

Informed Consent

The Ministry of Health and Long-Term Care is not responsible for the accuracy or completeness of the information below. It is not to be considered legal advice. The Ministry is not responsible for any liability whatsoever for the information below. Please consult with your legal counsel, local Medical Officer of Health or professional licensing body if you have any questions regarding any of the contents below.

Consent Form Information

The Ministry of Health and Long-Term Care is not in a position to provide, nor is it responsible for providing, an immunization consent form. However, the following information is provided to assist in obtaining informed consent from potential vaccine recipients.

Informed Consent

The Health Care Consent Act, 1996 (HCCA) provides specific information as to the consent required for treatment. According to the HCCA, and the College of Nurses of Ontario (CNO) and College of Physicians and Surgeons of Ontario (CPSO) standards, nurses and physicians are accountable for obtaining consent when providing treatment. It is therefore the responsibility of the health practitioner who is proposing the treatment to take reasonable steps to ensure that informed consent for that treatment is obtained. (www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm)

According to the HCCA, consent to treatment for a capable person is informed if, before giving the consent:

- a) the person received the information about the treatment that a reasonable person in the same circumstances would require to make a decision; and
- b) the person received responses to his/her requests for additional information about the treatment.

This information must include:

- The nature of the treatment
- The expected benefits of the treatment
- The material risks of the treatment
- The material side effects of the treatment
- Alternative courses of action
- The likely consequences of not having the treatment.

The elements required for consent to treatment include:

- The client must have the capacity to consent
- The consent must relate to the treatment
- The consent must be informed
- The consent must be given voluntarily
- The consent must not be obtained through misrepresentation or fraud.

Evidence of Consent:

Although the HCCA states that consent to treatment may be expressed or implied (i.e., written or verbal), the CNO and CPSO strongly advise nurses and physicians to document that consent was obtained from the client. Examples include: 1) a signed consent form and/or 2) documented consent in the client's health records.

Influenza Immunization Consent Form

Listed below is a partial list of the information that should be included on the consent form [based on information from the National Pandemic Vaccine Task Group (PVTG) and approved by the Canadian Immunization Committee (CIC), federal Special Advisory Committee (SAC), federal Deputy Ministers and the Chief Public Health Officer (CPHO)] the Arepanrix™ and Influenza A (H1N1) 2009 vaccine (without adjuvant)® virtual product information sheets, and the HCCA. However, it is important to note that this list is by no means exhaustive.

Suggested minimum information for inclusion in a consent form:

- Name and Age of client
- History of allergy/hypersensitivity to:
 - Previous dose of influenza vaccine
 - Eggs
 - Thimerosal (preservative)
 - ASO₃ (tocopherol oil-in-water base emulsion) (**Arepanrix™ only**)
- History of:
 - Guillain-Barré Syndrome (GBS)
 - Bleeding disorders
 - Evolving neurological conditions
- Confirmation that the client understands the benefits, side effects and risks of the immunization and the consequences of not having the immunization
- Confirmation that the client does not have a vaccine contraindication
- Confirmation that the client has had the opportunity to ask and receive responses for any additional questions
- Signed consent to receive the immunization.

Please refer to the *H1N1-2009 Vaccine Statement that will be posted on the Health Canada website:*

English: <http://web.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/index-eng.php>

French: <http://web.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/index-fra.php>