPIE question 1 was "Did you find this information understandable?" One participant scored out of the ITP by achieving a score of 9/9 on the ITPA after mode A.

The most prevalent theme across modes was "Understandable," which encompassed all participant responses indicating that they found the consent material understandable following that mode. The proportion of participant responses to ITPIE question 1 containing the theme "Understandable" following mode A (17 of 21, 81%) did not differ significantly from that of modes B or C (18 of 20, 90%), $z = -.82$, $p = 0.41$, two tailed. 2 participant responses indicated that they found mode A materials "Confusing,"

compared to no such responses for modes B or C. One participant responded, "*I did not understand it. It was confusing*" (Male, age 25) following mode A. 2 participant responses indicated that they found mode A "Somewhat clear," while 1 response indicated the participant found it "Hard," with only 1 participant also stating modes B and C were "Somewhat clear," respectively, and none indicating that either were "Hard." Additionally, 2 participant responses indicated that mode B "Improved understanding," and 3 expressed enthusiasm in their affirmation that mode B was understandable, while neither of these themes were coded in responses following modes A or C.

Table 8 presents the frequencies and percentages of each of the 21 themes identified, by mode, for question 2, "How did it feel to learn this information?". The most prevalent theme across modes was "Acceptable*."* One participant responded, "*It went well*" (Male, age 32) following mode C, another responded, "*The information, when he was reading it, I felt good about it*" (Female, age 72) also following mode C, and several responded "*Good*," or "*Fine*" – all of which was coded as "Acceptable." The modes differed in the number of participants responding that they felt the presentation of materials to be acceptable, with modes C (13 of 20, 65%) and A (13 of 21, 61.9%) having a greater proportion than mode B (7 of 20, 35%), though these differences were not statistically significant, (mode A v. B) $z = 1.72$, $p = 0.09$, two tailed; and (mode B v. C) $z = -1.90$, $p = 0.06$, two tailed. One participant responded, "*It was better than the first one*" (Male, age 31) stating their preference for mode B over mode A, while another responded, "*It was very interesting. It was put in a different way this time, but it was basically the same,"* (Male, age 29) observing that the (mode B) Easy Read consent

material is similar to the baseline consent form that it is derived from. Another participant responded, "*It felt good. It felt like helping people understand what I go through and other people go through*," (Female, age 57) reflecting her appreciation for the modified consent materials in mode C as well as possibly the overall goals of the project.

Table 8. ITPIE Question 2 Theme Frequencies by Mode

Theme	Mode A (n=21) Frequency (%)	Mode B (n=20) Frequency (%)	Mode C (n=20) Frequency (%)
1. Acceptable	13 (61.9)	7 (35)	13 (65)
2. Overwhelmed	1 (4.8)	0 (0)	0 (0)
3. Sarcastic	1 (4.8)	0 (0)	1 (5)
4. Interesting	3 (14.3)	3 (15)	1 (5)
5. Enthusiastic	3 (14.3)	5 (25)	5 (25)
6. Learned something	2 (9.5)	1 (5)	1 (5)
7. Understandable	1 (4.8)	0 (0)	0 (0)
8. Helpful	1 (4.8)	0 (0)	1 (5)
9. I don't know	1 (4.8)	1 (5)	0 (0)
10. It's a lot of information	1 (4.8)	0 (0)	0 (0)
11. Accommodating	0 (0)	1 (5)	0 (0)
12. Scary	0 (0)	1 (5)	0 (0)
13. Improved understanding	0 (0)	1 (5)	0 (0)
14. Proud	0 (0)	1 (5)	0 (0)
15. Well written	0 (0)	1 (5)	0 (0)
16. Learnable	0 (0)	0 (0)	1 (5)
17. Helping others understand experience of disability	0 (0)	0 (0)	1 (5)
18. Better than first mode	0 (0)	1 (5)	0 (0)
19. Similar to previous mode	0 (0)	1 (5)	0 (0)
20. I don't know	0 (0)	1 (5)	1 (5)
21. Did not directly answer the question/Did not understand the question	2 (9.5)	2 (10)	0 (0)

Note. ITPIE question 2 was "How did it feel to learn this information?" One participant scored out of the ITP by achieving a score of 9/9 on the ITPA after mode A.

Table 9 presents the frequencies and percentages of each of the 9 themes identified, by mode, for question 3, “Did you feel respected when (researcher) taught you this information?”. The most prevalent theme across modes was “Respected,” which encompasses a range of affirmative responses to the question. Most participants responded in some way that they did feel respected in all three modes, though at slightly lower proportions for modes A (18 of 21, 85.7%) and B (18 of 20, 90%) than in mode C (20 of 20, 100%), and while these differences approached statistical significance, (mode A v. C) $z = -1.76$, $p = 0.08$; (mode B v. C) $z = -1.45$, $p = 0.15$, they do not appear to be meaningful. While there were 3 participants who did not answer the question directly, and 2 who expressed that they did not know how to answer the question, overall, there were no participants who expressed that the process made them feel disrespected because the ITP was either too complicated or simplistic.

Table 9. ITPIE Question 3 Theme Frequencies by Mode

Theme	Mode A (n=21) Frequency (%)	Mode B (n=20) Frequency (%)	Mode C (n=20) Frequency (%)
1. Respected	18 (85.7)	18 (90)	20 (100)
2. Heard	2 (9.5)	0 (0)	0 (0)
3. Enthusiastic	2 (9.5)	1 (5)	1 (5)
4. He told me everything	1 (4.8)	0 (0)	0 (0)
5. Reading helps me understand	1 (4.8)	0 (0)	0 (0)
6. Accommodating	1 (4.8)	0 (0)	0 (0)
7. Learned something	0 (0)	1 (5)	1 (5)
8. I don't know	0 (0)	2 (10)	0 (0)
9. Did not directly answer the question/Did not understand the question	3 (14.3)	0 (0)	0 (0)

Note. ITPIE question 3 was "Did you feel respected while (researcher) taught you this information?" One participant scored out of the ITP by achieving a score of 9/9 on the ITPA after mode A.

Predictors of capacity to consent

Several approaches were used to identify predictors of ITPA performance. First, a Pearson correlation matrix of correlations between ITPA baseline (wave 1) and Final (wave 3) scores and continuous variables including demographics, academic, and cognitive measures was conducted (see table 10). ITPA baseline score was, unsurprisingly, strongly correlated with final scores of the same measure, r (19) = .86, p < .001. ITPA baseline score was also strongly correlated with IQ, r (19) = .77, p < .001; moderately or strongly correlated with all IQ subtests except block design, moderately correlated with Schonell Reading Test scores, r (19) = .46, p = .036, and moderately

negatively correlated with ARS scores, r (18) = -.58, p = .008, indicating that lower acquiescence was associated with higher ITPA baseline scores. Final ITPA scores at the completion of the ITP showed the same pattern of associations with the individual difference variables as did the baseline ITPA scores. Another interesting association is the moderate negative correlation between participant age and number of years in school, r (19) = -.63, p = .002. As expected, the WASI-II FSIQ-4 (i.e., IQ) and all IQ subtests were all strongly or moderately correlated with each other, although the block design subtest had a weaker association with the rest. IQ was also strongly associated with the Schonell Reading Test, r (19) = .79, p < .001, while IQ had a moderate negative correlation with ARS, r (18) = .50, p = .024.

