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Symposium Articles

Replacing Surrogate Decision-Making with Supported Decision-Making for Minimal Risk Research

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Abstract

We advocate for a change in the way individuals with cognitive impairment are enrolled in *minimal risk clinical research.* We do so in the hope that such a change will lead to more cognitively impaired individuals being enrolled in research. Our proposal applies only to cases where would-be participants retain some interest in decision-making as well as the ability to express a decision. In these cases, we argue that the common practice whereby researchers either obtain consent from the individual or consent from a surrogate and assent from the individual, is ethically unnecessary. Instead, a process of facilitated decision-making based on SDM (supported decision-making) should be employed. Although it is possible that this process of facilitation will enable some individuals to make a capacitated choice who would not otherwise have done so, this should not be a requirement of getting to choose. In those cases where a would-be participant, despite support, fails to make a capacitated choice, the individual should still have the final say about participation. In this respect, our proposal deviates from standard practice. However, we argue that our proposal offers participants as much ethical protection as the more common procedures involving surrogates.

Keywords: Cognitive Impairment; Clinical Research Ethics; Supported Decision Making; Minimal Risk Research

1. Introduction

Many people live with one or another form of cognitive impairment. Some cognitive impairments are lifelong (e.g. Down syndrome), others are acquired (relatively) late in life (e.g. Alzheimer's dementia), and still others can be acquired at any time (e.g. traumatic brain injuries). Despite the different kinds and degrees of cognitive impairment, however, all people living with such impairments potentially stand to benefit from clinical research aimed at (1) increasing our knowledge of particular types of impairment and (2) helping us identify potential cures, preventative strategies, and/or better ways to address problematic symptoms that accompany impairment.[1]

However, many barriers exist when it comes to carrying out clinical research with people with cognitive impairments.[2] To begin with, a lingering ethos of protectionism makes many clinical researchers and institutional review boards (IRBs) reluctant to enroll individuals with cognitive impairments. Historically, various groups, including women, children, and the elderly, have been either excluded from clinical research altogether or limited in their participation to a much greater extent than, say, young or middle-aged men.[3] Those with cognitive impairment are another such group.[4] Exclusion was originally intended to protect people thought to be more vulnerable than most to harm or exploitation. However, it is now widely recognized (at least in theory) that such protection can be as damaging in one way as it is beneficial in another. Because advances in clinical care depend on well-conducted clinical research, exclusion from research protects individuals in these categories from potential research harm at the expense of ensuring (1) that they cannot personally benefit from research *and* (2) that care for these patient populations does not advance through research.[5]

In addition to protectionism, some researchers may think recruitment of subjects is a more difficult process with individuals with cognitive impairment. Recall that individuals with known cognitive impairment must typically have their decision-making capacity carefully assessed.[6] If the individual is found to lack decision-making capacity (as often will occur in this population), researchers must then identify an authorized surrogate decision-maker. They are then required to obtain *both* the informed consent of the surrogate *and* the assent of the would-be participant.[7] It is the requirement that a "yes" be obtained from two individuals that can fuel worries about enrollment. The worry goes something like this: Surrogates (understandably) often tend towards protectionism, and so frequently decline to consent. If we add to this reality the fact that, within the (already small) class of surrogates willing to give

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consent to research participation, at least *some* of the would-be participants will not give assent, it becomes clearer why the process of finding sufficient subjects can seem daunting.

We do not wish to suggest that all caution be thrown aside, since there is significant truth in the claim that cognitive impairment can make an individual much more vulnerable to manipulation by others. But the very real need for more such individuals to enter clinical research does suggest that we need to do more than just remind people of the downsides of excessive protectionism. We need to get creative in our thinking about how to *safely* and ethically include more people with cognitive impairment in clinical research.

Here, we advocate for one particular change that would make it easier for individuals with cognitive impairments to participate in clinical research. This is a change in the way individuals with cognitive impairment are enrolled in *minimal risk research.* Moreover, it applies only to cases where would-be participants retain at least some interest in participating in decision-making (however this is expressed or communicated) as well as the ability to express a decision (however the decision is reached). We argue that, in this limited set of cases, the common practice whereby researchers first assess an individual's decision-making capacity, and then either obtain consent from the individual or obtain consent from an authorized surrogate and assent from the individual, should be set aside. Indeed, we believe, it is not ethically necessary that the individual making the decision make a capacitated choice. Instead, it is ethically sufficient if a certain process of facilitation occurs, one that is modeled on what is known as supported decision-making (SDM).

Supported decision-making is a process in which a family member, friend, or designated professional works to help a cognitively impaired individual understand, to the best of that individual's ability, the facts of the situation and the implications of various options they might select.[8] A distinguishing feature of SDM as it is typically implemented is that it aims to make capacitated decision-making possible and, supposing it is successful in that aim, decisional authority remains with the person being supported.[9] In many cases, the support provided by others really *does* enable an individual, who would otherwise have been deemed to lack decision-making capacity if assessed using traditional methods, to make their own capacitated decision. However, this is not always the case. Some individuals offered support will still not be able to make a *capacitated* choice (or it may not be possible to be sure that the decision is a capacitated choice).

Our proposal is that, for the special case of minimal risk research involving individuals with cognitive impairment who meet our minimal criteria, a facilitation process like that used in SDM should replace the current process. Significantly, however, on our proposal, independently of whether the individual has (or could be helped to have) decisional capacity, the would-be research participant would be allowed to have the final say over whether or not to participate. To avoid confusion, it is important to be clear that our proposal differs in this one respect from common understandings of SDM. However, having now highlighted this fact, in what follows we will simply refer to our proposal as a proposal for using SDM.

Adopting this proposal would have many advantages. Though the proposal applies only to a very specific kind of case, we do not think these cases are rare. Adopting our proposal would release researchers from the need to assess the decision-making capacity of each potential participant (unless, of course, decision-making capacity is relevant to the research question itself, which is an entirely different matter), and would also release them from potentially needing to work with, and obtain agreement from, *two* individuals.

This may at first appear like a radical suggestion, and ethical concerns may initially make people reluctant to consider it.[10] However, in what follows, we argue that our proposal is *as good at* satisfying the core ethical requirements for clinical research as the more traditional approach involving surrogate decision-makers. It provides *just as much protection* against harm and exploitation. Indeed, in some ways, we think it is actually ethically *superior* to the current approach.

