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Including Adults With Intellectual Disabilities in Research: Scientists' Perceptions of Risks and Protections

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Abstract Social and cognitive characteristics of adults with intellectual disabilities (ID) place them at risk for inappropriate inclusion in or exclusion from research participation. As we grapple with how to include adults with ID in research in order to secure their right to contribute to scientific advancements and be positioned to derive benefit from ensuing knowledge, it is critical to consider scientific gatekeepers' perspectives on risks of and protections for including adults with ID in research. We surveyed 199 Institutional Review Board members and intellectual disability researchers in the United States to identify their perceptions of specific risks and necessary protections in (hypothetical) research studies. The research studies varied as to whether they included adults with ID in the research sample and the level of harm to which research participants were exposed. Results suggest that identification of psychological, social, and legal risks and necessary protections varied by the disability status of the sample, the level of risk, and the role of the person reviewing the study. For example, participants identified more psychological, information control, legal, and social risks in higher harm research studies. Participants reported a need for more protections in high-harm studies as well as studies that included adults with ID. In some instances the nature of identified risks and protections and respondents' characterization of these risks and necessary protections suggested concerns related specifically to adults with ID. Implications for practice, policy, and future research related to access to research participation are discussed.

Key words: human research ethics, intellectual disabilities, research participation

Despite the scientific and social importance of including adults with intellectual disabilities (ID) in research (Aman & Handen, 2006; Yan & Munir, 2004), there are tensions about how to best treat this potentially vulnerable group in research. Notably, there is divergence of opinion regarding the research-related risks faced as well as how those risks are best addressed. Although discourse on these topics is growing, there is little empirical evidence available to inform policy and practice related to including adults with ID in research. Here, we examine perspectives of members of the scientific community—researchers and Institutional Review Board (IRB) members—on the risks and necessary protections for research with adults with ID. IRBs (also known as ethic review panels) provide independent ethical review of research with human participants. Of note, while there are universal principles that guide research deliberations, important legal considerations vary by locality.

Research suggests that researchers and IRB members may perceive greater amounts of risk for studies that involve adults with ID, particularly when the research poses greater harm (McDonald & Keys, 2008). However, we must look primarily to anecdotal accounts to understand the nature of these perceived risks. One of the primary concerns discussed in professional literature is whether adults with ID are able to make free, informed choices about participating in research. In the absence of this ability, adults with ID may be unwillingly involved in research (Stineman & Musick, 2001). Reasons for the concern about adults with ID's capacity to consent include that coercion may be heightened because of communication barriers, lack of experience with decision making, coercive social contexts, and social isolation (Brigham, 1998; Cambridge & Forester-Jones, 2003; Freedman, 2001; Stineman & Musick, 2001). Similarly, some wonder whether adults with ID can weigh the risks and benefits of participating in research (Yan & Munir, 2004). Of note, research

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suggests diverse decisional capacities among adults with ID (Arscott, Dagnan, & Kroese, 1998; Morris, Niederbuhl, & Mahr, 1993). Concerns about capacity to understand are not unique to adults with ID (Huntington & Robinson, 2007). Other risks include concern that adults with ID may disclose sensitive information to researchers without appreciating the consequences of doing so (Brown & Thompson, 1997) and may incur psychological harm because of unfulfilled expectations of continuing friendship with researchers (Stalker, 1998). Finally, some authors are concerned that researchers neglect to disseminate their findings in ways that positively impact the ID community (Malott, 2002).

IRB members and researchers may differentially assess risk. Some researchers feel that IRB members overestimate risks and that protective attitudes toward persons with ID may lead IRB members to place excessive limitations on their participation in research (Becker, Roberts, Morrison, & Silver, 2004; Lai, Elliot, & Ouellette-Kuntz, 2006; Oakes, 2002). Researchers describe concerns about conservative measures stipulated by IRBs, such as preventing researchers from directly contacting persons with ID during recruitment, requiring proxy or substitute consent for all participants with ID, and excluding participants with ID from research with no demonstrable direct benefit (Becker et al., 2004; Iacono, 2006). However, initial research does not support a pervasive differential assessment of risk (McDonald & Keys, 2008).