Independent-samples *t*-tests were conducted to explore whether academic and cognitive measures such as years in school, IQ, digit span, the Schonell reading test, and the acquiescence response set (ARS), were associated with the efficacy of the ITP, as measured by ITPA performance. A median split of participant's wave 3 ITPA performance produced two groups, a n=10 higher scores group that ranged from 5.5 to 9, and a n=11 lower scores group that ranged from 1.5 to 5.0. Independent-samples *t*-tests, grouped by the median split of ITPA scores, were performed to examine whether academic and cognitive variables were associated with ITPA performance. These results are reported in table 11.

Table 10. Means, Standard Deviation, and Pearson Correlation Matrix for Continuous Individual Difference Variables (N=21)

	M	*SD*	1	2	3	4	5	6	7	8	9	10	11	12
1. ITPA Baseline	3.74	2.39	-											
2. ITPA Final	5.93	2.12	.86***	-										
3. Age	39.24	17.88	.04	.01	-									
4. Years in school	11.90	2.64	-.30	-.21	-.63**	-								
5. IQ	62.86	14.60	.77***	.68**	<.01	<.01	-							
6. Block Design	27.00	6.60	.43	.31	.37	-.14	.69**	-						
7. Matrix Reasoning	30.10	10.11	.56**	.60**	-.14	.27	.84***	.44*	-					
8. Vocabulary	32.71	10.27	.75***	.66**	-.13	-.01	.92***	.49*	.71***	-				
9. Similarities	29.43	8.82	.83***	.70***	-.17	-.04	.89***	.50*	.63**	.88***	-			
10. Digit Span	3.19	2.42	.67**	.66**	-.22	.10	.87***	.36	.80***	.88***	.86***	-		
11. Reading Test	51.29	28.62	.46*	.53**	-.05	.27	.79***	.49*	.77**	.73***	.59**	.76***	-	
12. ARS (n=20)	6.20	2.02	-.58**	-.47*	.19	.06	-.50*	-.28	-.34	-.44	-.63**	-.50*	-.28	-

Note. *p < .05. **p < .01, ***p < .001. Block Design, Matrix Reasoning, Vocabulary, and Similarities are the 4 subtests of the WASI-II and are reported here as *t*-scores. Digit Span is a WASI-IV subtest and is reported here as a scaled score. Possible scores for Schonell reading test are 0-100 words read. Higher ARS scores indicate the endorsement of more pairs of logically opposite items endorsed, suggesting greater acquiescence.

Table 11. Independent Samples t-tests for Academic and Cognitive Measures by ITP Performance

	Higher ITPA scores (n=10)	Lower ITPA scores (n=11)			
	Mean (*SD*)	Mean (*SD*)	*t* (df)	*p*	*d*
Years in school	11.10 (3.21)	12.64 (1.86)	-1.36 (19)	.19	.59
IQ (FSIQ-4)	71.80 (14.27)	54.73 (9.52)	3.26 (19)	.004**	1.42
Digit Span SS	4.60 (2.63)	1.91 (1.30)	3.01 (19)	.007**	1.32
Reading score	65.00 (27.16)	38.82 (24.81)	2.31 (19)	.032*	1.01
ARS total [a]	5.40 (1.27)	7.00 (2.36)	- 1.89 (18)	.075	.85

Note. *$p < .05$. **$p < .01$. Possible scores for Schonell reading test are 0-100 words read.

[a] The ARS had a total sample size of 20. Higher ARS scores indicate the endorsement of more pairs of logically opposite items endorsed, suggesting greater acquiescence.

Participant responses to how many years they were in school did not significantly differ by median split ITPA performance groups, t (19) = 1.36, p = .19, two tailed. Participants with higher ITPA scores (M=11.10, SD=3.21) had significantly higher IQ scores, as measured by the FSIQ-4 on the WASI-II, than those with lower ITPA scores (M=54.73, SD=9.52), t (19) = 3.26, p = .004. Participants with higher ITPA scores (M=4.60, SD=2.63) had significantly higher WAIS-IV Digit Span total scale scores, a measure of attention to verbal stimuli or working memory than those with lower ITPA scores (M=1.91, SD=1.30), t (19) = 3.01, p = .007. Participants with higher ITPA scores (M=65.00, SD=27.16) had significantly higher Schonell Reading Test scores, which have a possible scoring range from 0-100 words correctly read, than those with lower ITPA scores (M=38.82, SD=24.81), t (19) = 2.31, p = .032. Participants with higher ITPA

scores (*M*=5.40, *SD*=1.27) had lower ARS scores, which indicates endorsement of fewer pairs of logically opposite items, than those with lower ITPA scores (*M*=7.00, *SD*=2.36), though this difference was not statistically significant, t (18) = -1.89, p = .075. Overall, superior ITPA performance was associated with higher IQ, greater attention to verbal stimuli or working memory, and greater reading scores. The negative association between higher ITPA scores and ARS scores suggesting a lower tendency to acquiesce was approaching significance at p = .075, with a medium effect size of d = .85.

Chi-square tests of association were conducted to explore whether demographic variables including gender, highest level of education, race/ethnicity, marital status, living situation, employment status, research participation, and developmental disability diagnoses were associated with the efficacy of the ITP, as measured by ITPA performance. Possible associations between these demographics variables and the two groups produced by median split of the ITPA wave 3 scores are listed in table 12.

Table 12. Chi-square Tests for Associations Between Demographics and ITP Performance

	Higher ITPA scores (n=10)	Lower ITPA scores (n=11)		
	Frequency (%)	Frequency (%)	X^2 (df)	*p*
Gender			.69 (1)	.41
Female	8 (38.1)	7 (33.3)		
Male	2 (9.5)	4 (19)		
Highest level of education			1.21 (3)	.75
No degree or certificate	2 (9.5)	2 (9.5)		
HS certificate	3 (14.3)	4 (19)		
HS diploma	4 (19)	5 (23.8)		
Associate degree	1 (4.8)	0 (0)		