Our argument overall has the following structure: (1) If we can secure a great benefit at no cost (including no ethical cost), we should do so. (2) Adopting our proposal would be greatly beneficial, for it would result in more people with cognitive impairment participating in clinical research and so, hopefully, more advances in care for this population. And finally, (3) our proposal offers *just as much protection* as the current system, hence it does not impose additional costs. So our proposal should be adopted. We defend (3) in section 3 and section 4 below. First, however, we need to say a bit more about SDM and how our proposal would work.

2. What Is SDM and How Would it Work?

Supported decision-making (SDM) primarily refers to a process in which one person (the supporter) engages another person (in our case, a potential research participant) in conversation (while using other deliberative aids as needed) with the aim of helping that person arrive at a decision (in this case, about whether to enroll in some particular clinical research protocol).[11] SDM is used in many different contexts where it can be implemented in slightly different ways. In the context of obtaining consent for research, the aim is to help the potential research participant achieve better understanding of the nature of the decision and its potential consequences — a level of understanding the person would not be able to reach on their own simply by reading a consent form, listening to a presentation about the research project, or engaging in a discussion about the project with a member of the research team. However, the aim is broader than just that of promoting understanding. It also includes helping the potential research participant bring the various strands of information together, evaluate their options, and reach a final decision, one that *hopefully* reflects in the right way the priorities, values, and concerns of the potential participant.

Usually, the supporter in SDM is a close family member or friend, someone the individual trusts and feels safe with. However, this is not always the case with SDM. In principle, the role of supporter could be filled by a professional (e.g. a social worker). When enrolling cognitively impaired individuals in minimal risk clinical research, we think there are two important supporter roles that need to be filled. In most cases, this will require that two people act as supporters, though in rare cases, a single person might be able to fill both simultaneously. First, there should be someone close to the potential research participant *who is chosen by them* and with whom they feel comfortable. Second, there should be someone familiar with clinical research and willing to explain it via SDM methods. Both roles are necessary if the process is to fulfill its aim of helping the potential participant make the decision on the basis of the best level of understanding they can achieve.

Although SDM is primarily a kind of *process* that aids decision-making, it can be implemented in different ways, depending on who has decisional authority. For the limited set of cases that concern us here, we propose that potential research participants retain exclusive decisional authority.[12] To grasp the true import of this, it is important to see that decisional authority is not the same thing as making (or being able to make) a decision. Rather, it is about whose

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decision, at the end of the day, will be honored. In the traditional framework, where a surrogate decides for an individual who has been deemed to lack decision-making capacity, it is the surrogate who has *decisional authority*, meaning that, at the end of the day, the individual can only participate in research if the surrogate agrees to participation on their behalf. The requirement of participant assent may seem like a form of decisional authority. But because assent only ensures that a "no" from the potential participant will be honored (but not a yes) it is better thought of as a *constraint* on the authority of the surrogate rather than a distinctive kind of authority in its own right.

The potentially radical aspect of our proposal is the decoupling of decisional authority from possession of decision-making capacity. Lacking decision-making capacity just means that an individual is not able to *reliably make decisions of a certain kind or quality*, e.g. if the individual is not able to reliably use information to advance their own ends.[13] It is a threshold notion. Ordinarily, if an individual were to make a decision that did not exhibit certain features to the right degree (e.g. sufficient understanding, appreciation, minimal but still coherent reasoning), decisional authority would be removed from the individual, ostensibly to protect them from themselves. However, as we argue below, the usual kinds of protective concerns that give sense to such a move are not present in the specific set of cases we are considering. Thus, in this limited set of cases, it can make sense to allow someone to retain decisional authority independently of whether they have (or are known to have) decision-making capacity.

Significantly, our proposal only applies to research that is minimal risk. According to federal regulations, research is minimal risk when "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[14] Some procedures widely accepted to be minimal risk include EEGs, the noninvasive collection of samples (such as a small amount of hair, sweat, saliva, or urine), a single blood draw, the use of tissue left over following a clinically indicated procedure (e.g. biopsy), observational and natural history studies, a standard physical exam, or the use of ultrasound. While there are, of course, variations in the way IRBs interpret minimal risk, even the more liberal interpretations we are aware of strike us as compatible with the proposal we make here.[15]

The following is how we imagine things would work if our proposal was adopted. In our view, it would be permissible in minimal risk research to forgo assessment of the decision-making capacity of individuals being considered as potential research participants. Obviously, some individuals with cognitive impairment are such that, were they to be assessed, they would be found to lack decisional capacity. But there are others who, despite cognitive impairment, would, if assessed, be found to *have it*. Our claim is that there is no need, when conducting minimal risk research with this population (or research that includes members of this population), to discover *prospectively* which individuals fall into which group. Ordinarily, this kind of prospective sorting would matter because facts about capacity would determine facts about decisional authority. But since our proposal retaining decisional authority does not depend on decision-making capacity, the usual rationale for assessment is absent. In addition, our approach has the advantage that it avoids what can often be a very difficult scenario. For when researchers assess capacity, they must, whenever they find that an individual lacks decision-making capacity, inform that individual that this is the case and that they will not be permitted to decide for themselves. That can be *deeply* distressing for the individual in question, and can make the situation uncomfortable for everyone involved.

Although no assessment of capacity needs to occur, individuals with cognitive impairment being considered for minimal risk research would still need to participate in a special kind of discussion with two supporters. One supporter would be someone chosen by the would-be participant, someone they trust and feel comfortable with.[16] The other supporter would be someone knowledgeable about clinical research and willing to engage in the extra kinds of support for understanding characteristic of SDM.[17] In certain respects, the conversation need not be that different from many conversations that occur during the process of obtaining informed consent to research with non-impaired individuals. For example, it would still be a requirement that all relevant information about the research — everything that would be conveyed to a non-impaired person — be conveyed to the potential research participant during the SDM process. The difference, however, is that the supporters would be prepared to use a variety of methods to try and help the potential participant understand the information.[18] The process would also differ in scope, since supporters would also be tasked with helping the potential participant relate the research information to their own priorities and concerns, and with helping the individual pull all the pieces together into a single yes-or-no decision. In general, supporters would need to be committed to doing what they can to help the potential participant make the best (i.e. most informed, coherent etc.) decision of which they are capable.