Researchers' responsibilities include implementing protections to safeguard participants from risks (Coleman, Menikoff, Goldner, & Dubler, 2005). While there is some evidence that researchers and IRB members favor increased protections in research that involves adults with ID, particularly in higher harm research (McDonald & Keys, 2008), we largely only have commentaries by scientists to understand *what* protections are perceived as necessary. Of note, there is little consensus on what protections are best suited for adults with ID. Considerable attention has been paid to addressing concerns related to capacity to consent. Some researchers believe we should systematically assess capacity (Arscott et al., 1998; Stineman & Musick, 2001; Weisstub & Arboleda-Florez, 1997). Other researchers have countered that doing so may place unjustified burden on the participant, that it may limit research, and that available means may be inadequate (Dye, Hare, & Hendy, 2007; Dye, Hendy, & Hare, 2004; McVilly & Dalton, 2006). Alternative proposals include conducting informed consent as an emergent process, with initial assent to participate followed by a series of agreements as the research proceeds and assessing necessary capacity in light of the individual's context and the specific research (Clegg, 2004; McVilly & Dalton, 2006). In instances when researchers believe that an adult with ID cannot provide competent consent, some feel that they should be excluded from participation; others suggest turning to representatives—formal or informal—to make decisions for them (Dalton & McVilly, 2004; Freedman, 2001; Iacono, 2006). Some have countered that excluding adults with ID from research revokes their right to volunteer, marginalizes them, and denies them benefits of scientific advancements (Arscott et al., 1998; Becker et al., 2004). There are also concerns associated with the use of proxy consent including relegation of adults with ID to a child role, the potential for proxies to make decisions based on their own wishes, and undermining principles of self-determination (Freedman, 2001; McVilly & Dalton, 2006; Stalker, 1997).

Concerns have also been discussed related to the recruitment of adults with ID for research. Differences in opinion may vary among researchers and IRB members about whether the research should be presented to the participant by a person who is known and trusted, by the researchers themselves, or by a neutral party or advocate (Becker et al., 2004; Clegg, 1999; Freedman, 2001). Researchers have also grappled with how to set incentives for participation in a way that avoids coercion but also considers the monetary situations of adults with ID (Becker et al., 2004; Gates & Waight, 2007). Researchers must also ensure that the terminology, materials, and time commitments of their projects reflect sensitivity to differences in participants' education, literacy, and culture (Cameron & Murphy, 2007; Diesfeld, 1999). Some researchers suggest considering the interdependent context of many adults with ID and engaging families and service providers in the research process (Clegg, 2004). Responding somewhat differently, others propose the use of participatory methods to promote ethically sound research, and others emphasize the need to clearly define the roles and identities of the researchers and participants (Dalton & McVilly, 2004; Gilbert, 2004).

Available, largely nonempirical literature suggests diverse opinions about the risks that adults with ID may be exposed to in research and how those risks are best mitigated. In the absence of knowing how research participants experience research risks and would like to be protected, researcher and IRB members' beliefs may become increasingly important in determining how research is conducted (Lai et al., 2006). ID researchers and those with close relationships to individuals with disabilities may have attitudes more consistent with disability-rights principles than IRB members and those without close relationships (McDonald et al., 2008). Here we examine researchers and IRB members' perceptions of risks and needed protections for research involving adults with ID as compared with research that does not include this population, in both low and higher harm research studies. Examining these perceptions may begin to indicate paths forward to promote the respectful inclusion of adults with ID in research.

METHODS

A three-factor mixed experimental design was used to examine the effects of Disability (No Disability, Intellectual Disability) × Harm (Low, High) × Role (IRB Member, ID Researcher, IRB Member-ID Researcher) on perceptions of risks and necessary protections. Disability and Harm were within-subject factors experimentally manipulated, whereas Role was a between-subjects factor. We used four strategies to identify participants. We identified U.S.-based researchers who had published social science research with adults with ID in any of 11 relevant journals over a 5-year period. We also included researchers at the University Centers for Excellence in Developmental Disabilities, university programs funded under the federal Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Public Law 106–402). We identified 532 researchers from 151 universities, excluding those from our university. We then identified 283 IRB chairpersons from these universities. We were able to locate reliable contact information for 388 researchers and 240 IRB members. We solicited participants through six personalized postal and electronic mail contacts during a 6-week period