Continued

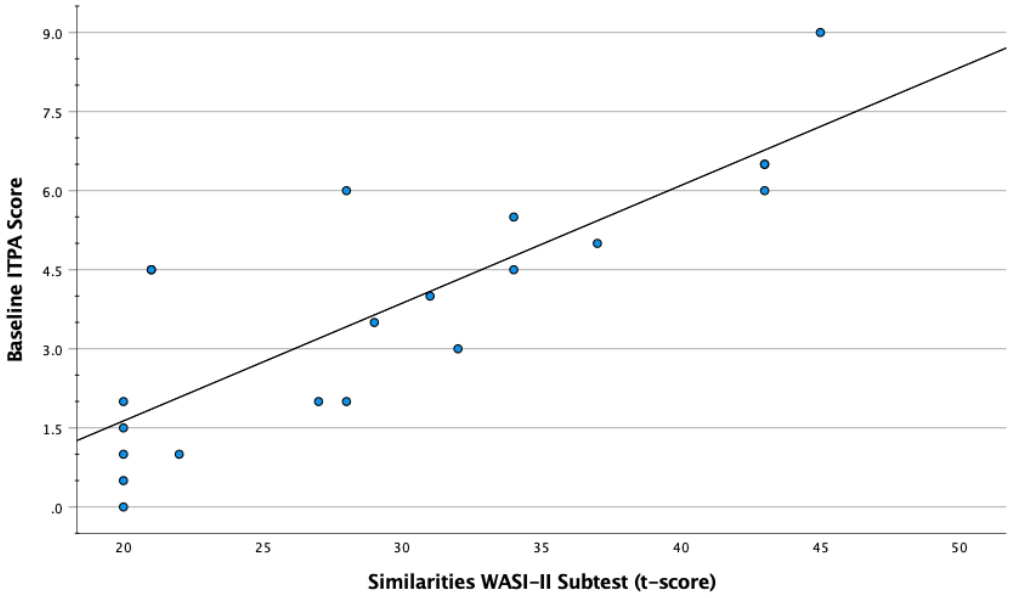
Table 12 Continued

Race/Ethnicity			5.46 (2)	.066
Caucasian/White	6 (28.6)	11 (52.4)		
Black or African Amer.	3 (14.3)	0 (0)		
Prefer not to respond	1 (4.8)	0 (0)		
Marital status			4.43 (2)	.11
Single	5 (23.8)	10 (47.6)		
Relationship, not married	4 (19)	1 (4.8)		
Widowed	1 (4.8)	0 (0)		
Living situation			9.41 (5)	.094
Independent/roommates	0 (0)	1 (4.8)		
Alone, <24-hour support	5 (23.8)	1 (4.8)		
With romantic partner	1 (4.8)	0 (0)		
Supported living	2 (9.5)	3 (14.3)		
With family	1 (4.8)	6 (28.6)		
Other	1 (4.8)	0 (0)		
Paid work			3.97 (3)	.27
Yes, part time	3 (14.3)	4 (19)		
No, volunteer/unpaid	4 (19)	2 (9.5)		
No, had paid work in past	3 (14.3)	2 (9.5)		
No, never employed	0 (0)	3 (14.3)		
Research participation			1.53 (1)	.22
Yes	2 (9.5)	5 (23.8)		
No	8 (38.1)	6 (28.6)		
Autism Spectrum Disorder			1.49 (1)	.22
Yes	3 (14.3)	1 (4.8)		
No	7 (33.3.)			
Down Syndrome			3.18 (1)	.074
Yes	0 (0)	3 (14.3)		
No	10 (47.6)	8 (38.1)		

The variables most strongly associated with baseline ITPA score were the WASI-II FSIQ-4 (IQ), and the vocabulary and similarities subtests. Since these three variables are also highly correlated with each other, a multiple linear regression was conducted to determine which variables were the strongest predictors of baseline ITPA score. Results

of the multiple linear regression indicated that there was a collective significant effect between FSIQ-4, vocabulary, similarities, and baseline ITPA score, F (3,17) = 12.50, p<.001, R^2=.69. The individual variables were examined further to determine which factor uniquely explained the most variance in baseline ITPA score. By comparing the change in R^2 when each individual factor was removed from the original model, it was determined that similarities was the single strongest predictor of variance. A simple linear regression to predict baseline ITPA score based on the similarities subtest was significant, F (1,19) = 40.70, p<.001, R^2=.68. A simple linear regression to predict final (wave 3) ITPA score based on the similarities subtest was also significant, F (1,19) = 18.69, p<.001, R^2=.50, though it explained a smaller proportion of the variance than it did for baseline ITPA scores.

Figure 2. Baseline ITPA Score by Similarities WASI-II Subtest



Note. N=21. Similarities subtest M = 29.43, SD = 8.82. Pearson correlation between baseline ITPA score and Similarities subtest is r (19) = .83, p < .001.

Chapter 4. Discussion

Inclusive participation allows more members of society to benefit from research. Instead of facilitating research engagement, the informed consent process often fails to elucidate the very elements that are essential to informed consent. There has been increasing interest and research on the topic of improving research accessibility for adults with ID in recent decades (Cohn & Larson, 2007; Mulhall et al., 2020). Multiple studies have attempted to adapt the informed consent process to more effectively teach the essential elements needed to provide informed consent to research. Researchers have used different assessments to measure potential participants' level of comprehension to determine research eligibility (Dye, Hare, & Hendry, 2007; Hurtado, Jones, & Burniston, 2014; Wheeler et al., 2020). Many more have written about the challenges of these approaches, including how establishing firm cut points, or even asking these questions at all, may actually be a form of discrimination toward those with ID (Calvaley, 2012; Dye, Hare, & Hendy, 2007; Iacono & Murray, 2003). While there is growing attention to methods for determining individual's capacity to consent to research studies, there is no consensus or empirical guidelines to evaluate capacity in adults with ID (Carey & Griffiths, 2017).

The primary goal of this pilot research was to evaluate whether a novel informed consent process was more effective than current conventional practice at teaching key elements of informed consent. The study evaluated a novel iterative teaching process (ITP) to teach and assess informed consent. Rather than establishing a firm cut point for capacity to consent, we created an iterative process where the key components of consent

were assessed, and then additional learning trials were provided through a series of distinct modes of presentation with the goal of filling in the remaining gaps in their comprehension. This novel approach did not seek to supersede IRB requirements or federal guidelines for what informed consent forms must look like and include, but rather, to provide a method to work within that existing framework and improve the teaching and assessment of participant's comprehension of consent materials with the ultimate goal of improving their ability to make an informed decision.

Few participants achieved our criteria for capacity to consent

Consistent with the findings of previous studies assessing capacity to consent in this population (Arscott, Dagnan, & Kroese, 1999; Dye, Hare, & Hendy, 2007; Hurtado, Jones, & Burniston, 2014; Wheeler et al., 2020), few participants achieved our criteria for demonstrating capacity to consent on the ITPA at baseline. The literature on this topic has emphasized the challenge for adults with ID to comprehend the standard complex and jargon-filled informed consent forms (ICF) for research (Arscott, Dagnan, & Kroese, 199; Iacono, 2006). In this study, only 2 of 21 (4.8%) participants achieved 9/9 correct responses on the ITPA and only 1 of the 20 (5%) who had not achieved capacity at baseline did so by the end of the ITP. These rates are similar to those found by other studies that adapted the informed consent process and assessed comprehension in adults with ID (Dye, Hare, & Hendry, 2007; Hurtado, Jones, & Burniston, 2014; Wheeler et al., 2020) although each of these studies used distinct assessment criteria and samples making direct comparison impossible. The fact that so few participants met our criteria for demonstrating capacity to consent may suggest that our scoring for some of the

individual items on the ITPA were too stringent or difficult, or that a complete score of 9 out of 9 on this assessment is simply unrealistic for this population even with three opportunities to learn the material. This finding supports the proposal that the criteria to demonstrate sufficient capacity to consent should be flexible and proportional to the complexity and risks of each study (Dye, Hare, & Hendy, 2007). However, the hypothetical study described in this pilot was a minimal-risk social science study, which raises concerns for how this population would perform on a similar assessment of a greater than minimal risk, more complex study where the criteria for demonstrating sufficient consent would necessarily be raised.

Despite the small number of participants who achieved the maximum ITPA score, the ITP assisted study participants in making significant improvements in their comprehension of consent materials following the baseline ITPA assessment. Final ITPA scores represented a 59% increased from baseline scores on average. Analyses found statistically significant improvement from baseline, to wave 2, to wave 3, with large and medium effect sizes. These analyses did not account for differences in teaching efficacy by mode of presentation, nor for the potential effects of being taught the same material 2 or 3 times, but they do demonstrate that adults with ID can significantly improve their comprehension of the essential elements of informed consent with accommodations and practice.