Whatever the supporters may ultimately think about how the process goes, the potential participant's decision would be final. It would stand, for example, even if attempts by the supporters at fostering understanding appear to have failed miserably.[19] The decision would change only if the participant for some reason were to change their mind. But then, that is no different from ordinary research requirements. Participants always retain the right to change their mind about research participation.[20]

3. The Ethics of Our Proposal: Autonomy & Welfare

There is more to the ethical conduct of clinical research than simply obtaining valid informed consent from research participants.[21] That said, informed consent remains an extremely important part of ethical clinical research, and since our proposal is, in effect, a proposal to change how consent is implemented (for one patient population in one specific kind of research), thinking through the ethicality of our proposal requires considering whether all the essential ethical bases would be covered just as well by our proposal as are covered by the more traditional approach.

Many bioethicists discuss the ethics of consent as if there were a single ethical rationale behind the requirement that researchers obtain the valid informed consent of each participant in clinical research, namely, respect for autonomy. However, we find it more plausible to recognize multiple, overlapping ethical rationales for this practice. As we see it, the two most significant ethical concerns addressed by informed consent (though not the only ones) are (1) respect for autonomy and (2) ensuring adequate protection of participant welfare.

3.1. Respect for Autonomy

The most frequent explanation of the need to obtain valid informed consent appeals to respect for autonomy.[22] In this context, that means respect for the capacity for autonomous choice. Although

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there are different ways of characterizing autonomous choice, the more practically useful accounts tend to describe it roughly as follows: An autonomous choice is a careful, reflective choice made by a capacitated person, a choice that takes account of relevant information the participant possesses and which is entirely voluntary.[23] This is what some would call a fully autonomous choice, recognizing thereby that a given choice can be more or less autonomous. However, a choice lacks autonomy altogether (as opposed to just having less of it) if (1) the person making the choice lacks decision-making capacity or (2) the choice is coerced, or (3) the choice is thoroughly impulsive, weak-willed, or irrational.

Bioethicists generally equate possession of decision-making capacity (in the clinical sense discussed so far) with the capacity to make autonomous decisions.[24] Respect for autonomy is therefore respect for the decision-making capacities of those who fall above the clinical threshold for possession of decision-making capacity. But what precisely does respect for autonomy require of us?

Minimally, it is a non-interference norm. It requires (1) *that those individuals who have decision-making capacity* be left free to make and act on their own decisions. It also requires that (2) we refrain from *manipulating* the decision-making process in any way (thereby ruling out deception or the withholding of relevant information, among other things).[25] However, there is more to it than just these two requirements. In the context of obtaining informed consent for research, respect for autonomy also requires (3) ensuring that potential research participants are able to make their decision in a setting conducive to good decision-making (for example, a setting in which potential participants feel safe, are free from distractions, and are not overly rushed). And it requires (4) providing individuals with the information they need so that their decisions can reflect their personal concerns, priorities, and values in the right way. When an informed person exercises their capacity for autonomous choice, they significantly improve the chance that their choice will reflect in the right way their concerns, priorities, and values. But without accurate information as input to this process, even the most careful, reflective decision-maker cannot trust that decisions will in fact reflect their interests and values. Therefore, part of respect for the special value people attach to autonomous choice is ensuring that individuals have what they need (in this case information) to make *effective use* of this capacity in running their own lives.

While all four of the requirements just listed must be met if one is to truly respect autonomy, it is important to notice what is *not* required. There is no requirement that participants actually make autonomous choices.[26] It *is* required that choice be voluntary. But while voluntariness is necessary for autonomous choice, it is not sufficient. There is no requirement that potential participants make careful, reflective decisions. We may, of course, encourage potential participants to do so, but there is no requirement to ensure such advice is taken and no requirement to exclude from research participation those we suspect have not chosen carefully or reflectively. Thus, the ethical requirement of respect for autonomy is best thought of as the requirement that researchers *make it both possible and easy for potential participants to make an autonomous decision*, whether or not they do so. The informed consent process when carried out ethically *facilitates autonomous choice but does not ensure it.* Implementing policies that require researchers to respect people's autonomy thus differs from implementing policies that either require or guarantee that people will engage in autonomous decision-making.

Some might assume that respect for autonomy does not apply to research involving individuals with cognitive impairment. Of course, they may realize that if a surrogate decision-maker becomes involved, researchers are required to facilitate autonomous decision-making *for the surrogate.* But they may assume that respect for autonomy does not, in these cases, ethically constrain interactions with the potential participant. However, such an assumption is wrong for the simple reason that not all individuals with cognitive impairment lack decision-making capacity.[27] For example, individuals with mild Alzheimer's disease express a range of cognitive deficits but often retain the capacity to make their own decisions.

Because some individuals with cognitive impairments may possess decision-making capacity, it is important when enrolling cognitively impaired participants in research that it be both possible and easy for individuals who *possess* capacity to make autonomous choices. In other words, care must be taken to respect the autonomy of those who have capacity, whether that be all the participants in a particular study or only a few.

Significantly, our proposal anticipates and meets this requirement since it is already designed to respect the autonomy of any participants who may be capable of making autonomous choices. To see this, recall that it is part of our proposal that potential research participants participating in an SDM process receive all information relevant to research participation — i.e. the same information a surrogate would receive in the traditional model. Moreover, it is built into SDM that the choice environment be supportive in the ways described above, and that others not manipulate the potential participant's decision-making process. Finally, since in our proposal, individuals retain decisional authority, it follows that individuals who have capacity are left free to make and act on their own decisions. Therefore, our proposal already ensures that respect for autonomy will be given to those who have decision-making capacity, even though no attempt will be made to identify which individuals these are.