(Dillman, 2000). We asked everyone to forward the invitations to colleagues at their institution. These recruitment efforts yielded 199 scientific gatekeepers with usable data. Participants included 114 IRB members and 85 researchers in the field of ID (*ID researchers*). Slightly more than half of the sample of 199 was female (51%) and almost two-thirds (62%) of the sample was between the ages of 40 and 59 (33%: 50–59; 29%: 40–49). Respondents were primarily Caucasian (89%). Almost three-quarters of participants reported holding a PhD (70%), 12% reported holding an MD, and 11% reported holding a master's degree. About one-half of participants were trained in the social sciences (46%). Another 39% of participants were trained in the health sciences professions. One-half of participants were tenure-track professors (51%), 17% were non-tenure-track faculty, and 10% were research scientists.

As approved by our IRBs, we used an Internet-based survey. Respondents logged into a password-protected Web site and, as part of a larger study, completed two instruments. First, respondents read and responded to research vignettes, which presented respondents with four fictitious research studies that either did or did not involve adults with ID and either presented little potential harm or more significant harm. This created a 2×2 design of the within-subject factors. Each respondent completed one vignette, in random order, from each of the following categories: (1) No Disability-Low Harm[1]; (2) No Disability-High Harm; (3) Intellectual Disability-Low Harm; and (4) Intellectual Disability-High Harm. Vignettes included information from fictitious consent forms that conveyed the study's purpose, procedures, sample, and harm posed to participants (McDonald & Keys, 2008). Each vignette was based on recently published research from social science journals. Respondents were asked to review each vignette either as an IRB member or as a researcher providing ethical guidance to a more junior graduate student or colleague. Following each vignette, respondents were asked to identify specific risks and protections that participants in the fictitious research might experience or need to secure their well-being. Respondents also completed questions on their age, sex, race/ethnicity, level and field of education, and current occupation.

Risk and protections data were analyzed separately through a grounded theory process (Lincoln & Guba, 1985; Miles & Huberman, 1994; Strauss & Corbin, 1990). Analysis began by having two to three researchers identify emergent themes. Then, two researchers independently read each segment of data and coded each unique risk or protection. Two researchers coded about 10–20% of the data at a time, meeting to compare codes. Codes were refined, merged, and developed. Coding discrepancies ranged from 1 to 34% of all codes; higher discrepancies were noted during early phases of coding. All coding discrepancies were resolved through a consensus process involving a third researcher when necessary. After all text was coded, we identified 80 risk codes and 14 additional protections. We present percentages of risks and protections identified by at least 5% of respondents to reflect the prevalence of each response across the three factors under study. We make no presumptions regarding the statistical significance of differences. Although translation of qualitative data into quantitative data is controversial, doing so allows for increased complexity of description and confidence in inferences and generalizability (Onwuegbuzie, 2003). See Tables 1 and 2 for an overview of these findings.

[1]*Low harm* vignettes presented the potential for little to no harm to participants. For example, participants were asked to provide opinions on packaging preferences or hit a button each time an image appears on a computer screen. In these vignettes, potential risks included feeling uncomfortable providing one's opinion or becoming tired while concentrating on the task. Conversely, *high harm* vignettes presented the potential for more significant harm to participants. For example, participants were asked to discuss sexual practices or potential criminal activity in a focus group. In these vignettes, potential risk included negative feelings associated with recalling negative or embarrassing events, feeling upset listening to other people's experiences or beliefs, and a breach of confidentiality by other focus group participants.

FINDINGS

Risks

Psychological risks identified by respondents included embarrassment, emotional distress, performance anxiety, and general psychological discomfort. Both respondent groups more commonly identified risks in high harm vignettes than in low harm vignettes, with more risks for the no disability vignette (54–55%) than the ID vignette (45–47%). They also identified psychological risks more often in the low harm, ID vignette (28–43%)—with more IRB members than ID researchers perceiving such risk—than in the low harm, no disability vignette (13–18%). Psychological risks associated with no disability vignettes were often related to embarrassment and emotional distress associated with content discussed during the research, as noted by this IRB member: "*Participants may experience distress during and after the revelation of their sexual experiences*." Those associated with the ID vignettes, however, suggested that this population is more prone to confusion and to emotional distress resulting from interaction with others and from discussion of sensitive topics in the research context. For example, one IRB member stated, "*To expose intellectually disabled people to questions about criminal actions, especially if they have not perpetrated such activities, may be psychologically damaging to them*." Respondents also suggested that persons with ID are more susceptible to negative emotional or behavioral influences, as exemplified by this IRB member's statement: "*This population is highly susceptible to suggestion. The study involves discussions of illegal behavior that in the setting may be construed by the subjects to be acceptable behavior*."

