

## Immunization Consent Standards

**Purpose:** provide standards on informed consent to all those who administer publicly funded vaccine in the New Brunswick Immunization Program.

**Preamble:** A vital component of any immunization program is an open and informed decision-making partnership between the immunization provider and the vaccine recipient (or his/her parent/legal guardian).<sup>11</sup> This partnership forms the basis of the informed consent required prior to vaccines being administered. For all vaccine programs in Canada, clear vaccine risk and benefit disclosure are essential to avoid confusion, promote the integrity of the consent process and build trust in the vaccine program and the vaccine itself.

Informed consent is derived from the *Patient's Bill of Rights* (Canada) (unproclaimed) and the *Health Charter of Rights and Responsibilities Act* (New Brunswick) (unproclaimed). The Health Charter of Rights and Responsibilities Act states the rights and responsibilities of New Brunswickers relating to publicly funded health-care programs, including the New Brunswick Immunization Program. The following excerpts from the *Health Charter of Rights Act* speak to principles of informed consent:

- 3(1) Every resident of New Brunswick has the following rights:
- (b) A right to receive relevant health care information. This entails a right to receive information about the treatments, interventions and procedures that are appropriate to one's identified health care needs.
  - (c) A right to take informed health care decisions. This entails:
    - A right to be involved in planning and review of one's care, and to have treatments, interventions and procedures, as well as risks, side-effects and alternatives, explained by an appropriate health care professional;
    - A right to consent, or refuse consent to any treatment, intervention procedure;
    - A right to ask questions and have them answered.
- 3(2) Every resident of New Brunswick has the following responsibilities in relation to the appropriate and effective exercise of the rights set out in subsection (1):
- (b) a responsibility to learn about and to make healthy lifestyle choices,
  - (c) a responsibility to share appropriate health information with health care providers,
  - (d) a responsibility to inform health care providers of any special communication requirements,
  - (e) a responsibility to participate actively in health care decisions,
  - (f) a responsibility to communicate health care decisions.

All immunization providers of publicly funded vaccine and biologics must obtain consent for immunization. The following must be considered in obtaining consent:

### **Informed consent for immunization:**

To be able to give informed consent to receive a particular vaccine or series of vaccines, the immunization provider must ensure that the recipient and/or parent/legal guardian is informed of the following:

- nature and purpose of the vaccine;
- benefits of the vaccine;
- risks of the vaccine;
- possible consequences if the vaccine is refused;
- the need for follow-up, for example if immunization requires a series of injections;
- information on signs or symptoms of complications and actions to be taken if such symptoms occur; and
- any alternatives (including doing nothing) and their risks.

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<sup>11</sup> In instances where the child is in the care of the minister of Social Development, the immunization provider must ensure that the person giving consent is legally able to do so.

Furthermore, the recipient of the vaccine and/or his parents/ legal guardian will be given the opportunity to ask questions and have them answered before immunization.

### **Legal age of consent and consent of minors:**

Under the *Medical Consent of Minors Act*, minors who have reached the age of 16 can consent to medical treatment in the same manner as if they had reached the age of majority. A parent/legal guardian needs to consent to immunization for minors younger than 16; however, the *Medical Consent of Minors Act* does allow for medical treatment (including any procedure undertaken for the purpose of preventing any disease or ailment) of a minor younger than 16 without the need for a parent/legal guardian's consent when certain conditions are met:

- 3(1) The consent to medical treatment of a minor who has not attained the age of 16 is as effective as it would be if he had attained the age of majority where, in the opinion of a legally qualified medical practitioner, dentist, nurse practitioner or nurse attending the minor:
  - (a) the minor is capable of understanding the nature and consequences of a medical treatment; and
  - (b) the medical treatment and the procedure to be used is in the best interests of the minor and his or her continuing health and well-being.

When a child is sufficiently mature to be considered competent to make a medical decision and the parent/ legal guardian refuses consent, the child can choose to be vaccinated.

### **Obtaining consent and recording consent:**

Consent can be obtained in writing from the recipient (e.g. a consent form, written statement). However, in a clinical practice setting, consent is often implied when the recipient or his/her legal guardian presents for an immunization. Consent may also be stated verbally, directly or by telephone; such consent should be obtained and recorded in keeping with organizational policy.

When verifying past consent, the Public Health Nurse should consider that parents/legal guardians can provide consent for immunization for their children prior to the date of administration. Once parents/legal guardians provide consent, a relative, babysitter or friend can accompany the infants/children for subsequent visits to the Pediatric Immunization Clinic.

Consent for primary childhood series should have an expiry date on the child's 7<sup>th</sup> birthday for those completing their immunization series prior to age of 7 years. For off schedule vaccination, with vaccines being received after 7 years of age, consent will be expired after the completion of the primary series. School consents are valid from September 1st to August 31st of the current school year.

### **Refusal of consent:**

If vaccination is recommended but refused, a detailed note of both the consent discussion and the refusal should be made in the client/patient record. Alternately, the patient could be asked to sign a standard form stating that he/she has been informed of the benefits and risks of the vaccine but has refused the vaccine(s) despite being aware of the risks of doing so. Public Health Nurses will document refusal of consent in the Public Health Information Solution (PHIS).

### **Withdrawal of consent:**

At any time, an individual or a minor's parents/legal guardian can withdraw previous consent for a single vaccine or a series of vaccines. Documentation that an individual or parent/legal guardian is withdrawing consent should be completed (written statement signed by individual/parent/legal guardian, or verbal withdrawal of consent). Additionally, a detailed note of the consent withdrawal discussion should be made in the client/patient record. The Public Health Nurse will document withdrawal of consent by expiring the consent in the Public Health Information Solution (PHIS).