In many cases, research with cognitively impaired individuals will include some people who have decision-making capacity, some who lack it, and some whose level of capacity varies over time. In the traditional model, this kind of diversity among participants in terms of levels of decision-making capacity would, when combined with the need to ensure that we show respect for the autonomy of individuals who possess decision-making capacity, necessitate assessing the decision-making capacity of all participants initially and then reassessing periodically over time. For only then would it be possible to *ensure* that different protocols were followed when obtaining consent from capacitated, as opposed to incapacitated, individuals. In our proposal, however, there is no need for this since the process and environment are always such as to facilitate autonomous choice (whether or not a potential participant has the capacity to do so). For this reason, we can be certain that any individuals able to make autonomous choices will find that it is both possible and easy to do so. There is no need to assess capacity and sort participants into groups based on this assessment.

3.2 Adequate Protection of Participant Welfare

Another distinct but still highly important ethical function of informed consent is protection of participant welfare. This differs from respect for autonomy in that respect for autonomy is about facilitating a *certain kind of process* whereas protection of welfare is about avoiding bad outcomes and realizing good outcomes *for* the individual whose welfare it is. It is true that inasmuch as one wishes to make choices that promote one's own welfare, autonomous choices, because they are reflective, careful, etc., are more likely to do so. But not all autonomous choices are aimed at promoting

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personal welfare (a person can choose autonomously to prioritize the interests of others over his own). And even when they are, there is no *guarantee* that an autonomous choice will produce the best welfare outcome.

In ordinary research with participants who have decision-making capacity, participant welfare is protected through a two-part process. First, federal regulations require that research protocols present a favorable risk/benefit ratio.[28] This in itself is no guarantee that participation in a study will be in the overall best interests of a participant because benefit is calculated by considering both the potential benefit to the individual from research participation *and* the potential benefit to society from the knowledge gained.[29] Federal regulations also require that studies be classified by the degree of risk involved. IRBs are responsible for ensuring that particular protocols present a favorable risk-benefit ratio, and that particular studies are labeled appropriately according to the level of risk they pose.

This, however, is only the first step that helps to ensure adequate protection for participant welfare. When, in ordinary research, potential participants go through the informed consent process, they are given the kind and degree of information necessary *to assess for themselves* the potential welfare impact of research participation on their lives. Since, at this point, they are still deciding whether to participate, this means that individuals have a window of opportunity within which they may act to safeguard their own welfare. It is this opportunity that we describe as a "second layer of protection." Participants are able to do two things with the information they receive. First, they can assess the extent to which the IRB's determination of risk (which in part reflects judgments about the kinds of outcomes most people consider harmful) matches their more personal assessment of risk. Often it will, but not always. Individuals whose personal circumstances vary from the norm have the opportunity to recognize (where and if it is true) that the value for them of a given possible outcome is higher or lower than it would be for most people and so higher or lower than the IRB assumes. Second, independently of whether they think the IRB's assessment of risk matches theirs or not, they are able to assess whether the degree of foreseen risk is *acceptable* to them. If the risks (however they assess them) are deemed unacceptable, they can simply decline to participate.

However, individuals lacking decision-making capacity are not able to protect themselves in this way, at least not to the same extent. The "second layer of protection" is largely or wholly missing in their case, because even when they are provided with information and conditions conducive to good decision-making, they are not reliably able to make choices that promote, or align with, their own interests. To see that this is so, one need only recall how (in theory) decision-making capacity thresholds are ethically set. They are the outcome of reflection on the perennial problem of how to properly balance two genuine values: namely, concern for individual welfare and concern for individual freedom of choice.[30] The threshold for capacity represents the point at which an individual's various mental abilities leave her insufficiently able to recognize threats to her own welfare.[31] It is the point at which the chances of serious self-harm if someone is left free to make all their own decisions are thought to be both higher than usual *and* unacceptably high. Those deemed to lack decision-making capacity, therefore, are precisely those people whose ability to make decisions aligned with their own interests is weak enough and/or unreliable enough that restricting their freedom of choice seems justified for the sake of their own safety.[32]

Most people can agree that those who fall beneath that threshold deserve our protection. And most can agree that, when it comes to obtaining consent to participate in clinical research from such individuals, the second layer of welfare protection is largely or wholly missing. However, many people jump from this to the conclusion that what is needed if such individuals are to be enrolled *is an increase in welfare protection*, i.e. something to substitute for the missing second layer.[33] Since our proposal offers no such substitution it may seem ethically problematic.

However, such a judgment would be too hasty. It overlooks the fact that people only need extra protection of their welfare in cases where their welfare is actually threatened. We fully grant that individuals lacking decision-making capacity may be less able to look out for their own interests than ordinary people are in the research setting. And we grant that in the context of riskier forms of research involving those with cognitive impairments, adding extra layers of protection for participant welfare is warranted.[34] However, we think this is not relevant in the kind of case that concerns us, namely, minimal risk research. And this is because in minimal risk research no serious threats to personal welfare exist.

To see this, let us say that a harm is something that makes your life clearly worse than it otherwise would have been. It genuinely lowers lifetime welfare to some degree. And let us contrast the idea of harm with the idea of a burden which is something that, if it occurs, makes you *a little* worse off *for a period of time*, but which is small enough not to register in the calculation of the welfare value of your life as a whole.[35]

Now consider the definition of minimal risk research, which is defined as research where "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[36] Although this requires interpretation, we think its intent is *relatively* clear.

Consider that genuinely harmful events — events that have a significant negative impact on your life as a whole — are rare in daily life. On any given day, the chance of such an event occurring is, for most people, extremely low; so low, in fact, that we are able to put the risk out of mind entirely. Risks that small are not the kind of thing we usually allow to enter into our decision-making about what to do. We don't change our plans if someone reminds us of such a risk. The minimal risk standard implies that research might include some such risks, but if the analogy with ordinary life is to hold, these are low enough to be negligible. If we do not allow the presence of such risks to shape our own decisions about what to do, then it is not clear why the presence of such risks should lead us to worry if cognitively impaired people are allowed to participate in such research.

On the other hand, there are various burdens (in the special sense defined above) that enter our lives with some regularity. Because some such burdens are part of ordinary life, we can assume that some minimal risk trials may saddle participants with a few burdens. But recall that such events are temporary and constitute such mild negatives that they do not figure in the greater scheme of things. They have no effect at all on the goodness or badness of your life as a whole. These are things that fall in the category of annoyances, frustrations, or mild discomforts. Since that is all they are, and since most of us do not go to any great lengths to avoid such events in our lives, it is hard to see why we should worry about cognitively impaired individuals signing up for research that may saddle them with a few such mild negatives, for example having to spend thirty minutes answering questions or lying still for an ultrasound.