Many respondents identified confidentiality risks (i.e., information control), especially in the higher harm vignettes, without indicating precisely how research participants might be harmed by the disclosure of information. IRB members and ID researchers more commonly identified risks related to information control in the high harm, no disability vignette (58 and 52%, respectively) than the high harm, ID vignette (39 and 38%, respectively). Concern regarding personal information being shared outside the research context was commonly expressed, as by this ID researcher: "*Information about the subjects could be shared with anyone from the general public*." This risk appeared to be associated with poor judgment or comprehension for participants with ID, as suggested by this IRB member: "*People with intellectual disabilities may not be able . . . to judge whether to make*

TABLE 1
Percentage of risks identified by role, disability, and harm for each of the four research vignettes

	IRB ($n = 114$)				IDR ($n = 85$)			
	No ID		ID		No ID		ID	
Risk	**Low harm**	**High harm**	**Low harm**	**High harm**	**Low harm**	**High harm**	**Low harm**	**High harm**
Psychological	18	54	43	47	13	55	28	45
Information control	3	58	4	39	1	52	0	38
Legal	0	23	0	58	0	4	0	44
Social	0	25	4	18	0	18	5	9
Decisional competency for consent	0	0	5	11	0	1	6	11
Economic	0	8	0	4	0	2	0	5
Physical	39	0	2	1	35	1	1	0
General	7	1	6	1	9	2	0	2
Risk, unspecified	0	16	0	11	0	26	4	11
Total risks	67	185	64	190	58	161	44	165
No additional identified risks	45	8	41	9	46	8	58	16

Notes: Table presents percentage of respondents (rounded to the nearest whole number) who indicated a risk to the research participants in each vignette. Any risk that was selected by less than 5% of respondents in any category is not reported.
IRB = Institutional Review Board; IDR = Intellectual Disability Researcher; No ID = No Intellectual Disability; ID = Intellectual Disability.

certain disclosures and to weigh the benefits/harms that might result." Fewer respondents indicated information control risks for low harm vignettes (0–4%).

Legal risks were noted primarily in high harm vignettes, with the most legal risks reported in high harm vignettes with adults with ID (which focused on criminal behavior). Forty-four percent of ID researchers and 58% of IRB members noted legal risks in the high harm, ID vignette. Although 4% of ID researchers noted legal risks in the high harm, no disability vignette, 23% of IRB members perceived legal risk. Concerns for legal consequences for participants with ID were commonly associated with deficits in comprehension or judgment. For example, one IRB member suggested, "*Subjects may not understand that their responses could reveal incriminating information about themselves*," and an ID researcher stated, "*Individuals may reveal that they have committed a crime that they did not realize was against the law*."

Eighteen to 25% of IRB members and ID researchers reported social risks in the high harm, no disability vignette and 9–18% did so in the high harm, ID vignette. Less than 5% of respondents reported social risks in either of the low harm vignettes. Social risks described by respondents for participants with and without ID included damage to relationships, damaging public image, and labeling or stigmatization. Some respondents identified social risks that were specifically related to ID; for example, one IRB member noted that focus group participation "*could expose this population, with limited coping skills, to ridicule from the group*."

When a research vignette included adults with ID, concerns related to decisional capacity to consent were increased, particularly when the research involved more harm. For example, although 0–1% of all respondents noted concern for participants' decision-making abilities for nondisabled participants, 5–6% of respondents noted this risk for the low harm, ID vignette and 11% noted the same risk for the high harm, ID vignette. This perceived risk may be related to adults with ID's poor comprehension of the risks (e.g., as noted by an IRB member, "*Because the person may not appreciate the consequences of revealing such information, the person cannot be expected to act in his or her own best interest in withholding information about illegal past acts*") and research procedures (e.g., as noted by another IRB member, "*These participants may not be as able to strategize about disclosure and less able to keep others' confidences*").

