NEWS

Decisional capacity and informed consent, explained

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Some autistic people with communication challenges need extra support before they can participate in research. To give informed consent, they need to have the risks and benefits of a study explained to them in ways they can understand.

The United States' Common Rule, which regulates human subjects research, requires "additional safeguards" for participants "vulnerable to coercion or undue influence." While that description applies to some autistic people — particularly those who are non-speaking or intellectually disabled — the Rule doesn't specify what safeguards should look like. The federal Office for Human Research Protections (OHRP) **acknowledges** that regulations "are silent on the consent procedures specific to subjects with impaired decision-making capacity."

Minimally verbal and intellectually disabled autistic people are **underrepresented in research**, and even projects meant to highlight the lived experiences of autistic people **seldom include** those with high support needs. But provided that institutional review boards (IRBs) include members or consultants who have the requisite expertise, the boards are free to develop informed consent processes "that best match the needs of [research] subjects," according to the OHRP. By working with IRBs, investigators can create accessible informed consent processes and include a fuller range of autistic participants.

Here, we explain what those processes can look like.

Is informed consent just paperwork?

The groundwork for informed consent begins before any forms are signed. Advertisements, recruitment materials and informational phone calls are all tools investigators can use to relay key information to potential participants.

Even after someone expresses initial interest, it's not enough to simply give them a list of facts about the study, according to the Common Rule. Investigators also need to help them understand why they might or might not want to join.

A written consent form can help document this process and act as an informational resource, but informed consent should really be an ongoing conversation between researcher and participant — one grounded in respect for the participant's autonomy to "choose what shall or shall not happen to them," as set forth by the 1979 **Belmont Report**.

This should include the investigator explaining the study and its purpose as well as potential risks and benefits. They should explain that the participant can withdraw at any time, and they should offer to answer any questions. If the study is offering an experimental treatment, the participant should hear about existing alternatives.

How can investigators ensure that participants understand the study's details?

While investigators explain the specifics of a study, they also need to pay attention to participants' levels of comprehension, explains **Paul Appelbaum**, professor of psychiatry, medicine and law at Columbia University in New York City.

If someone doesn't seem to understand, the research team may bring in an outside clinician, says **Benjamin Silverman**, instructor of medical ethics at Harvard Medical School and an IRB chair at several Boston-area hospitals. That clinician will talk to the participant and make a determination about their "decisional capacity."

In studies that are higher risk or involve groups of people more likely to "lack capacity," all participants may be required to undergo more formal screening, says Appelbaum. Just because participants already have a diagnosis that involves some level of cognitive impairment, he says, that doesn't necessarily mean they'll be unable to consent.

However, the required level of decision-making capacity increases in tandem with "the level of risk or burden" of a study, Silverman says. For example, a participant may have enough decisional capacity to consent to an online survey, but not an experimental surgery.

How can researchers support potential participants who struggle to understand?

If an autistic person is having difficulty understanding information about the study, they may need extra support. Investigators are free to adapt communication strategies as necessary to help, and

indeed, the Common Rule requires that information “be in language understandable to the subject.”

Autistic people can especially benefit from asynchronous and text-based communication options like email, which allows people who process information more slowly to have the time they need to think and respond.

The Autistic Self-Advocacy Network (ASAN) suggests using specific communication formats intended to facilitate comprehension, such as “**Plain Language**,” an easy-to-understand writing style required in some government documents, and “**Easy Read**,” a format designed to be more accessible to readers with intellectual disabilities. Researchers should also be prepared to take all the time necessary to work with participants who use augmentative and alternative communication systems, says R. Larkin Taylor-Parker, legal director at ASAN.

Using the supported decision-making (SDM) model — originally developed to help disabled people retain legal autonomy over responsibilities like finances and health care — can also help participants who need help making decisions about research, according to a recent **commentary** in *Nature Medicine* that Silverman co-authored. People using SDM draw upon formal or informal networks from their own communities to help them think through decisions rather than rely on a legal representative to make choices in their stead.

What if someone is legally incapable of giving informed consent at all?

Surrogate decision-making models — most notably guardianships — remain common for autistic adults. People under guardianship legally lack any capacity to consent to research because a court has transferred their ability to make decisions about some or all areas of their life to a third party.

Guardianship law varies by state. Some states prohibit research on those under guardianship, while others allow it in specific circumstances, such as research meant for rehabilitation or prevention of a serious health risk. IRBs also restrict guardians’ ability to consent to research on their wards’ behalf. An IRB might approve a study if it involves minimal risk, but as the level of risk goes up, the potential benefits to the ward must also increase. Institutions often restrict or prohibit altogether the use of surrogate decision-making to enroll people in research “that’s greater than minimal risk with no direct benefit,” says Silverman.

Even when the law requires that investigators first secure consent from a legally authorized representative, investigators can also plan to get “assent” from participants themselves, Appelbaum says. Assent — intentionally seeking a participant’s yes or no in addition to that of their legal representative — is already common in research that includes children.

Many people under guardianship can still communicate their wants and needs, says Taylor-Parker. Even if a participant lacks legal autonomy, they say, researchers should be prepared to use all the

communication tools at their disposal to make sure that the individual understands the research and wants to be part of it.

Where do these guidelines come from? Why do they matter?

The current approaches to informed consent are often grounded in a “desire to protect,” Silverman explains. For example, the Belmont Report, which provided the ethical foundation for today’s Common Rule, was developed in the context of 20th century research transgressions targeting vulnerable members of society.

But underrepresentation of groups of people in research can have long-lasting consequences, according to Appelbaum. The exclusion of women and children, for example, produced “lacunae in our knowledge base,” he says — holes that, decades later, scientists are still working to fill.

“If you exclude people with disabilities from research,” Silverman says, “the outcome of the medical products that get approved won’t be helpful for them.”

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