There may be the occasional individual with idiosyncratic responses, someone who reacts more negatively than most people

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to ordinary procedures. For example, someone might have a quirky, highly individual fear of a minimal risk ultrasound. It would certainly be good if such differences could be discovered prospectively. This would be good for researchers who really need certain kinds of data, because then they could avoid enrolling subjects who are likely to refuse key tests or procedures and/or withdraw before the study is over. It would also be good for potential participants, who would thereby avoid unnecessary distress. Often someone who knows the potential participant will be able to convey such information ahead of time. However, the most important point is that even these stronger negative reactions to ordinary burdens do not constitute serious harms.[37]

We therefore feel confident that the welfare risks presented by minimal risk research are so low that we need not worry about offering greater protections to cognitively impaired individuals.[38] This is further supported by the fact that ordinary minimal risk research with capacitated subjects can be approved without their consent at all.[39] But given that it is the consent process that provides the "second layer of welfare protection," this suggests that a more general recognition already exists that minimal risk research poses no serious threat to welfare.

4. Concrete Respect and a Sense of Control

In addition to respect for autonomy there is a more general form of respect owed to individuals. Some theorists call it respect for persons.[40] However, the word "person" can be contentious in part because, historically, many philosophers have used the word "person" in such a way that only humans who are fully autonomous or have relatively complex mental lives count as persons.[41] Therefore, we shall speak instead of *respect for our fellow human beings*. The main point is not what label we give it, but rather that we recognize a concrete form of respect that is realized in interactions between people. To begin with, respect for our fellow human beings requires demonstrating through our behavior that *they matter for their own sake*. We do this in numerous small ways: by genuinely listening to what they tell us, by taking time to ensure they understand something, and by addressing their fears and anxieties in ways that are not at all condescending. This kind of respect also requires recognizing that these individuals are like us in that particular things *matter to them*. We therefore show respect by inquiring about what matters to them, by trying as much as we reasonably can not to frustrate their desires with respect to what matters to them, and by taking seriously the task of helping them reach decisions that fit with, and do not threaten, what they care about.

The point is to communicate certain attitudes through our actions as well as through the allocation of our attention, with the result that the individual *feels respected*, i.e. feels seen and heard and taken seriously. Of course, even when we act respectfully, there may be some individuals who do not "get" what is being communicated and/or do not feel respected. But that is why success in the fulfillment of this requirement should not be measured in terms of the other person's response.[42] Instead, it is enough if one treats others in ways that are generally understood to express respect and which generally lead others to feel respected.

This kind of concrete respect is not equally important in all interactions with our fellow human beings, since at least some of our fellow human beings may not be capable of grasping the significance of such actions, and may feel no differently whether treated with concrete respect or not. For example, a patient in PVS is not capable of recognizing when they are treated with concrete respect (which is expressed in one's behavior), nor capable of feeling either respected or disrespected, though it remains important for other reasons not to treat them disrespectfully.[43] But for the kind of research we have been discussing here, it is always incredibly important to show concrete respect. This is because our proposal only applies to a subset (albeit a very large subset) of individuals with cognitive impairment. Minimally, the individuals we are concerned with have the capacity to care whether they participate in research (even if they lack the capacity to truly understand the full extent of what it involves) and they have the ability to form and express preferences. Without at least these capacities, the process of SDM-style facilitation with potential research participants would be meaningless. But then, given their level of awareness and their active concerns, we should, when working with such individuals, always show them concrete respect.

Luckily, our proposal covers this. For the very idea of SDM incorporates the kind of concern for helping people choose that expresses concrete respect. As part of working through a decision with a potential participant, the supporters will inquire about what matters to the individual, take the time to help the individual see how a particular choice might impact something they care about, and so on. It is also part of the process that supporters not be condescending and that they not rush the individual who is making a decision. The process itself therefore builds in concrete respect.

Not only do people generally desire to be treated respectfully, most people also care a great deal about retaining some control over their lives. Sometimes the focus in bioethics on making decisions can lead us to forget this simple fact. After all, making one's own decisions is the primary way that people exercise control. But often, making decisions is just one way of maintaining control, a way that some individuals will relinquish if they can do so while still retaining control. For example, it is a familiar fact that sometimes competent patients who are seriously ill will turn over the task of making medical decisions to a friend or family member. Such cases might suggest that these people do not care about control. However, in such cases, it is often true that the patient still wants to be informed about everything that happens and wants to know why particular decisions are being made the way they are. Here, what looks like relinquishing control is really a case of holding onto it by retaining a veto power. They are sparing themselves the burden of making decisions, but keeping the door open to rejecting particular decisions they view as particularly problematic or even rescinding the other's authority altogether.

Currently, when it comes to enrolling individuals who lack decision-making capacity in any kind of clinical research, it is necessary for a surrogate to make decisions for the participant. Obviously, this removes control from the individual and is often deeply distressing to the individual. The distress can sometimes be mitigated a little if the surrogate works closely with the potential research participant and tries as much as possible to make decisions that align with the individual's preferences. However, it is not always possible to do this fully if, for example, the participant's current preferences are at odds with their own deeply held values (but for some reason, in the moment, the individual cannot see this). The distress from loss of control is also sometimes mitigated somewhat through the requirement that the potential participant give her assent. However, control is still limited. For while this means that an individual can veto participation, the individual is still not able to decide to participate if the surrogate says no.

Given how distressing this can be, we should remove control from individuals only when this is *absolutely necessary*. In other, riskier forms of clinical research, removing control is necessary to protect the individual's overall interests. But when it comes to

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minimal risk research, where the chances of any serious harm to the participant are so low as to be negligible, removing control is *not* absolutely necessary. Moreover, retaining control may be especially meaningful to some of these patients with cognitive impairments, since they may routinely have control over various decisions taken away from them. Our proposal recognizes both the importance of retaining some control, and also that removal of control is not necessary in minimal risk research. Thus, our proposal does a *better job* than standard practices do of living up to the requirement that we only remove control when doing so is absolutely necessary.