Respondents also identified a variety of other risks. Responses regarding economic and other general or vaguely articulated types of risk were elicited primarily by high harm vignettes. Physical risk (e.g., "*eye strain*" or "*physical discomfort*") was noted mainly in response to the low harm, no disability vignette, which involved repetitive computer-mediated tasks. Eight to 58% of respondents reported no additional risk or provided no response, indicating that they perceived no risks beyond those already identified. More respondents identified no additional risks in low harm vignettes (41–58%)—with 58% of ID researchers identifying such for the low harm ID vignettes—than in high harm vignettes (8–16%).

Protections

Respondents reported a need for research protocol protections primarily in high harm research vignettes. Thirty-four to 58% of respondents indicated a need for research protocol

TABLE 2
Percentage of protections identified by role, disability, and harm

	IRB ($n = 114$)				IDR ($n = 85$)			
	No ID		ID		No ID		ID	
Protection	**Low harm**	**High harm**	**Low harm**	**High harm**	**Low harm**	**High harm**	**Low harm**	**High harm**
Research protocol	**2**	**34**	**4**	**52**	**13**	**58**	**11**	**47**
Certificate of confidentiality	2	32	2	45	7	48	6	40
DSMB	0	3	1	12	4	20	5	24
Recruitment	**7**	**13**	**31**	**28**	**21**	**34**	**39**	**41**
Introduction by someone known	2	2	21	14	8	7	24	26
Introduction by neutral party	1	11	11	14	7	25	15	19
Exclusion of vulnerable individuals*	4	1	1	3	7	2	0	4
Consent	**18**	**40**	**78**	**78**	**34**	**67**	**74**	**73**
Family or guardian consent	3	4	59	69	18	26	58	59
Assess competence to consent	8	14	43	56	14	25	28	47
Advocate during consent	0	4	28	56	8	25	40	47
Waiting period	0	13	3	12	0	36	4	22
Accommodations*	1	2	5	1	5	0	9	1
Procedures	**8**	**69**	**11**	**64**	**14**	**78**	**14**	**69**
Modifications of procedures	5	56	8	54	6	67	11	52
Resources for participants	3	32	4	27	7	35	2	29
Removal of specific questions	0	10	4	21	0	25	1	25
Do not conduct with these participants	**0**	**1**	**4**	**28**	**0**	**14**	**0**	**34**
One or more protections	**24**	**85**	**85**	**96**	**47**	**98**	**79**	**98**

Notes: Table presents percentage of respondents (rounded to the nearest whole number) who indicated a protection was needed to safeguard research participants. Any protection that was selected by less than 5% of respondents in any category is not reported. Bolded numbers indicate the percentage of respondents who indicated one or more protection within the category. IRB = Institutional Review Board; IDR = Intellectual Disability Researcher; No ID = No Intellectual Disability; ID = Intellectual Disability; DSMB = Data Safety Monitoring Board. Asterisks denote recommendations for protections that emerged from qualitative analysis of responses to open-ended questions.

protections for high harm vignettes, with a certificate of confidentiality[2] being recommended more often than a data safety monitoring board. For high-harm research involving participants with ID, IRB members (34%) were less likely than ID researchers (58%) to recommend research protocol protections.

Many respondents were concerned with how participants were recruited when the research involved adults with ID and/or presented greater harm. When the research involved adults with ID, about one-quarter of ID researchers expressed a preference that the individual recruiting be known to the potential participant regardless of harm level. IRB members recommended this recruitment strategy for participants with ID less frequently, particularly for the high harm vignette (14%). ID researchers were more likely to recommend recruitment via a neutral party compared with IRB members, suggesting this strategy most commonly for the high harm, no disability vignette (25%). Eleven to 19% of respondents indicated a preference for this strategy when participants had ID, with ID researchers suggesting this strategy more often than IRB members. A wider range of respondents (1–25%) expressed a preference for this recruitment strategy for vignettes that did not involve individuals with ID. With the exception of a few respondents noting that individuals with a specific condition might be more at risk in a particular type of study (the low harm, no disability vignette involved flashing images), few respondents felt that more vulnerable individuals should be excluded.