Each item on the ITPA represents a core element of capacity to consent to a research study. We found that not all of these concepts where equally challenging for participants to comprehend. For example, 100% of study participants (N=21) were able to

provide a correct answer to the question, “Can you be paid for being in the study?”. Eighty-six percent (n=18) provided correct answers to questions about study duration, and the right to withdraw, with 76% (n=16) providing correct answers regarding voluntariness. A much smaller proportion of participants correctly answered questions regarding study purpose and procedures, at 24% (n=5) and 19% (n=4), respectively. This finding provides a strong rationale to improve our methods of teaching study purpose and procedures, given the apparent difficulty of these concepts, as we continue to work toward the goal of improving accessibility to research for adults with ID.

Comparing methods of teaching consent

The second research aim for this pilot study was to explore which mode of the ITP, Easy Read or Conversational, was more effective in increasing comprehension of consent materials among adults with ID. The fact that the two groups differed on baseline ITPA scores complicated our ability to make direct comparisons at wave 2, when each group was exposed to a different mode. The difference in baseline ITPA scores was attributed to an unequal distribution of IQ scores between groups. Comparisons between each group’s change scores from baseline to wave 2 was expected to be the primary focus of our analyses to determine whether the Easy Read or Conversational modes were more effective. What we found was that, despite the significant baseline differences, change scores did not significantly differ by group. This is surprising because, in addition to each group receiving a different mode of presenting the materials in wave 2, the ACB group had earned higher baseline scores and had higher average IQ scores. The significant difference observed between groups on wave 2 scores was attributed to higher baseline

ITPA scores in group ACB. Therefore, direct group comparisons at wave 2 cannot contribute to our understanding of the relative efficacy of modes B versus C.

Arguably the most interesting finding of the entire analysis was the significant difference found in wave 2 to 3 change scores by mode, coupled with that the overall group difference was no longer statistically significant in wave 3 after being significant in waves 1 and 2. Group ABC, which was presented with mode C, Conversational in wave 3 had a significantly greater change score from wave 2 to 3 compared to ACB. This change appeared to close the gap between the groups that emerged at baseline. Surprisingly, this finding may suggest that a relatively lower IQ group can catch up to those with higher IQ and make meaningful gains in comprehension of consent materials with additional time and education. While we did not intend for the groups to significantly differ on IQ, we may not have been able to observe this effect if the groups had been more balanced on that variable. This finding may suggest that the Conversational mode is superior to the Easy Read mode for improving comprehension of consent materials. The two modes were not statistically different in wave 2, but the Conversational mode was statistically superior in wave 3 despite being presented to the group with a lower average IQ. Alternatively, this significant difference in change scores may have been a result of a ceiling effect for the ACB group in that those participants had already correctly answered most of the questions they were capable of comprehending when assessed in waves 1 and 2.

To compare the effects of mode of presentation on the individual ITPA items, we examined the proportion of participants in each group (ABC vs. ACB) who had given a

correct answer for each question in wave 2. Participants answered questions correctly following mode C at higher proportions for all 9 questions when compared to mode B, although not all of these differences were statistically significant. Two questions, evaluating confidentiality and the right to withdraw, were answered in significantly greater proportions following mode C than following mode B. Given that this is a pilot study with a very small sample, it is also worth mentioning that two other questions, evaluating study purpose and risks of participation, were answered at a greater proportion following mode C than following mode B and trending toward statistical significance (i.e., $.1 \geq p \geq .05$). A limitation to this finding is that it comes from a cross-section of wave 2 only, the finding that mode C is superior is confounded by the fact that that mode was taught to the ACB presentation group with higher average IQ scores.

Participant impressions of the ITP

Our third research aim was to explore if participants prefer one mode of the ITP over the others as well as relative strengths and weaknesses of each approach, which was assessed by examining their qualitative responses to the iterative teaching process impressions evaluation (ITPIE). Overall, participant responses to the three questions of the ITPIE provide a strong endorsement of the approach. Participants answered that they found the ITP information understandable in 81% (n=17), 90% (n=18 of 20) and 90% (n=18 of 20) of responses following modes A, B, and C, respectively. These responses also represent a notable discrepancy between participant confidence in their understanding of the materials and their relatively low scores on the ITPA.

Participant responses to ITPIE question 2, “How did it feel to learn this information?” was more varied. The modes differed in the number of participants responding that they felt the presentation of materials was acceptable, with mode C having a greater proportion of this response than mode B, though the difference was trending toward significance at $p = .06$. Participant responses to question 3, “Did you feel respected when (researcher) taught you this information?” also varied by mode. The most prevalent theme across modes was “Respected”, which encompassed a range of affirmative responses to the question. A greater proportion of participants provided responses coded as “Respected” following presentations of mode C materials than mode B, though this difference was not statistically significant. Questions 2 and 3 qualitatively contribute to emerging evidence suggesting that mode C might be more effective and preferred by participants over mode B.

Predictors of comprehension

Our final research aim was to explore whether individual differences are associated with the efficacy of the ITP. Multiple variables representing participants’ cognitive and academic differences were strongly correlated with baseline (wave 1) and final (wave 3) ITPA scores (see table 10). The WASI-II FSIQ-4 as well as the matrix reasoning, vocabulary, and similarities subtests were each moderately or strongly correlated with both baseline and final ITPA scores. Notably, the block design subtest did not significantly correlate with ITPA scores, indicating that this test may not serve as a useful predictor of capacity to consent in adults with ID. Participant age and years of education were similarly poor predictors of capacity to consent in this sample. The

WAIS-IV digit span subtest, a measure of attention to verbal stimuli and working memory, was significantly correlated with ITPA scores, but not as strongly correlated as vocabulary or similarities which are measures of verbal intelligence. The Schonell Reading Test and Acquiescence Response Set (ARS) were each moderately correlated with ITPA scores. The negative correlation between the ARS and ITPA suggests that participants who endorsed fewer pairs of logically opposite items were more likely to comprehend the consent materials; lower acquiescence is associated with greater capacity to consent. Associations between demographic variables and final ITPA scores were also explored. Differences in participant race, marital status, living arrangement, and having Down Syndrome were all found to be trending toward significant differences between a median split of high and low wave 3 ITPA scores. While these relatively weak associations between demographic characteristics and capacity to consent are interesting and warrant further investigation, it is unclear if they would remain in a larger, more representative sample.

Results from a Pearson correlation matrix and multiple linear regression indicated that the WASI-II similarities subtest was the single variable most predictive of participant comprehension of consent materials. The strong association between participant performance on the similarities subtest and the ITPA was predictable as both measures require verbal and abstract reasoning. The similarities subtest performed only marginally better than the vocabulary subtest, and together these two subtests make up the Verbal Comprehension Index (VCI). The WASI FSIQ-4, which includes 4 subtests, was also strongly correlated with ITPA performance. The marginal differences observed between

these variables' strong associations with comprehension of consent material should be interpreted with caution in such a small sample, especially given that the three measures are closely related. In practice, an abbreviated IQ test and related measures (e.g., working memory, reading ability) all appear to be predictive of capacity to comprehend consent materials in a sample of adults with ID. Although the WASI-II, an abbreviated IQ battery of only 4 subtests, can be administered in approximately 30 minutes, the Verbal Comprehension Index (VCI) subtests or even the similarities subtest alone are likely to be sufficient measures to predict the efficacy of the ITP for this population. Adults with ID frequently have impairments in memory, as well as in receptive and expressive language (Arscott, Dagnan, & Kroese, 1999; Murphy & Clare, 1995). These findings suggest that more supports and teaching of consent materials are indicated for those with relatively lower IQ scores, or even better, low verbal IQ.