5. Conclusion

We have argued that in the special case of minimal risk research with cognitively impaired individuals it is ethically permissible, and so should become legally permissible, to forgo evaluation of decision-making capacity and the related process (for those found to lack decision-making capacity) of obtaining surrogate consent and participant assent. Instead, consent should be obtained from potential participants after they engage in a process of facilitated decision-making modeled on SDM, a process with two supporters, one person the potential participant is comfortable with and one person familiar with the research project. All the same information should be provided to the potential research participant as would ordinarily be supplied in the informed consent process with a capacitated participant, and all efforts should be made to ensure good conditions for reflection and consideration. However, the potential participant should retain decisional authority, and this should not depend on the extent to which the efforts of supporters at helping the individual understand the situation are successful or not.

Respect for autonomy requires that we facilitate autonomous choice for those individuals capable of autonomous choice. Our proposal meets this, because it ensures that it is both possible and easy for any potential participant capable of making an autonomous choice to make one. It also ensures adequate protection of participant welfare, not in the usual way, by giving potential research participants an opportunity to guard their own welfare, but simply by limiting the proposal to minimal risk research, where participants may encounter burdens (mild discomfort, annoyances etc.) but are not exposed to any serious risks of long-term harm. Our proposal also shows respect for persons, because the SDM-style facilitation process is one that takes individuals and their concerns seriously and seeks to help individuals make decisions that fit with their values if possible. And finally, it has the additional advantage of not removing personal control from individuals in a situation where that is not strictly necessary. It acknowledges and accommodates the fact that individuals living with cognitive impairment frequently experience the loss of control in their lives in negative ways and offers them a chance to participate in research without adding to such experiences.

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References

1. The general population of people with cognitive impairment would also benefit if more individuals with cognitive impairment were included in research studies related to other health conditions. Some forms of cognitive impairment may not make a difference to how individuals respond to treatment, but some forms might. For example, it would be useful to know if individuals with Down syndrome respond differently to particular forms of treatment used for conditions they are as likely to develop as anyone else. See Maurice A. Feldman et al., "Where are Persons with Intellectual Disabilities in Medical Research? A Survey of Published Clinical Trials," *Journal of Intellectual Disability Research* 58, no. 9 (2014): 800–809, https://doi.org/10.1111/jir.12091.
2. There are probably other barriers besides those we list here. Moreover, the reluctance of researchers to include participants with cognitive impairment increases when research is riskier. For example, when it comes to cognitively impaired individuals who lack decision-making capacity and so cannot consent for themselves, researchers tend to adhere to widely accepted norms that exclude such patients from all research that is more than minimally risky *unless* the study has the potential to offer direct benefit to the participant. This is so despite the fact that federal regulations in the United States do not explicitly forbid such research, but merely require surrogate consent. Here we will only be discussing minimal risk research. For a discussion of the potential role of SDM in riskier research see Aaron Segal et al., "Supported Decision-Making and the Inclusion of People who Lack Decisional Capacity in Greater Than Minimal Risk Research," *Journal of Law, Medicine & Ethics* 54, supp. 2 (2026): 1–8 https://doi.org/10.1017/jme.2025.10190.
3. Pregnant women have long been excluded with problematic results. See Katherine L. Wisner, Catherine S. Stika, and Katie Watson, "Pregnant women are still therapeutic orphans." *World Psychiatry* 19, no. 3 (2020): 329, https://doi.org/10.1002/wps.20776; Rebecca L. Zur, "Protected From Harm, Harmed by Protection: Ethical Consequences of the Exclusion of Pregnant Participants from Clinical Trials." *Research Ethics* 19, no. 4 (2023): 536–545, https://doi.org/10.1177/17470161231189843. However, the problem is not limited to pregnant women. See also Anna C. Mastroianni, Ruth Faden, and Daniel Federman, "Women and Health Research: A Report from the Institute of Medicine," *Kennedy Institute of Ethics Journal* 4, no. 1 (1994): 55–62, https://doi.org/10.1353/ken.0.0121. Children have also traditionally been excluded. See e.g. Harry Shirkey, "Therapeutic Orphans," *Journal of Pediatrics* 72, no.1 (1968): 119–120; reprinted in full: *Pediatrics* 104, no.3 (pt. 2) (1999): 583–84. Finally, for discussion of the exclusion of

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elderly patients, see e.g. Miriam Thake and Andrew Lowry, "A systematic review of trends in the selective exclusion of older participants from randomized clinical trials," *Archives of Gerontology and Geriatrics* 72 (2017): 99–102, https://doi.org/10.1016/j.archger.2017.05.017.