Many respondents indicated a need for protections during consent, particularly with research involving adults with ID. Fifty-eight to 69% of respondents expressed the need for family or guardian consent in ID vignettes, and some, such as this IRB member, referenced relevant guidelines: "*My understanding is that such an adult may be involved in research following the consent of a parent or guardian and following his or her assent*." IRB members reported a need for this form of consent (69%) more often than

[2]A certificate of confidentiality is issued for research funded by the U.S. National Institutes of Health to protect identifiable research information from forced or compelled disclosure.

ID researchers (59%) for the high harm, ID vignette. The two groups responded similarly regarding the need for family or guardian consent in response to the low harm, ID vignette (58 and 59%). Lastly, although 3–4% of IRB members indicated a need for family/guardian consent in the no disability vignettes, ID researchers considered the protection for nondisabled participants as well in both harm conditions (18 and 26%). Fifty-six percent of IRB members and 47% of ID researchers endorsed assessing capacity to consent in response to the high harm, ID vignette. In reference to participants with ID, one IRB member noted, "S*ince they are a protected population, safeguards should be in place to make sure of [capacity to consent]*." However, fewer ID researchers (28%) than IRB members (43%) endorsed assessment in the low harm, ID vignette. Assessment of capacity was less frequently recommended for nondisabled participants and was more often suggested by ID researchers (14–25%) than by IRB members (8–14%). Respondents also expressed a preference for advocate presence during consent when research included adults with ID. For example, 56% of IRB members and 47% of ID researchers endorsed advocate presence for the high harm, ID vignette. Forty percent of ID researchers and 28% of IRB members perceived a need for an advocate in the low harm, ID vignette. When participants did not have a disability, 0–4% of IRB members recommended that an advocate be present during consent compared with 8–25% of ID researchers who made this recommendation. Other consent-related protections recommended included offering the participant a waiting period in which to decide whether to consent to participation, and various accommodations, often related to disability, that the researcher could offer to participants to facilitate informed consent. A waiting period was suggested most often in response to high harm vignettes (12–36%), and accommodations were recommended by less than 10% of respondents for any vignette.

A number of respondents noted a need for safeguards related to the research procedures, most notably for higher harm vignettes. Approximately one-half of IRB members and 52–67% of ID researchers wanted to see the procedures modified for the high harm vignettes, suggesting such modifications as changing from group to individual interviews or anonymous surveys. Procedural protections recommended less frequently were provision of resources to participants and removing specific, sensitive questions from the interview guide. Less than 5% of respondents suggested the provision of procedural accommodations to participants in any vignette. Lastly, 28% of IRB members and 34% of ID researchers indicated that the study should not be conducted as proposed for the high harm, ID vignette. For other vignettes, 0–14% noted that the study should not be conducted.

DISCUSSION

This research explored the nature of perceived risks and necessary protections among ID researchers and IRB members. In general, more risks were noted by respondents when the hypothetical study was high harm than low harm, and IRB members identified more risks than ID researchers. Psychological risks, information control, and, to a lesser extent, social risks were prominent risks for high harm vignettes; the low harm study with adults with ID elicited more responses indicating psychological risk than the low harm, no disability vignette.

The higher prevalence of estimated risks for high harm vignettes as well as among IRB members is consistent with theory and scientific discourse and was anticipated (Coleman et al., 2005). It may be that IRB members perceive research participants as more vulnerable to harm. Or those who have worked on IRBs may simply be more experienced in identifying the range of risks inherent in research or believe that research involves more risk than do researchers. The largely similar ratings of numbers of risk irrespective of the disability status of participants is more conceptually rich to unpack, especially in light of previous findings that scientists rated research including adults with ID as higher risk than research with nondisabled participants (McDonald & Keys, 2008). In interpreting this difference, it is important to note that it cannot be assumed that a greater number of risks noted by respondents necessarily correlates with perception of a greater severity of risk. It may be that assessments of level of risk, rather than reflecting the number of perceived risks, represent a combination of the risks inherent in the study and how the assessor views the resources that are available to mitigate those risks. These resources include those provided by researchers as well as personal skills and resources of participants. Adults with ID are perceived as possessing a more limited range of personal skills and resources because of cognitive deficits and social inequities that impact their abilities to make free informed choice, to avoid coercion, and to protect themselves legally or socially (Cameron & Murphy, 2007; Dalton & McVilly, 2004; Freedman, 2001; Stineman & Musick, 2001). These perceptions may lead members of the scientific community to view risks as more severe (McDonald & Keys, 2008). Another consideration is attitudes; attitudes toward persons with ID have been shown to influence global assessments of level of research-related risk (McDonald & Keys, 2008). These attitudes may become less influential or apparent when respondents are required to specify particular risks to participants.

