

INFORMED CONSENT¹

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 of Persons**.² 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
- respecting their decisions

There are two parts to informed consent

1. An informing process (e.g., staff explain what is on a document and/or what a document will be used for)
2. Documentation of the informing process and its outcome (typically, but not always, a signature on a consent form)

Organizations need to obtain informed consent 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**³)
- 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 service reviews by internal or external evaluators, such as CET surveyors)
- Consent to allow individuals’ names, stories and/or images to appear in public relations materials (e.g., brochures, newsletters, annual reports, web site, displays, social media)

It is common for organizations to believe that their informed consent obligations are limited to the individuals accessing service and their legal guardians. In fact, organizations also have an obligation to get the informed consent of staff, volunteers and members of the Board of Directors prior to participating in research projects (including service reviews) and to including personal information (as defined by **FOIP**⁴) in public relations materials.

¹ Appendix *Glossary*: informed consent

² Appendix *Ethical Principals of the Alberta Council of Disability Services*

³ Appendix *Glossary*: policy, procedure

⁴ Appendix *Freedom of Information and Protection of Privacy Act and Records Management Regulation*

In order for consent to be “legal,” it must meet four prerequisites.

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
 - 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 a 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 feel 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
- 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

- Assessing the individuals’ competency to give consent is what determines whether individuals need guardians or trustees
- To be considered competent, individuals must be able to
 - understand what actions are being proposed
 - understand the nature of a decision and the consequences of making a decision
 - weigh the various alternatives
 - make a *reasonable* choice based on those alternatives
- Whether a choice is *reasonable* needs to be judged in light of the individuals’ values, attitudes and goals
- Individuals who are competent to make decisions in some areas but need help in other areas can have those areas written into a Guardianship Order (see When Individuals need Help with Decision Making on next page)
- While the guardians’ informed consent may be required to meet the competency requirements of a valid consent, if individuals are required to take cooperative action (e.g., participate in conversations with a CET surveyor), the guardians’ ongoing consent is critical to the success of the activity

When Individuals need Help with Decision Making^{1, 2, 3}

Before consent can be given, a decision must be made. Alberta's *Adult Guardianship and Trusteeship Act* provides decision-making options for individuals who either need help with making decisions or are incompetent to make decisions. The Act requires the individuals' competency to be assessed (using a Capacity Assessment Process) whenever someone applies for guardianship, trusteeship or co-decision-making.

- Guardianship
 - Guardianship gives legal authority for someone to make personal decisions and give consent for individuals who are not capable of doing so for themselves
 - Guardians cannot act on a dependent individual's behalf in regards to voting or making out a will
 - The guardians' authority may be limited to matters based on the individuals' needs (e.g., decisions or consent concerning health care) and this will be written into the guardianship order
 - When individuals are able to make decisions with the support of a family member or friend, then co-decision-making may be a better option
- Co-Decision-Making
 - Co-decision making is less intrusive than full guardianship
 - It applies when individuals need formalized support to make personal decisions
 - Co-decision-makers cannot unilaterally make decisions for the individuals
 - Consent must be obtained from both parties
 - While the individuals and their co-decision-makers work through decisions together, the individuals always have the final say⁴

Making Consent Understandable

If a consent form that uses legal jargon and/or is written at or above an undergraduate level were to be challenged in court, it would almost certainly be declared invalid because the individual who signed it probably did not understand it. Therefore, it is important for service providers to make and document efforts to ensure that individuals understand what they are consenting to.

There are three key points that will make consent understandable.

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
- Most individuals naturally feel anxiety and have difficulty making sense of the "fine print," especially if they are required to sign a form in front of witnesses

¹ Guardianship of an adult – How it works. (2016). Alberta Human Services

² *Adult Guardianship & Trusteeship Act Frequently Asked Questions*. (2010). Alberta Health Service Clinical Policy Department

³ *Planning for Illness: Decision-making options, Personal Directives, and Powers of Attorney*. (n.d.). LegalAve: Your guide to legal information in Alberta.

⁴ *Understanding Co-decision-making*. (2010). Government of Alberta.