Strengths of this pilot study

The novel ITP was an overall success. Participant scores on the ITPA increased in each wave of presenting consent materials. Qualitative responses to the ITPIE were overwhelmingly positive, with the majority of participants stating that they found the materials understandable and that they felt respected during the teaching trials. Interrater reliability of ITPA was high, which is important and meaningful in this pilot study of a novel intervention and assessment. The use of open-ended questions (appendix D) with predetermined scoring criteria (appendix E) for the ITPA, as compared to multiple choice assessments of capacity to consent (Hurtado, Jones, & Burniston, 2014; Wheeler et al., 2020), reduces the ability for participants to provide a correct answer about a concept

they do not truly understand (i.e., a false positive). Open-ended questions also allow for the assessment to be administered multiple times without becoming significantly easier with each trial. A strength of this study was the use of a control condition (mode A), where a conventional informed consent form was read aloud. This mode controlled for the standard practice used in the majority of research for this population. Mode A provided meaningful data on participant comprehension following standard consent practices. The findings of this study are most directly applicable to minimal risk studies in the behavioral and social sciences, though future studies might examine whether they can be adapted to greater than minimal risk studies or research in other fields and disciplines.

This pilot study had several additional strengths overall. Participants were randomized to one of two orders for presenting the ITP consent materials, allowing researchers to compare the relative efficacy and strengths of the Easy Read and Conversational teaching approaches. Each participant met with two researchers during their study visit, one researcher who administered the ITP materials and most study measures, and a second researcher who administered the primary outcome measures (i.e., ITPA and ITPIE) who was blind to the ITP mode being assessed in an attempt to reduce both measurement bias, and participant desirability bias to share positive impressions of the materials presented by the first researcher. Additionally, the research team made strong efforts to lower barriers to inclusion when possible by reimbursing for travel to the study visits including parking or taxi, conducting study visits at participants' homes or places of work, utilizing minimal inclusion and exclusion criteria in order to recruit a

diverse and representative sample, and allowing for flexibility when participants were most comfortable with a caregiver remaining present throughout data collection procedures.

Limitations

This study also had several limitations. This pilot recruited a small sample (N=21) of adults with ID and, as a result, the randomized groups were not well balanced for gender or measures of intelligence. The sample was also notably lacking in diversity, being primarily composed of non-Hispanic, white participants. The sample underrepresented those with severe and profound ID, which was anticipated but not our intent. The majority of participants were recruited from a relatively small number of day programs in central Ohio and the Hudson Valley region of New York.

The primary obstacle to study recruitment was the Covid-19 global pandemic which led to a suspension of all in-person research activities and greatly limited interest in study participation when recruitment resumed. There were participants scheduled for study visits and others who had expressed interest in participating who were lost to follow up and never recruited to the study after the pandemic began. We do not know how the five participants who agreed to participate in the study during the pandemic might have differed from those n=16 who completed the study prior to the suspension of in-person activities. The possible impact of revised study protocols that included distancing and the use of personal protective equipment (PPE) during data collection is unknown.

A significant limitation to our study design was confounding information provided through the legitimate informed consent process as part of entering the pilot itself. Multiple participants provided answers during the ITPA indicating that they were confused between the information provided as part of the legitimate informed consent process, and that of the hypothetical study as part of the ITP. The study design described and used by McCormack et al., (2019) included two separate study visits, one for consent and initial testing, and the second for education and assessment related to the hypothetical study. Separating the genuine informed consent process from discussion and assessment of hypothetical consent into two days could serve as a useful model for overcoming this limitation. Participants performed most poorly on ITPA questions regarding study purpose and procedures. The correct answers to these items were considerably different between the actual ITP study and the hypothetical study they were being asked about in the ITPA. As a result, participants' ability to comprehend these items may actually be underestimated in this sample. In contrast, a greater proportion of participants answered questions regarding voluntariness and the right to withdraw; these are essentially the same concept regardless of what study is being discussed. The high proportion of participants answering those questions correctly may be partly attributed to participants being first exposed to this information during the informed consent process before the ITP study even began.

Some studies examining adaptive informed consent procedures for adults with ID conceptualize and measure four aspects of decisional capacity. These are understanding, appreciating, reasoning, and expressing a choice (Kong, Efrem, & Campbell, 2020;

McCormack et al., 2019; Wheeler et al., 2020). A 2018 systematic review of the literature examining measures of informed consent identified a narrow focus on understanding, or comprehension, of the consent materials (Gillies, Duthie, Cotton, & Campbell, 2014). The novel measure of informed consent used in this study (ITPA) follows this trend. The ITP paradigm could have placed more emphasis on appreciating (i.e., linking the decision to one's own situation) and reasoning (i.e., considering all of the information and weighting the consequences). Nevertheless, the Conversational mode of presenting consent materials is particularly useful for facilitating appreciation and reasoning. While we could have asked participants to express a choice about whether they would consent to the sham study, we decided against asking this question. With all of the care taken to explain that the study was hypothetical, we were concerned that such a question would only serve to confuse participants. Furthermore, it is unclear how to interpret a participant's inconsequential choice whether or not to participate in an explicitly hypothetical study. Similar studies that have chosen to ask participants with ID whether they would like to consent to a hypothetical study have acknowledged that this question may be too abstract and unlikely to reflect how they would actually respond during a real informed consent process (Wheeler et al., 2020).

Recommendations and future directions

The results and experience of completing the present pilot study led to several ideas for improvements and alternative approaches in future studies. Given the relatively small number of participants with ID who achieved a maximum score on the ITPA assessment, it would be interesting and informative to complete a similar study with a

sample of typically developing adults with average cognitive functioning. An active control group that is exposed to repeated trials of the same consent material might assist in approximating the unknown effect of repeated exposure to consent materials independent of the specific mode of teaching. Given that our randomized groups for the present study were imbalanced on a meaningful predictor of capacity to consent (i.e., IQ) it might be useful to stratify randomized samples for IQ or other individual differences of interest such as participant's sex, race, or developmental disability diagnosis.

The ITP in the present study compared the conventional approach to informed consent (A) with an Easy Read (B) and a Conversational presentation (C). Future studies should compare these promising modes of presenting informed consent materials with relatable social stories depicting characters who are considering entering a study through an illustration or other visual aid (Dye, Hare, & Hendy, 2007; Hurtado, Jones, & Burniston, 2014), a video presentation, or an interactive application on a tablet or computer (McCormack et al., 2019; Wheeler et al., 2020). Finally, we propose that future studies investigating adaptive informed consent processes be as closely approximated to the real teaching, discussions, and decision making to enter research studies as possible. The best way to achieve this would be to conduct a pre-study to collect data and evaluate real informed consent processes with real consequences (Ho et al., 2016) rather than conducting a confusing and inconsequential simulation of a similar experience.

