Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg
Caring for Health / *À l'écoute de notre santé*

WRHA Immunization Program Clinical Practice Guidelines

TITLE: Informed Consent for Immunization

CODE

APPROVED BY:

Program	Date	Program	Date
☑ Population and Public Health	Oct.6,2010	☐ Primary Care	
☐ Occupational Health		☐ Home Care	
☐ Infection Prevention and Control		☐ Personal Care Home	
☐ Community Health Services Leadership Team		☐ Pharmacy	

Sept 2015

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1.0 PURPOSE

1.1 To provide operational guidance for immunization providers in procedures to apply the WRHA Policy - Informed Consent (for procedures, treatments, and investigations) 110.000.0051. http://home.wrha.mb.ca/corp/policy/files/110.000.005.pdf

2.0 DEFINITIONS

2.1 See WRHA Policy – Informed Consent (for procedures, treatments, and investigations) 110.000.005 [1] for definitions.

2.2 Immunization Provider: A health care professional who is registered or licensed to provide health care under an Act of the Legislature and who is authorized under that Act to administer vaccines [1] Eg. registered nurse (R.N.), physician, licensed practical nurse (L.P.N.) registered psychiatric nurse (R.P.N.), pharmacists, health care provider students under the supervision of a clinical instructor or physician

2.3 Individual: Patients, residents, clients, tenants or staff (including volunteers).

3.0 SCOPE & GOAL

3.1 This practice guideline is applicable to all immunization providers within programs/facilities directly owned or funded by the Winnipeg Regional Health Authority (WRHA).

3.2 Informed consent, written or verbal, is required for each vaccine being administered to an individual.

[1] Manitoba Health, Communicable Disease Control, Immunization Manual Protocol, Informed Consent Protocol

4.0 PROCEDURE

4.1 Consent shall be given by an individual or parent/substitute decision-maker according the **WRHA Policy - Informed Consent (for procedures, treatments, and investigations) 110.000.005,** who is able to understand the benefits and risks of immunization.

4.2 The discussion to enable informed consent to immunization should include the following topics:

- The risks of the disease in the absence of vaccination and with vaccination
- Benefits and risks of the vaccine to the individual
- Details about the vaccination route and the schedule
- Common side effects and their management
- Contraindications
- Choices of vaccines where applicable
- The benefits to the community of immunization programs
- Risks to the individual and community of not being fully immunized
- Immunization information documentation in the provincial immunization registry.

4.3 Informed consent should be obtained or confirmed by the person who is administering the vaccine.

4.4 Documentation of Consent

4.4.1 Informed consent shall be documented by the immunization provider. In certain situations, as specified by the program, site, or region, additional documentation may be required.

4.4.2 An approved site/program specific immunization consent form shall be used to document the consent (or refusal) within the various Winnipeg region facilities and funded agencies, unless the documentation occurs in the client's health record. Consent can be either oral or written. However, written consent is preferred. The individual's signature should be obtained on the consent form whenever possible.

4.4.3 If a consent form is not used, documentation shall occur in the health record indicating that informed consent has been obtained.

4.4.4 A consent form shall be considered a "health record" in whole or in part.

4.5 Consent when a series of vaccines will be given (e.g. 3 doses of hepatitis B vaccine):
4.5.1 The number of doses should be clearly stated in the consent form or communicated verbally.
4.5.2 Consent should be "updated" between doses if necessary. This means the provider should communicate any important new information that could alter a decision to be immunized. This could include changes to the vaccine formulation (e.g. now contains an additional antigen) or a change in the risk for adverse reactions based on reactions occurring after a previous dose.

4.6 Duration of Consent: Consent should not normally be considered valid more than one year after it is given.

4.7 Mature Minors Informed Consent

4.7.1 If a minor presents for immunization and has not obtained parental/guardian consent, then it is necessary to determine if the individual has decision making capacity according to 2.2 Decision Making Capacity in the **WRHA Policy - Informed Consent (for procedures, treatments, and investigations) 110.000.005**.
http://home.wrha.mb.ca/corp/policy/files/110.000.005.pdf

4.7.2 Special considerations for those under 18 years of age
For those clients under 18 years of age, a determination should be made as to whether the client has the capacity to provide informed consent. If it is determined that the client has capacity to provide informed consent, the parent or legal guardian can only be contacted with the consent of the client. Notwithstanding the above, it is recommended that a reasonable attempt be made by the provider to encourage the client to consent to parental/ legal guardian involvement in immunization discussions. If it is determined that a client does not have the capacity to provide informed consent, and the client refuses to disclose legal custody/guardianship arrangements, the provider should seek further advice as to whether to involve the Child and Family Services.

4.7.2.1 The younger an individual is, the higher the standard for obtaining informed consent. More time needs to be spent with these individuals to allow a judgment on their capacity to provide informed consent.

4.7.3 If a minor is determined to have decision making capacity, they can consent to their own immunization.

4.8 Third Party Consent

4.8.1 For individuals who have do not have decision making capacity, the parent/substitute decision maker should be involved and sign the consent form.

4.8.2 When the child to be immunized does not have decision-making capacity and is accompanied by someone other than the parent or legal guardian, follow section 2.9 Substitute Decision-Maker in the **WRHA Policy - Informed Consent (for procedures, treatments, and investigations) 110.000.005.**In this situation, a signature from this individual, their address, and the relationship to the child should be documented on the consent form.

4.8.2.1 For children in the permanent custody of Child and Family Services, the assigned social worker signs the consent form.

4.8.2.2 For children in temporary custody or in foster care, the parent/legal guardian signs the consent form. The assigned social worker will facilitate this process.

4.8.2.3 If the immunization provider becomes aware that the guardianship of the child has changed, where the individual who originally gave consent is no longer the legal guardian, a new consent must be obtained.

5.0 VALIDATION

5.1 Winnipeg Regional Health Authority Informed Consent Policy # 110.000.005
http://home.wrha.mb.ca/corp/policy/files/110.000.005.pdf

5.2 Manitoba Health, Communicable Disease Control, Immunization Manual Protocol, Informed Consent Protocol
http://www.gov.mb.ca/health/publichealth/cdc/protocol/consentguidelines.pdf

6.0 RECOMMENDED READING

6.1 WRHA Policy, Regional Program, Clinical Services, Informed Consent Policy # 110.000.005

6.2 National Advisory Committee on Immunization, (NACI), Canadian Immunization Guide, Evergreen version

6.3 Manitoba Health, Communicable Disease Control, Immunization Manual Protocol, Informed Consent Protocol