Patterns among risks and protections suggest a perception that ID creates an additional vulnerability to risks and that protections are needed to mitigate these risks. The identification of psychological risk for participants with ID in both high and low harm vignettes suggests a perception that the presence of disability may increase psychological harm. This interpretation is supported by the nature of responses regarding psychological risk. For those with disabilities, psychological risk was attributed to perceived emotional vulnerability; respondents described participants with ID as more easily traumatized by exposure to sensitive information, easily influenced by others to behave against their own interests, and lacking in coping skills necessary to manage their distress. In contrast, psychological risk for nondisabled participants was typically attributed to features of the study that might cause embarrassment or emotional distress. This is an intriguing finding, as research has had little to offer regarding perceptions of psychological vulnerability of adults with ID in research, except for noting the potential for disappointment at the conclusion of their relationships with researchers (Stalker, 1998). Perceptions of adults with ID as possessing an inherent vulnerability to psychological harm may partially explain conservative or sheltering attitudes toward them and their participation in research held by members of the scientific

community (Lai et al., 2006; McDonald & Keys, 2008). IRB members appeared particularly sensitive to this risk, perhaps because they have less frequent contact with adults with ID, making them more likely to assess risk based on common assumptions or stereotypes about persons with ID as being vulnerable. Future research is needed to elucidate the extent to which such perceptions of vulnerability reflect measurable reality or attitudes toward adults with ID. It will be necessary to examine the nature and severity of psychological risk experienced by adults with ID who participate in research, with an aim of determining what additional accommodations or protections, if any, are needed to mitigate such risk.

Respondents' perceptions of information control risks were clearly affected by the level of harm associated with the research, but some responses suggested that the presence of ID can exacerbate this risk. A common specific concern related to information control was that participants from group interviews would breach their fellow participants' confidentiality after the research had concluded. When participants had ID, responses often echoed researchers' concerns that such participants may lack the judgment to limit disclosure of sensitive information and may have trouble comprehending and following confidentiality procedures, placing themselves and other participants at increased risk of confidentiality loss (Brown & Thompson, 1997; Fisher, Cea, Davidson, & Fried, 2006). Interestingly, both respondent groups noted information control risks less frequently for disabled participants than for nondisabled participants. IRB members and ID researchers may have considered nondisabled participants to have more to lose as a result of confidentiality or privacy loss, perhaps indicating diminished concern for the privacy of adults with ID. This may reflect recognition that persons with ID often lead lives in which their privacy is already limited because of frequent monitoring and supervision. However, participants with ID may reveal unique information to researchers.

Beliefs that research participation may result in damage to participants' legal and social lives seemed heightened when the study involved more harm, but responses regarding participants with ID again suggested differences in perceptions of risk based on disability status. The high harm, disability vignette elicited the most legal risk responses, possibly because it involved discussion of potentially illegal behavior. However, some responses suggested that legal risk is heightened for participants with ID because they are unable to differentiate between legal and illegal actions and because of their inability to anticipate the risks of disclosing particular information (Brown & Thompson, 1997). Higher harm studies also elicited more concerns regarding participants' social risks, particularly for nondisabled participants. Specific responses suggested that research participation may jeopardize participants' social relationships and their public images and result in negative labeling or stigmatization. More frequent responses of social risks for nondisabled participants may indicate a perception that they have more at stake socially than participants with ID. This may be because many people with disabilities experience social isolation and devaluation (Stineman & Musick, 2001).