4. Feldman et al., "Where are persons with intellectual disabilities?"; Victoria Shepherd et al., "Protection by exclusion? The (lack of) inclusion of adults who lack capacity to consent to research in clinical trials in the UK," *Trials* 20, no. 1 (2019): 474. https://doi.org/10.1186/s13063-019-3603-1; Janelle S. Taylor et al., "The disappearing subject: exclusion of people with cognitive impairment and dementia from geriatrics research," *Journal of the American Geriatrics Society* 60, no. 3 (2012): 413–9. https://doi.org/10.1111/j.1532-5415.2011.03847.x;
5. Zur, "Protected from Harm"; Wisner et al., "Pregnant Women Therapeutic Orphans"; Mastroianni et al., "Women and Health Research"; Shirkey, "Therapeutic Orphans,"; Thake and Lowry, "Systematic Review"; Feldman et al., "Where are persons with intellectual disabilities?"
6. US Federal regulations allow that adults unable to consent for themselves may be included in research if a surrogate decision-maker decides for them. But beyond that, they do not give much in the way of specific direction. However, various other guidance documents address research with adults unable to consent and defend the need to assess decisional capacity whenever it is anticipated that some participating individuals will lack decision-making capacity. See, e.g. (1) The Secretary's Advisory Committee on Human Research Protections (SACHRP), Recommendations *Regarding Research Involving Individuals with Impaired Decision-Making*, Recommendation 3(b)(i) (U.S. Department of Health & Human Services, March 4, 2009) https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2009-july-15-letter-attachment/index.html; (2) Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans (Council for International Organizations of Medical Sciences, 2016), ISBN 978-929036088-9, https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/.
7. See, e.g. SACHRP, "Recommendations Regarding Research," Recommendation 6 (g); Human Research Protection Program, "Enrolling Individuals with Cognitive Impairments and Assessing Decisional Capacity," University of California San Francisco, https://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity; Dave Wendler and Kiran Prasad, "Core Safeguards for Clinical Research with Adults Who are Unable to Consent," *Annals of Internal Medicine* 135 (2001): 514–52, https://doi.org/10.7326/0003-4819-135-7-200110020-00011.
8. See Robert Dinerstein, "Implementing Legal Capacity Under Article 12 of the UN Convention on the Rights of Persons with Disabilities," *Human Rights Brief* 19, no. 2 (2012): 8–74; Nina A. Kohn, Jeremy A. Blumenthal and Amy T. Campbell, "Supported Decision-Making: A Viable Alternative to Guardianship," *Penn State Law Review* 117, no. 4 (2013): 1111–1158; Peter Blanck and Jonathan G. Martinis, "'The Right to Make Choices': The National Resource Center for Supported Decision-Making," *Inclusion* 3, no. 1 (2015): 24–33.
9. Dinerstein, "Implementing Legal Capacity"; Kohn, Blumenthal, and Campbell, "A Viable Alternative"; Blanck and Martinis, "The Right to Make Choices"; Benjamin C. Silverman et al., "Supported Decision-Making Can Advance Clinical Research Participation for People with Disabilities," *Nature Medicine* 28 (2022): 2250–2253, https://doi.org/10.1038/s41591-022-02035-3.
10. Implementing our suggestion would require a change to the common rule, since current regulations require surrogate consent from individuals who lack decisional capacity. Our argument is intended as a *moral argument* for why such a change would be a good change to make.
11. See note 9.
12. This is different from the proposal some of us (AS, DW, DH) make for SDM in research involving more than minimal risk. Segal et al., "Supported Decision-Making and the Inclusion of People who Lack Decisional Capacity in Greater Than Minimal Risk Research." 1–8. There, due to the elevated risks of research participation, it is argued that while the potential participant may not wield full decisional authority over whether to participate in research, they retain some decisional authority, and deference is owed to their actual choices in some situations, even if the supporter would not have made a similar decision through the process of surrogate decision-making.
13. Here, and in the next sentence, we refer to the basic cognitive requirements that are part of what is known as "the four-abilities model" of decision-making capacity. While not universally used, it is *widely* used, and many of the other forms of assessment resemble it closely in terms of its focus on basic cognitive capacities that underwrite making choices that align with one's ends. The four-abilities model was developed by Paul Appelbaum, Thomas Grisso, and their colleagues. Two clear expositions of how the model is intended to work are: Thomas Grisso and Paul S. Appelbaum, *The Assessment of Decision-Making Capacity: A Guide for Physicians and Other Healthcare Professionals* (Oxford University Press, 1998); Scott Y. H. Kim, *Evaluation of Capacity to Consent to Treatment and Research* (Oxford University Press, 2010).
14. 45 C.F.R. § 46.102(j) (2025).
15. While it is known that there are variations in the way IRBs interpret minimal risk, for the most part, IRBs are cautious. However, even some of the more inclusive and slightly less cautious interpretations of minimal risk that we are aware of strike us as compatible with the spirit of our proposal. For the variability of how IRB members interpret minimal risk, see: Seema Shah et al., "How do institutional review boards apply the federal risk and benefit standards for pediatric research?," *JAMA* 291, no. 4 (2004): 476–82. https://doi.org/10.1001/jama.291.4.476.
16. Some impaired individuals may not be capable of trust or of maintaining trusting relationships. However, we assume that most individuals with the basic capacities mentioned earlier as necessary for implementing our proposal would have such an ability. The more pressing problem is that some individuals, though capable of trust and of forming trusting relationships, simply fail to have someone they actually trust who is available to fill the role of supporter. Our proposal is not that having such a person in the role of supporter be a requirement. We merely mean to suggest that any participant who has someone they trust be encouraged to have that person as a supporter. If no such person exists or is available, this should not automatically be a barrier to inclusion, though it should prompt careful consideration of how best to support the individual and whether it is necessary to identify a supporter for them.
17. It is worth noting that some states have SDM statutes that place limits on who can formally fulfill the role of supporter. Obviously, researchers would want to be familiar with how the role of "formal supporter" is defined (e.g. could the second supporter we suggest count as an informal supporter?) and other aspects of the law that might impact the details of how our proposal is implemented. For more about state SDM laws, see the introductory chapter of this collection: Nina A. Kohn, Robert Dinerstein, and Megan S. Wright. "The Legal Landscape for Supported Decision-Making in the United States," *Journal of Law, Medicine & Ethics* 54, supp. 2 (2026): 1–9 https://doi.org/10.1017/jme.2025.10202.
18. Supporters may use a variety of methods to help someone understand and think about a decision — many kinds of decisional aids are available. A variety of tools and ideas for supported decision-making for different types of decisions can be found at https://supporteddecisionmaking.org/resource-library/.
19. Here we note a difference between how we envision SDM to work in minimal risk research and how SDM may work in more than minimal risk research. As some of us (AS, DW, DH) discuss elsewhere, in more than minimal risk research, the potential participant's decision may not be final depending on the other risks and benefits of research participation. See Segal et al., "Supported Decision-Making and the Inclusion of People who Lack Decisional Capacity in Greater Than Minimal Risk Research."
20. In addition to what we discuss here, there are often issues about ongoing consent. Our proposal could be applied here as well and would simplify this process since there is no need to assess decision-making capacity, only the need to engage the participant periodically in an SDM process. Here, for simplicity, we have focused on enrollment.
21. Ezekiel J. Emanuel, Dave Wendler and Christine Grady, "What Makes Clinical Research Ethical?" *JAMA* 283, no. 20 (2000): 2701–2711, https://doi.org/10.1001/jama.283.20.2701.
22. Nir Eyal, "Informed Consent," in *The Stanford Encyclopedia of Philosophy*, ed. Edward N. Zalta (Spring 2019 Edition, Metaphysics Research Lab, Stanford University), https://plato.stanford.edu/archives/spr2019/entries/informed-consent/.