- 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 know
 - that they have a choice
 - that, even if they say “yes” now, they can withdraw their consent later
 - whom they can tell if they wish to withdraw consent and how to go about it.
- A common concern of service providers around consent withdrawal is that individuals with challenging behaviours could withdraw consent to service verbally just before throwing themselves in front of an oncoming car
 - The 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’ behaviour 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 service), 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

Assessing Understanding as Part of the Consent Process

An important part of the 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.

A Short History of the Research on “Do you understand?”

At its simplest, “Do you understand?” is an example of a yes-no question. While this question seems an obvious way to determine whether someone has been adequately informed for consent, research involving individuals with developmental disabilities suggests it is not.

The problem is a strong tendency for people to respond “yes” to yes-no questions. Reasons suggested for this include

- wanting to comply with the perceived wishes of authority figures
- giving what appears to be the “safe” response when one does not understand the question or the information it relates to
- experiencing memory difficulties

Any or all of these may be involved at least some of the time

Some researchers who study **self-determination**¹ have looked at various ways of measuring choice making and concluded that open-ended questions give more reliable information about what individuals with developmental disabilities prefer, do or believe.²

¹ Appendix *Glossary*: self-determination

² Stancliffe, R. (1992). *Approaches to measuring choice making*. Paper presented at the meeting of the American Association on Mental Retardation, New Orleans, LA.

You can probably recall a time when you were given information that “went over your head” but, when asked if you had any questions (or asked if you understand), you declined to display your ignorance. If *we* are sensitive about concealing *our* ignorance to people we work with or to our service providers (e.g., doctors), it is likely that those who typically have less understanding might want to do likewise.

What is the Alternative?

The simplest alternative for working with individuals who have some verbal skill is to ask them to restate what you told them in their own words. The critical pieces of information for understanding usually have to do with

- what they are being asked to do
- what will happen as a result

If it involves participating in an individual or group conversation, they need to have an understanding of the kinds of questions they will be asked and what the information will be used for.

Individuals should feel free to tell you what they should do if they do not want to answer a particular question or if they do not want to continue the conversations in that kind of situation.

Right to withdraw consent is a standard part of any ethical consent process. One can simply ask the question, “If they/we ask you a question and you don’t want to answer it, then what?”

Confidentiality vs. privacy of information gathered (or its limits) is another area where service providers need to assess understanding. These concepts may have different meanings for the persons getting and giving consent within this population.

Assessing understanding of consent with someone who is less able to communicate verbally is a bit more complex. Sometimes they can show you what they think will happen. Given a set of pictures, they may be able to pick the one for which they are being asked to give consent. This approach is not without problems (e.g., picture position biases), but it is a start.

One observes behaviour for signs that consent is continuing or being withdrawn throughout the course of the specific activity. This is true for both verbal and non-verbal individuals.

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)
- recreation and leisure activities
- in relation to whom individuals want to spend time with, etc.

Formal vs. Informal Consent

When is a formal consent form required and when will verbal consent do? For the average person, the act of completing a consumer questionnaire or interview is taken as informed consent for the activity. No signed and witnessed form is required.

However, when providing services to individuals with developmental disabilities, formality is applied even in activities that would not normally require consent procedures and forms.

In instances where individuals give “verbal” consent only (e.g., when they cannot read or write, if their representatives provide consent by phone), the service provider should identify

- the means or medium by which consent was conveyed (e.g., nodded, said “OK,” agreed by phone)
- who gave consent to whom
- the time and date consent was given

Staff have two roles in ensuring individuals are giving informed consent.

1. Obtain written informed consent from the individual and/or guardian before sharing any information (e.g., with a doctor, shared photos)
 - This is usually kept in the individual’s file
2. Ensure that
 - the individual has been informed about and included in any discussion about the reason for the consent
 - the individual wants to participate in the activity or event

This can be done as simply as asking them, perhaps when the monthly calendar is created. It is important for staff to have repeated discussions to ensure that the individual continues to agree and give consent.

