

Informed Consent for COVID-19 Immunization

Informed Consent/Decision-Making

In law, consent is a voluntary agreement to an action, for example, to treat or to vaccinate, proposed by another person. The individual who is consenting must be of sound mind and old enough to be able to give consent. Consent between two parties can either be verbal or written.

Informed consent/decision-making must be made at the time of immunization with the person(s) present.

Background Information

The [Alberta Immunization Policy](#) (Alberta Health)¹ includes information on:

- The legislative authority
- Alberta Immunization Strategy
- Administering vaccines
- Recommended immunizations
- Management of biological products
- History of biological products used in Alberta
- Recommended websites
- Glossary

Even though some of the context and products are a bit different, the British Columbia Centre for Disease Control, Communicable Disease Manual², [Chapter 2: Immunization](#) is an excellent resource, where you will find information on:

- Relative risks of diseases and immunization
- Vaccine immunogenicity, efficacy and effectiveness
- Vaccine development and licensing
- Administration of biological products
- Reducing injection pain

In the [Informed Consent for Immunization](#) section, there are some excellent video scenarios for the various components of an informed consent.

Components of an Informed Consent/Decision

Mature Minors

In Alberta, there is no legislated “mature minor” or “age of consent” other than the age of majority, that is, 18 years. However, anyone under 18 years of age who can understand the actions and consequences must be part of the decision-making process.

Informal Caregivers

In First Nations (FN) communities, children are frequently cared for by people who are not their parents/legal guardians. The Health Canada, FNIHB legal department has reviewed these “informal adoptions” and agreed to the following:

“...in cases where a child is placed in the care of another person who is **not the parent or legal guardian**, the person providing the care and nurturing for the child can consent to the treatment of the child if the child is unable to understand the process. This is assumed that the person has the best interest of the child.”

“Care” and “nurturing” are defined as providing for the needs of the child every day; this would not include sitters or daycare workers.

Obtaining Informed Consent

To obtain informed consent for any immunization from the parent/legal guardian/informal caregiver/person receiving the vaccine:

1. Discuss:
 - The diseases that the vaccine protects against³
 - The components of the vaccine^{4,5}
 - The immune process and the immunization schedule for the particular vaccine(s)
 - The benefits of the vaccine
 - Assessment of “fitness to immunize” at the time of the vaccine
 - The adverse events, common and rare, associated with each vaccine, including an assessment for adverse events associated with any previous dose(s) of the same vaccine(s)
 - What to do in case of an adverse event, including:
 - use of comfort measures
 - use of acetaminophen/ibuprofen
 - when to notify CHN
 - when to contact a physician or other primary care provider for assessment
2. Provide a pamphlet with the information on the vaccine and on aftercare

Children

For all school-based immunization programs, it is best if the parent/legal guardian/informal caregiver signs a consent form giving permission to immunize their child as they will not be with the child at the time of immunization.

If consent forms are not returned and the parent/legal guardian/informal caregiver cannot be contacted, the immunizer must determine whether the child can understand the information and make a decision. If the child does not have this capacity, then a parent/legal guardian/informal caregiver who can give informed consent **must** be present. ***In normal circumstances, children in Grade 5 and above are generally considered capable of informed consent/decision-making.*** The nurse telling the child about the vaccines should give the child the information pamphlet on vaccine and aftercare to take home to the parent/legal guardian/caregiver.

Consent Forms

Use the AHS consent [Consent for COVID-19 Immunization](#) form if the parent/legal guardian/informal caregiver will not be with the child at the time of immunization; the signed form must accompany the child.

Notes:

- Signing the consent form only means that the parent/legal guardian/informal caregiver agrees to the vaccination process; it does not mean that they have read all of the information or that they understand it.
- A witness does not need to verify the signature on the consent form.

References

1. Alberta Health: Alberta Immunization Policy. <https://www.alberta.ca/alberta-immunization-policy.aspx>
2. BC Centre for Disease Control. Communicable Disease Control Manual. <http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm>
3. Dorothy L Moore, Editor. Your Child's Best Shot 4rd edition. 2015. Canadian Paediatric Society <https://bookstore.cps.ca/stock/details/your-childs-best-shot-a-parents-guide-to-vaccination-4th-edition>
4. Offit, Paul A.; Jew, Rita K. Addressing Parents' Concerns: Do Vaccines Contain Harmful Preservatives, Adjuvants, Additives, or Residuals? Pediatrics Vol 112 No 6, December 6, 2003. <http://pediatrics.aappublications.org/content/112/6/1394.full.pdf>
5. Immunization Action Coalition. <https://www.immunize.org/talking-about-vaccines/responding-to-parents.asp>