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23. Views like this are simpler than many philosophical theories of autonomy, but also more practical. See for example Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (Oxford University Press, 1986): 238–239.
24. Allen E. Buchanan and Dan W. Brock, *Deciding for Others: The Ethics of Surrogate Decision-Making* (Cambridge University Press, 1990).
25. As Tom L. Beauchamp and James F. Childress wrote, "Forced information, forced choice and evasive disclosure are inconsistent with this obligation [respect for autonomy]." Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* 5th ed. (Oxford University Press, 2001): 63.
26. Beauchamp and Childress, *Principles*: 63.
27. Thomas Grisso and Paul S. Appelbaum, *Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals* (Oxford University Press, 1998): 18–20; Scott Y. H. Kim, *Evaluation of Capacity to Consent to Treatment and Research* (Oxford University Press, 2010): 11–12.
28. 45 C.F.R. § 46.111(a)(2) (2025).
29. 45 C.F.R. § 46.111(a)(2) (2025).
30. Kim, *Evaluation of Capacity*: 15–16; Buchanan and Brock, *Deciding for Others*; Grisso and Appelbaum, *Assessing Competence*: 12–14.
31. We assume that decision-making capacity is decision-relative and ought to be assessed that way. So, it is quite possible that someone capable of making one decision may be incapable of making another.
32. Kim, *Evaluation of Capacity*: 15–16; Buchanan and Brock, *Deciding for Others*; Grisso and Appelbaum, *Assessing Competence*: 12–14.
33. This is a common assumption. See, for example, SACHRP, "Recommendations Regarding Research," Recommendation 4, which states "Consent to research by the legally authorized representative (LAR) stands in for the consent by the prospective research participant, but it is not fully equivalent to consent by the participant him or herself. Therefore, when the participant is unable to protect his or her interests through the process of consent, additional protections or safeguards at the level of IRB review are required."
34. As some of us (AS, DW, DH) argue in Segal et al., "Supported Decision-Making and the Inclusion of People who Lack Decisional Capacity in Greater Than Minimal Risk Research." 1–8
35. The contrast between "burdens" and "harms" occurs various places in the research ethics literature. The contrast has also been made between risk of discomfort and risk of harm. See Anna E. Westra et al., "How best to define the concept of minimal risk," *The Journal of Pediatrics* 159, no. 3 (2011): 496–500. Our own use of the distinction to signify differences *in the overall impact on welfare* has been inspired in part by Annette Rid., "Setting Risk Thresholds in Biomedical Research: Lessons from the Debate about Minimal Risk." *Monash Bioethics Review* 32 (2014): 63–85, p.67.
36. 45 C.F.R. § 46.102(j) (2025).
37. We have so far been discussing *minimal risk research.* But it is also worth pausing briefly to note the risks associated with consent itself. In short, there is always a *small risk* that a consent process may not suffice to get people to decide not to participate who, for one reason or another, ought not to participate. For example, in ordinary research with individuals who have decision-making capacity, it is always possible that a person will consent to participation in research, despite the fact that her own idiosyncratic preferences and values mean she will find participation distressing and perhaps even harmful. This could happen, for example, if the individual is idiosyncratic in certain ways, but does not pay close attention to the information given in the consent process. However, if the consent process has been well-thought out and well-conducted, the risk of that happening should be *extremely low.* Our claim is that if our proposal is implemented, the risk that a cognitively impaired person would be enrolled in research that harms her (as opposed to merely imposing a burden) is also extremely low, and indeed, as low as such risks generally are in well-conducted clinical research.
38. People may have non-welfare interests that are at risk even in minimal risk research. See Raymond G. De Vries, et al., "The moral concerns of biobank donors: the effect of non-welfare interests on willingness to donate," *Life Sciences, Society and Policy* 12, no. 1 (2016): 3, https://doi.org/10.1186/s40504-016-0036-4. See also Dana Howard and Allison McCarthy, "The Value of Non-Domination in Supported Decision-Making for Research Participation for Individuals with Intellectual and Developmental Disabilities," *Journal of Law, Medicine & Ethics* 54, supp. 2 (2026): 1–11 https://doi.org/10.1017/jme.2025.10193. It remains an open question how and whether to consider and protect non-welfare interests in minimal risk research. It may turn out that if there are certain predictable non-welfare interests at risk in a certain minimal risk study, SDM may need to be amended to protect against such risks or it may not be appropriate. It is beyond the scope of this paper to discuss these concerns. It should be noted, however, that current regulatory framework and ethical practices also do not clearly address these concerns.
39. 45 C.F.R. § 46.116(f) (2025).
40. A more concrete behavioral notion of respect is spelled out and defended in Sarah Buss, "Appearing Respectful. The Moral Significance of Manners," *Ethics* 109 (1999): 795–826, https://doi.org/10.1086/233946. A more developed exploration of how to broaden our understanding of what concrete respect requires in specifically clinical contexts is Supriya Subramani and Nikola Biller-Andorno, "Revisiting Respect for Persons: Conceptual Analysis and Implications for Clinical Practice," *Medicine, Healthcare and Philosophy* 25 (2022): 351–360, https://doi.org/10.1007/s11019-022-10079-y. However, it is not fully clear even in these papers how easily the notion of showing concrete respect would extend beyond interactions with others who have decision-making capacity. Hence our suggestion in the text.
41. The classical source for this understanding is John Locke, *Essay Concerning Human Understanding*, ed. Alexander Campbell Fraser (2nd edition., Oxford: Clarendon Press, 1694), Book II, chapter 27. More recently see, David DeGrazia and Joseph Millum, *A Theory of Bioethics* (Cambridge University Press, 2021): 179–80.
42. Moreover, there are going to be situations where one may feel respected, but the manner in which they are treated (either without their knowledge or without their understanding) betrays a lack of respect. In such situations, treating others in ways that are generally understood to express respect is important regardless of uptake.
43. We do not mean that such individuals are not owed respect. Rather, our point is that "respect" can mean different things and require different things of us in different contexts. We are here talking about a concrete ethical requirement to treat people in ways that *communicate to them* that they are taken seriously and valued. Our point is just that a communicative requirement of this sort does not apply to people who cannot receive the message.

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