Consent for Specific Purposes

Consent must be based on an understanding of some key pieces of information, namely

- what the program or project aims to do (i.e., intended outcome or result)
- what is required for the program or project to achieve its aim (e.g., talking with people, taking a particular action when a challenging situation or behaviour occurs)
- what the individuals are being asked to do (e.g., cooperate with staff in achieving goals, meet for how long, talk about what things, be videotaped speaking in public)
- what possible risks are associated with participation (e.g., a certain topic may bring up hurtful feelings)
 - as well as what will NOT be at risk (e.g., not losing services by either talking to or choosing not to talk to surveyors)
- what the likely benefits will be for participating (e.g., learning more, feeling better about self, meeting others with the same experiences)
- that participation
 - is voluntary (i.e., nothing bad will happen if they say “no”)
 - continues to be voluntary with respect to every part of it (e.g., answering particular questions, participating in particular group activities)
 - can be ended either by the person offering the program or leading the project or by the individuals (including how to end it, such as telling staff you don’t want to participate any more)
- how the privacy of what individuals say or do is protected, or the degree to which it is protected (e.g., if videotaped, they will see the video and be told whether it will be kept or erased; if they are going to be quoted, they will be told whether their name or picture will accompany the quotation)

Public Relations Use of Photos and Names

Service providers must abide by legislation and obtain informed consent before using the names or photographs of individuals and of staff, volunteers, board members and others, for public relations materials (e.g., newsletters, annual reports, brochures, public displays, websites, social media).

One of the common reasons for getting permission is to protect the whereabouts of people who have been **abused**¹ from an abuser. A display or online post could unintentionally compromise their security.

General Principles

- The public use of a photo must preserve the dignity of the individuals and neither hold them up to contempt nor damage their reputations.
 - The exception is when someone poses as a model to convey a specific image or feeling.
- Consent for public relations use of a photograph **MUST** be obtained when
 - the individual is recognizable (i.e., full face and 3/4 profile, but not back of head or 1/4 profile; use judgement on recognizability of anything in between) **AND**
 - the photograph was taken in a private setting (e.g., home, private function, part of the workplace not normally accessible to the public, anywhere that taking a photograph might be considered an invasion of privacy—such as a hospital room) **OR**
 - the photograph is of a single individual in a public setting
- Consent for public relations use of a photograph **NEED NOT** be obtained when
 - the individual is not recognizable **OR**
 - the photograph is of a group of individuals in a public setting that revolves around some sort of public event (e.g., open house, rally) because images captured in such a context are considered public domain
- Photographs should include captions that identify the context and individuals accurately
- Use of old photographs should be limited to retrospective displays and not treated as if they are current
 - There is no official age at which a photo is considered “old,” but it may be considered old if
 - clothing or hairstyles seem out-of-date
 - the person’s appearance has changed significantly
- Photos of deceased individuals should not be used unless careful consideration leads one to believe that this would be acceptable to family members or friends who are still living
- Photos should be limited to retrospectives if
 - the people are no longer in the organization’s employ
 - the individuals no longer access service
- If a photograph has been published elsewhere in the public domain (e.g., newspaper, eMagazine, Facebook), it is generally acceptable to use it again without re-obtaining permission, if the use is respectful and accurate

¹ Appendix *Glossary*: abuse

Consent Forms

While different consent forms will include different information and may have varying time limits, this section is about consent forms in general.

A consent form, even when signed by the individuals or guardians, should not be confused with “consent.” The most important part of the consent process is the explanation staff give and the dialogue they have with individuals about the proposed treatment, activities, photographs, etc. The form is merely the written evidence that explanations were given and that the individuals agreed to what was proposed.

Organizations that keep supporting documents (e.g., initial invitation to participate, progress notes, photographs) with the consent forms can provide additional evidence that the individuals were adequately “informed” prior to signing the consent form.

To keep from having to get consent forms signed each time something occurs, consents can include time limits and, if appropriate, check boxes to let individuals indicate what they are consenting to. Example situations may include

- the re-administration of a medication
- the re-scheduling of an outing
- the re-use of the individuals’ photographs and/or names in a number of venues
 - In these cases, there could be check boxes for individuals to check off those venues that are acceptable

Guidelines for Preparing Consent Forms

Regardless of its particular use, the following guidelines will apply to most consent forms.

- Use the individual’s proper name and not nicknames or initials
- Include the title of the project or activity as well as specific information about the matter requiring consent
- Make the form time limited and include a place to write in the timeline
- Use plain language (i.e., avoid legalistic phrases or industry terminology)
- Include a place to sign and date the form, including a place for witnesses to sign if needed
- If the form is for research or a study, then include the purpose of the research or study and include information on any criteria under which prospective participants would be excluded

Store consent forms in a location that is accessible to whoever is facilitating the thing being consented to.