

Informed Consent

What is “Informed Consent?”

Consent implies voluntary agreement or permission for something to occur. Informed consent implies that the individual’s agreement or permission is based on a full understanding of what is being agreed to and the likely consequences of giving consent.

By presuming individuals have the capacity to make free and informed decisions, organizations are showing Respect for the Dignity for Persons. In practical terms, the principle of respect relative to free and informed consent translates into a process that includes acknowledging the individuals’ rights, discussing the need for consent in clear terms and plain language, providing information in a way individuals can understand, giving them time to ask questions and think about what is being asked of them and respecting their decisions.

There are 2 parts to informed consent

1. An informing process
2. Documentation of the informing process and its outcome (typically, but not always, a signature on a consent form)

Informed consent is needed by organizations in several types of situations

- Consent to receive services under the conditions set by the organization (e.g., confidentiality or information sharing rules, service planning and review practices, medication administration policies and procedures)
- Consent to a restriction of rights in order to safeguard individuals or others
- Consent for individuals to travel out of town in the company of staff (e.g., vacation or meeting)
- Consent to participate in a specific program, treatment, research or project of a time-limited nature (including program reviews by internal or external evaluators, such as Creating Excellence Together (CET) surveyors)
- Consent to allow individuals’ names, stories and/or images to appear in public relations materials (e.g., brochures, newsletters, annual reports, website, displays)

1. Be Informed

All stakeholders (i.e., individuals, guardians, staff) must be knowledgeable about the decision to be made, the various courses of action they can choose and the implications (i.e. pros and cons of each) from the perspective of their unique values, attitudes and goals. In other words, if the individuals do not know exactly what they are consenting to, the consent should not be considered valid.

2. Be Specific

The consent must outline what the individuals and others (e.g., service provider staff) are expected to do, under what circumstances or conditions and within what timelines. Most consent processes and forms are lax when it comes to setting all specific time when the consent expires or must be reviewed or renewed. For example, how often do permissions allow organizations to use a person's photograph for a particular public display to a specific audience at a specific time? While more "blanket" consents tend to be accepted for a variety of situations (restrictive procedures being the exception), there needs to be some liability stated for organizations that fail to recognize that consent has been withdrawn by the individuals in question and that continue to act as if it had consent.

3. Be Voluntary

Consent must be given freely and with the awareness that individuals have the right to say "no" or to withdraw consent. If individuals fee; that they might lose services if they say "no", even if the organization does not actually threaten to do so, the consent is not truly voluntary. Furthermore, the validity of any voluntary consent given may be nullified if an organization indicates that it cannot provide service to high-risk individuals unless they consent to restrictions on their rights or limits on their confidentiality.

4. Be Competent

Competency to give consent is a basis for deciding whether individuals need guardians or trustees. In order to be considered competent, one must be able to understand what actions are being proposed, to weigh the various alternatives

and to make a reasonable choice based on those alternatives. Whether it is reasonable needs to be judged in light of the individuals' values, attitudes and goals. Individuals who have guardians are considered to be competent to make decisions in areas not covered by the guardianship order. (For example, a guardian cannot vote for or make a will in behalf of a dependent adult) While the guardians' informed consent may be required to take cooperative action (e.g., participate in interviews with a CET surveyor), their ongoing consent is critical to the success of the activity.

Informing for Consent

Informing for consent can present a challenge for people who work with individuals who have developmental disabilities. Most standard consent forms use legal jargon and are written at or above an undergraduate level. If challenged in court, such consents would almost certainly be declared invalid by virtue of being uninformed. Therefore, it is important for service providers to make and document efforts to ensure that individual's understand what they are consenting to.

There are 3 key points to remember in informing for consent.

1. Present information in simple language

Sometimes the individuals' understanding of the words is enhanced by pictures or by role-playing what can be expected to happen.

2. Give individuals plenty of time to think things through

Individuals need time to figure out what they need to know to make a decision, and most individuals naturally feel anxiety and have difficulty making sense of the "fine print" under circumstances whereby they are required to sign a form in front of witnesses. If the process produces feelings of pressure, this can invalidate their consent.

3. Let individuals know that it is okay to say "no"

Individuals need to feel that they have a choice and that, even if they say "yes" now, they can withdraw their consent later. As well, they need to know whom they can tell if they wish to

withdraw consent and not to go about it. (A common concern of service providers around consent withdrawal is that individuals with challenging behaviors could withdraw consent to service verbally just before throwing themselves in front of an oncoming car. The obvious solution is to require individuals to communicate withdrawal of consent to someone other than the support staff providing assistance in the community. The safety of individuals in life-threatening circumstances requires staff to take action, regardless of apparent withdrawal of consent). Service providers have an obligation to pay attention to the individuals' behavior to determine whether they continue to consent or wish to withdraw their consent. If their behaviour indicates that they wish to withdraw their consent (e.g., to continue with an activity or program), the service provider needs to assure them that it is okay to change their minds and to remind them of the process for withdrawing consent.

Informed Consent on a Day-to-Day Basis

In addition to obtaining signed consent forms on an annual basis for the activities mentioned above, it is important for organizations and staff to obtain verbal informed consent on an ongoing, day-to-day basis for activities of daily living (e.g., what to eat, what to wear), for recreation and leisure activities, in relation to who individuals what to spend time with, etc.

Assessing Understanding as Part of the Consent Process

Part of the "informing for consent" process is ensuring that, when individuals say "yes," they are aware of what they are saying "yes" to, with all its personal ramifications. However, it is not enough for staff simply to ask, "Do you understand?" after they have given their explanation (although this is the easiest method for follow-up). Rather, staff need to devise ways for individuals to demonstrate that they understand.

Staff signature

Date

Team Leader signature

Date