Beyond studies that are specifically investigating the informed consent process, the results of the present pilot have meaningful implications for researchers who work with adults with ID. Comprehension of informed consent materials can be taught to, and

learned by, adults with ID with the proper materials, patience, and educational scaffolding in place. Researchers may consider using Easy Read guidelines (Department of Health, 2010) when creating assent forms that are not necessarily required to include all of the same details and strict templates that IRBs mandate for informed consent forms. Even when a long, detailed, consent form is being provided, an additional Easy Read form could be provided to participants with ID. A method for having conversational iterations, alternating with assessment of comprehension, could be incorporated into the consent process for research with adults with ID, as well as individuals with lower IQ, reading ability, and other groups that may require extra attention and assistance to reach their highest potential comprehension of the consent materials. We propose that the threshold for demonstrating capacity to consent should be proportional to the complexity and risk of each study, though this should not be used as an exclusion criterion for participants who might benefit from the research. Instead, these assessments and adjustable thresholds should be used as indicators to initiate ongoing education as well as the possibility of supported decision making or even proxy consent. There are multiple ways to ethically minimize the risks of research participation, and no individuals should be excluded from research on the basis of capacity to consent.

Conclusion

In conclusion, this pilot study found encouraging evidence for the efficacy and feasibility of a novel iterative teaching process for teaching and assessing informed consent to research for a sample of adults with ID. A small number of participants achieved the maximum comprehension score; however, the ITP approach was successful

overall in improving comprehension of the essential elements of consent through successive teaching trials. Results did not support a clear advantage of one mode of presenting the materials over another; both the Easy Read and Conversational modes were effective in teaching the materials and were well liked by adults with ID. Several cognitive variables were predictive of capacity to consent to research with measures of verbal intelligence emerging as the strongest predictors in this sample. The original materials, design, and findings of this project contribute to the growing literature on improving accessibility to research for adults with ID by taking a significant step toward validating a process for both teaching and evaluating informed consent. This process can be used to improve comprehension of information that individuals of diverse cognitive abilities need to weigh their decision when considering enrolling in a research study. Future research is needed to improve these practices as well as practical guidance for improving the ethics and efficacy for researchers obtaining informed consent from adults with ID for research on any topic.

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Appendices

Appendix A: ITP Mode A - Sham Consent Form

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Perceptions of Health and Physical Activity in Adults with Intellectual Disability.**
Principal Investigator:	**Jesse Strickler**
Sponsor:	**Center for Clinical and Translational Science**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

The reason we are doing this project is to study people's beliefs and practices related to health and physical activity and how these might affect a person's mood. We will interview you about your beliefs and practices related to physical activity and other health behaviors such as diet. We will also ask you questions about your mood and physical health. The interview will take about 60 minutes to complete.

There is minimal risk with this study and there are no benefits to you for participating. If you do decide to participate, you would be helping us to better understand beliefs and practices related to physical activity and health in adults with intellectual disability.

1. Why is this study being done?

The reason we are doing this project is to study people's beliefs and practices related to health and physical activity and how these might affect a person's mood.

2. How many people will take part in this study?

There will be a total of 30 people who will take part in this study.

3. What will happen if I take part in this study?

We will interview you about your beliefs and practices related to physical activity and other health behaviors such as your diet. We will also ask you questions about your mood and physical health.

4. How long will I be in the study?

The interview will take about 60 minutes to complete.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There is minimal risk with this study. You may find certain questions upsetting, difficult to answer, or objectionable. You do not have to answer any questions that you don't want to answer. You may participate in the interviews as much or as little as you wish.

7. What benefits can I expect from being in the study?

There are no benefits to you for being in this study. If you do decide to participate, you would be helping us to better understand beliefs and practices related to physical activity and health in adults with intellectual disability.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs of taking part in this study.

10. Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
    - Height/Weight

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
    - working for or with the sponsor; or
    - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;

- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact ***Jesse Strickler at 614-685-8724***

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ***Karel Smith at 614-688-8544***

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251

_____

Date and time

Appendix B. ITP Mode B - Easy Read Consent Form

Easy Read Informed Consent Form

Study Title	Perceptions of Health and Physical Activity in Adults with Intellectual Disability.
Principal Investigator	Jesse Strickler
Sponsor	Center for Clinical and Translational Science

- These papers use words and sentences that may be hard to understand. **Please ask for help** in reading these papers if it will help you.
- **This is a consent form for entering a research study.**
  - A **consent form** is a paper that tells you what you need to know about a research study. If you sign a consent form you agree that you understand the study. You only sign a consent form if you want to be in the study.
  - A **research study** is what people do when they want answers to hard questions.

  This consent form will tell you everything you need to know about this research study. Also the consent form tells you what can happen if you decide to be part of the study.

  Please think about the words on these papers carefully. Feel free to **talk about the study with your friends and family.** Please ask questions before making your decision whether or not to be in the study.
- You are being asked to think about being a part of this study.

- If you decide to be part of the study, you will be asked to sign these papers. You will also be given a copy of the papers.

- Summary:
- We are doing this project to learn more about the health of people with an intellectual disability.
- In this study we will ask you questions about healthy things you do such as exercising and your diet. We will also ask you about how you feel.
- You will be in the study for about 60 minutes or 1 hour.
- The study is very low risk.

---

1. The reason that this study is being done

We are doing a study about health. We want to learn more about the health of people like you who have an intellectual disability. The reason we are doing this is to see how healthy things people do might be connected to how they feel.

- Here are some examples of healthy things:
    - Eating healthy foods such as fruits and vegetables
    - Exercising by playing sports or going to the gym
    - Relaxing your body or mind
    - Having fun with friends or family

2. How long will you be in the study

You will be in the study for about 60 minutes or 1 hour.

---

3. What will happen in the study

- In this study we will ask you questions about healthy things you do such as exercising and your diet.

- We will also ask you about how you feel in your body and mood or emotions. Mood is how you feel emotionally in your mind instead of in your body, like excited or sad.

4. Your choice to be in the study or not

Your decision to be part of the study is voluntary.

- **Voluntary** means you can choose to be part of the study or choose not to be part of the study. It is completely up to you. Nothing bad will happen if you choose not to be part of the study.
- No one should be upset if you choose not to be part of the study. If someone is upset about your choice, we will keep this private and we will not tell anyone about your choice.

---

5. Leaving or stopping the study after it starts

- If you decide to be in this study, you can say you want to **stop for a break at any time**. You can also say you want to **stop and leave the study at any time**.

- By signing the paper you agree to be in the study. But you do not have to stay in the study just because you sign.

- If you leave the study **nothing bad will happen** to you and you will not lose anything you already have. Your answer will not affect your future at The Ohio State University. If you are a student or you work at Ohio State, your answer will not affect your grades or job.

6. Payment

- You will not be paid for being in the study.

- No one else will be paid for being in the study either.

- We cannot pay you because we do not want people to be in the study only for the payment.

---

7. Benefits

- You will not get any payment for being in the study.

- If you decide to be in the study, you will be helping us to answer the questions we have about health and mood in people who have an intellectual disability.

- **Please ask for help or support** if you need it at any time while you are here.

8. Confidentiality

Confidentiality is the protection of your personal information.

In the study we will keep all of the things you tell us about yourself **private**. We will not share anything you say here with anyone who isn't working on the study.

We will try our best to keep your study-related information confidential. But, we may have to give this information to certain groups if the law requires it.

Your records may be reviewed by the following groups

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices
- The sponsor supporting the study and their agents or study monitors

---

9. Risks

The study is very low risk.

- **Risk** means there is a chance of something going wrong. We do not expect anything to go wrong.

- Your private information might be released accidentally.

- You might not like some of the questions we will ask. If any questions upset you or you do not want to answer for any reason just tell us. **You can choose which questions you want to answer or not.**

Signature Page

Do you want to be in this study? YES or NO

If yes, you can write your name here. Remember you can always change your mind.