Risks to participants with ID were often perceived as increased because of cognitive and psychological shortcomings, inability to strategize, social inequities, and emotional sensitivity. These descriptions create an image of participants with ID as highly vulnerable and in need of protection from risks related to the research procedures, as well as from risks derived from psychological fragility and poor judgment. These perceptions may underlie the strong recommendation that family members or guardians provide informed consent for the participant with ID and also that researchers assess competence. Interestingly, there were few responses noting specific risks related to decisional capacity. ID researchers were notably less likely to recommend assessment of capacity for lower harm studies. ID researchers may favor viewing the individual-in-context and perceive a need for less capacity for less risky decisions, possibly reflecting their adherence to contemporary principles of self-determination and dignity of risk (Dye et al., 2004). The presence of more harm, however, may prompt more protective responses. Or researchers may view assessing capacity to consent as burdensome, insulting, and placing barriers on their participation, leading them to recommend the practice less frequently when the research-related risk was low (Fisher et al., 2006). The majority of the responses related to decisional capacity, however, did concern participants with ID, and respondents expressed concerns that adults with ID may have difficulties with understanding research procedures and related risks as described during informed consent procedures. And, endorsements of a need for advocates during consent indicate sensitivity to coercion and decision-making capacity. ID researchers' stronger endorsements of using advocates and waiting periods may suggest their preference for measures that promote self-determination. However, the infrequent suggestion that researchers provide accommodations to the participant with ID during consent suggests less awareness of ways to improve comprehension of informed consent materials. Investigation into and development of such accommodations are in the interests of adults with ID and the scientific community, as this provides adults with ID additional opportunities for self-determination and may also increase the participation of this population in research.

Recommendations for recruitment strategies indicate a discrepancy in views regarding how to introduce research to participants with ID, suggesting a lack of clarity on this issue in the scientific community. When participants had ID, respondents preferred to conduct recruitment through someone known to the participant. This practice is endorsed because the person assisting with recruitment will be more trusted by the participant and will also be able to assist the participant with understanding and navigating the recruitment process (Becker et al., 2004). To a lesser degree, respondents recommended that participants with ID be recruited through a neutral party, possibly in an attempt to reduce concerns about privacy infringement and coercion, especially for adults who may experience unequal power relationships (Cameron & Murphy, 2007). Both of these approaches, however, have advantages and disadvantages. While using someone known to the participant may facilitate the inclusion of people with ID in research, it may also create a coercive context. On the other hand, using a neutral party may avoid some forms of coercion but may also limit communication between the person with ID and the researchers. More research will be needed to explore researcher and IRB member thinking on this issue (Lai et al., 2006), as well as to learn how adults with ID would prefer to be recruited.

Strengths and Limitations

This study presents a unique empirical exploration into perceptions of risks and protections among researchers and IRB members. Among the strengths of this research are that the vignettes used were developed based on recently published social science research and were pilot tested. We were also able to collect data from a relatively large sample of researchers and IRB members from a wide variety of geographic locations. The gathering of a more representative set of opinions and the direct comparison of the experimental factors makes a substantial contribution to the limited empirical work in this area. Despite the strengths of this study, it also presents some limitations. The open-ended questions regarding risks and protections followed survey questions about the study that may have primed participants to answer in a particular way. Some participants indicated that more detail in the vignettes, such as the level and severity of participants' disability, would better inform—and potentially alter—their responses. While more information would be included in a typical IRB application, it may not necessarily preclude the biases individuals hold. Also, the typical review process allows for group decisions and outside consultation, which was not done in this study. However, this may result in interpretations better reflecting individuals' opinions and attitudes. Moreover, this research only included members of the scientific community from the United States. Future research should examine international contexts and also include other important stakeholders (e.g., citizen advocates on IRBs, surrogate consent makers, and adults with ID).

CONCLUSION

The respectful inclusion of adults with ID in research is important given the social and scientific benefits associated with engagement in this aspect of community life. As we make initial strides toward elucidating perceptions of risks and necessary protections held by members of the scientific community, we move one step closer to identifying new policies and practices that will help promote the self-determination, voice, and visibility of adults with ID in research. We need to assess whether these perceptions reflect experienced risks and examine different stakeholder groups' evaluations of the acceptability of various risks and protections.

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