Participant signature: _____

Date: _____

Appendix C: ITP Mode C – Conversational Script

Introduction and summary:

You are being asked to think about being a part of this study. If you decide to be part of the study, you will be asked to sign this paper. If you sign, you agree that you understand the study. You only sign if you want to be in the study. You will also be given a copy of the papers.

I will tell you everything you need to know about this research study. I will also tell you what can happen if you decide to be part of the study. Please think about what I tell you carefully. Feel free to talk about the study with your friends and family. Please ask questions before making your decision whether or not to be in the study. I am going to use words and sentences that may be hard to understand. Please ask me to repeat or explain what I am reading if it will help you.

We are doing this project to learn more about the health of people with an intellectual disability. In this study we will ask you questions about healthy things you do such as exercising and your diet. We will also ask you about how you feel. You will be in the study for about 60 minutes or 1 hour. The study is very low risk.

1. Study purpose

We are doing a study about people's health. We want to learn more about the health of people like you who have an intellectual disability. The reason we are doing this is to see how healthy things people do might be connected or related to how they feel.

Here are some examples of healthy things:

- Eating healthy foods such as fruits and vegetables
- Exercising by playing sports or going to the gym
- Relaxing your body or mind
- Having fun with friends or family

2. Study Duration

You will be in the study for about 60 minutes or 1 hour.

3. Study procedures

In this study we will ask you questions about healthy things you do such as exercising and your diet. We will also ask you about how you feel in your body and emotions.

4. Voluntariness

It is your decision whether to be in the study or not. No one else can make this decision for you. If you decide to be in the study but later change your mind, you can choose to leave at any time. No one should be upset if you choose not to be part of the study. If someone is upset about your choice, we will keep this private and we will not tell anyone about your choice.

5. The right to withdraw

If you decide to be in the study but later change your mind, you can take a break or leave at any time.

6. Payment for being in study

You will not be paid for being in the study. No one else will be paid for being in the study either. We cannot pay you because we do not want people to be in the study only for the payment.

7. Benefits of being in study

You will not get any payment for being in the study. If you decide to be in the study, you will be helping us to answer the questions we have about health and emotions in people who have an intellectual disability. Please ask for help or support if you need it at any time while you are here.

8. Confidentiality

Confidentiality is the protection of personal information. Here in the study, confidentiality means keeping all of the things you tell us about yourself private. We won't share your answers or anything you say as part of the study with anyone who isn't working on the study.
We will try our best to keep your study-related information confidential. But, we may have to give this information to certain groups if the law requires it.

9. Risks of being in study

The study is very low risk. Your private information might be released accidentally. You might not like some of the questions we will ask. If any questions upset you or you don't want to answer for any reason, you can choose which questions you want to answer or not.

Appendix D: Iterative Teaching Process Assessment (ITPA) questions

1. Study Purpose: What is the purpose of the study?

2. Study Duration: How long will you be in the study?

3. Study Procedures: What will happen in the study?

4. Benefits of participation: What are the benefits of being in the study?

5. Risks of participation: What are the risks of being in the study?

6. Confidentiality: What does confidentiality mean in this study?

7. Participation incentives: Can you be paid for being in the study?

8. Voluntariness: Do you have to be in the study? Explain.

9. The right to withdraw: If you decide to start the study and then change your mind, what can you do?

Appendix E: Iterative Teaching Process Assessment (ITPA) sample answer key

1. Study Purpose: What is the purpose of the study?
    - *(1.0) Sample answers receiving full score:*
        - To learn about the health and mood of people with intellectual disability
        - To learn about the health behaviors (or exercise or diet) of people with intellectual disability
    - *(0.5) Sample answers receiving partial score:*
        - To learn about health
        - To learn about intellectual disability / disability
        - To learn about the things I do and how I feel about them
    - *(0.0) Sample answers receiving no score:*
        - To learn about me / people like me
        - To exercise
        - To diet

2. Study Duration: How long will you be in the study?
    - *(1.0) Sample answers receiving full score:*
        - An hour
        - About an hour
        - 60 minutes
        - About 60 minutes
    - *(0.5) Sample answers receiving partial score:*
        - *No partial score answers for question #2*
    - *(0.0) Sample answers receiving no score:*
        - Not too long
        - A long time
        - Until I feel like leaving
        - For as long as you need me

3. Study Procedures: What will happen in the study?
    - *(1.0) Sample answers receiving full score:*
        - An interview about health and mood/feelings
        - Answer questions about health and mood/feelings
    - *(0.5) Sample answers receiving partial score:*
        - An interview
        - Answer questions
    - *(0.0) Sample answers receiving no score:*
        - I (participant) ask questions
        - I do exercise
        - I eat

4. Benefits of participation: What are the benefits of being in the study?

- *(1.0) Sample answers receiving full score:*
    - There are no benefits of participation
    - To help the research only / help answer the questions only
- *(0.5) Sample answers receiving partial score:*
    - To help you
- *(0.0) Sample answers receiving no score:*
    - The money / the compensation / the pay
    - Participant lists any other benefits

5. Risks of participation: What are the risks of being in the study?
    - *(1.0) Sample answers receiving full score:*
        - Some questions may be difficult / upsetting
        - Breach/loss of confidentiality
    - *(0.5) Sample answers receiving partial score:*
        - Low risk
        - The questions
    - *(0.0) Sample answers receiving no score:*
        - Risk of getting hurt
        - No risk

6. Confidentiality: What does confidentiality mean in this study?
    - *(1.0) Sample answers receiving full score:*
        - You won't share the things I say
        - Protection of personal information
    - *(0.5) Sample answers receiving partial score:*
        - A safe secret / a secret
    - *(0.0) Sample answers receiving no score:*
        - That I (the participant) keep things a secret

7. Participation incentives: Can you be paid for being in the study?
    - *(1.0) Sample answers receiving full score:*
        - No
        - There is no pay / incentive
    - *(0.0) Sample answers receiving no score:*
        - Yes
        - I might be paid

8. Voluntariness: Do you have to be in the study? Who decides?
    - *(1.0) Sample answers receiving full score:*
        - I don't have to be in the study if I don't want
        - It is my choice to be in the study
        - I decide to be in the study
    - *(0.5) Sample answers receiving partial score:*
        - No (one word answer)
        - I want to be in the study
    - *(0.0) Sample answers receiving no score:*

    - Yes / I have to be in the study
    - You asked me to be in the study
    - I'm already here

9. <u>The right to withdraw</u>: If you decide to start the study and then change your mind, what can you do?

- *(1.0) Sample answers receiving full score:*
    - I can ask to leave / stop / go home
    - I can leave / stop / go home
    - I don't have to stay
- *(0.5) Sample answers receiving partial score:*
    - Ask for help
- *(0.0) Sample answers receiving no score:*
    - Finish (the study)
    - I can't do anything

Appendix F: Iterative Teaching Process Impressions Evaluation (ITPIE) Questions

Part A: Open-ended evaluation questions:
Provide prompts if open-ended questions are answered with yes, no or otherwise short answer.

1. Did you find this information understandable?
    a. *Prompt*: Could you tell me more about that?
    b. *Prompt*: What was/wasn't understandable about it?
2. How did it feel to learn this information?
    a. *Prompt*: Could you tell me more about that?
3. Did you feel respected while I taught you this information?
    a. *Prompt*: Could you tell me more about that?
    b. *Prompt*: What was/wasn't respectful about it?

Part B: Forced choice evaluation questions:
Ask forced choice evaluation questions if answer is not already made clear by response to open-ended evaluation questions (Part A)

1. Did you find this information understandable?
    a. (1) Yes
    b. (2) Somewhere in the middle
    c. (3) No
2. How did it feel to learn this information?
    a. Good
    b. Somewhere in the middle
    c. Bad
3. Did you feel respected while I taught you this information?
    a. Confusing
    b. Just right
    c. Childish or too simple

Visual aid for Part B on next page

Visual aid for Part B:

1. Did you find this information understandable?

Yes

Somewhere
in the middle

No

2. How did it feel to learn this information?

Good

Somewhere
in the middle

Bad

3. Did you feel respected while I taught you this information?

Confusing

Just right

Childish or
too simple

Appendix G: Demographics Questionnaire

Participant Demographic Information: Self-Report

1. **Age (in years):**_____

2. **Gender:**
□ Female (1)
□ Male (2)
□ Other (3) _____

3. **Years in school**: _____

4. **Type of degree or certificate:**
□ No degree or certificate (0)
□ high school degree (1)
□ high school certificate (2)
□ Associate's degree (3)
□ Bachelor's degree (4)
□ Other (please describe) (5) _____

5. **Ethnicity (please check all that apply):**

□ Prefer not to respond (0)
□ Black or African American (1)
□ Caucasian/White (2)
□ Latino/Latina (3)
□ Asian/Pacific Islander (4)
□ Native American (5)
□ Bi-racial/Multi-racial (6)
□ Other (please describe) (7)
_____

6. **Marital Status:**
□ Single (1)
□ In a romantic relationship, but not married (2)
□ Married (3)
□ Divorced/Separated (4)
□ Other (please describe) (5) _____

7. **Current Living Situation (please check all that apply):**

□ Independently - Alone (1)
□ Independently - Roommate(s) (2)
□ Less than 24 hrs support staff - Alone (3)
□ Less than 24 hrs support staff – Roommate(s) (4)
□ Supported Living (5)
□ With romantic partner (6)
□ With family (7)
□ Other (please describe) (8):_____

8. Are you paid for working?

□ Yes - Full-time (40 or more hours/week) (1)
□ Yes - Part-time (*less than* 40 hours/week) (2)
□ No – Volunteer / unpaid work (3)
□ No – Have had a job in the past (4)
□ No – Have never been employed (5)

9. If you are currently employed, what is your job?

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10. If you are not currently employed but have been in the past, what is the job that you have held for the longest period of time?

Job: _____

How long? _____

11. Have you been in in a research study before today?

□ Unsure (0)
□ Yes (1)
□ No (2)

12. If yes, how many? _____

13. What kinds of research studies have you participated in? (*Check all that apply)*

□ None (0)
□ Biomedical/Clinical trials (1)

□ Behavioral and social science (2)
□ Simple questionnaire or interview (3)
□ Other (4) _____

14. Have you ever consented to a medical procedure?
(Such as a surgery)

□ Unsure (0)
□ Yes (1) _____
□ No (2)

15. Do you have any of the following conditions?
(Check all that apply)

□ Not specified or known (0)
□ Autism Spectrum Disorder (1)
□ Down syndrome (2)
□ Other genetic (Fragile X, 22q11.2) (3)
□ Cerebral Palsy (4)
□ Perinatal trauma (5)
□ Postnatal Trauma (6)
□ Traumatic Brain Injury (7)
□ Infection (8)
□ Metabolic (9)
□ Nutritional (Malnutrition) (10)
□ Maternal disease (placental disease) (11)
□ Environmental (Alcohol, other drugs, toxins, teratogens) (12)
□ Other cause of ID not listed (13) _____

16. What is the severity of your Intellectual Disability, (listed on your medical records)?

□ Unknown (0)
□ Mild (1)
□ Moderate (2)
□ Severe (3)
□ Profound (4)

Read out-loud:

(To caregiver/guardian) Thank you for your help. I am going to ask that you please leave the room for the rest of the study. I will let you know when we are done.

Appendix H: Matched Pairs of Logically Opposite Items

(Winkler, Kanouse, & Ware, 1982)

The original set of 12 pairs (24 items) was modified for administration as three sets of eight items. The scale will be administered in three sets to temporally separate matched-pairs from each other and to minimize participant confusion.

Original matched pairs (Winkler, Kanouse, & Ware, 1982):

1. Prescription drugs frequently do more harm than good.
   Prescription drugs are almost always helpful.

2. A person should take medicine only as a last resort.
   It is always silly to suffer if a medicine will make you feel better.

3. Good health is largely a matter of luck,
   When it comes to health there is no such thing as bad luck.

4. Anyone can learn a few basic health rules which will go a long way in preventing illness.
   There is little a person can do to prevent illness.

5. Taking care of yourself won't affect whether you get sick or not.
   In the long run, people who take good care of themselves stay healthier and get well more quickly.

6. It mainly takes good medical care to get over an illness.
   Medical care can't do much for you if you're really sick.

7. I'd rather my doctor just told me what to do.
   When there is an important medical decision to make regarding my treatment, I want to be given enough information so that I can help make that decision.

8. Doctors are very careful to check everything when examining their patients.
   Doctors don't always check everything they should check when examining their patients.

9. Good doctors nearly always agree on how to treat a specific illness.
   Even good doctors disagree about how to treat an illness.

10. Doctors never expose their patients to unnecessary risks.
    Sometimes doctors prescribe treatments that involve unnecessary risks.

11. When a treatment involves risks, doctors always discuss those risks with the patient.

Doctors don't always explain to their patients the risks involved in certain treatments.

12. Most doctors carefully explain what will happen to their patients.
    Doctors don't usually explain your medical problem to you.

Three sets of eight items to be administered in the present study:

A researcher will read the following instructions before each set and then read the items as displayed below: *I am now going to read you some statements. After I read each statement, please answer yes if you agree with the statement or no if you disagree with the statement.*

The first eight items will be administered after the WASI-II:

1. Prescription drugs frequently do more harm than good.
2. Anyone can learn a few basic health rules which will go a long way in preventing illness.
3. Doctors never expose their patients to unnecessary risks.
4. I'd rather my doctor just told me what to do.
5. It is always silly to suffer if a medicine will make you feel better.
6. Doctors don't always check everything they should check when examining their patients.
7. In the long run, people who take good care of themselves stay healthier and get well more quickly.
8. Doctors don't always explain to their patients the risks involved in certain treatments.

The second set will be administered after the digit span subtest:

1. Prescription drugs are almost always helpful.
2. Good health is largely a matter of luck,
3. Sometimes doctors prescribe treatments that involve unnecessary risks.
4. There is little a person can do to prevent illness.
5. Good doctors nearly always agree on how to treat a specific illness.
6. When there is an important medical decision to make regarding my treatment, I want to be given enough information so that I can help make that decision.
7. It mainly takes good medical care to get over an illness.
8. Most doctors carefully explain what will happen to their patients.

The third and final set will be administered after the Schonell reading test:

1. A person should take medicine only as a last resort.
2. Doctors are very careful to check everything when examining their patients.
3. When it comes to health there is no such thing as bad luck.

4. When a treatment involves risks, doctors always discuss those risks with the patient.
5. Medical care can't do much for you if you're really sick.
6. Even good doctors disagree about how to treat an illness.
7. Taking care of yourself won't affect whether you get sick or not.
8. Doctors don't usually explain your medical problem to you.