

**Health**

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**Santé**

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October 30, 2009

Dear Colleague:

**Re: H1N1 Pandemic Influenza (pH1N1) Vaccine Information**

- A. Informed Consent Requirements**
- B. Adverse Events Following Immunization (AEFI) Requirements**

This letter is intended to provide information about Informed Consent and Adverse Events Following Immunization (AEFI) requirements.

**Informed Consent Requirements (applies to all immunizations)**

- Immunization providers are reminded that prior to administering an immunizing agent, they must obtain and document informed consent. Expected benefits and risks of the vaccine(s) must be addressed including an assessment of previous vaccine reaction(s). An electronic copy of the consent form specific to the pH1N1 vaccines can be downloaded from the Manitoba Government website:  
[http://www.gov.mb.ca/health/publichealth/sri/docs/consent\\_form.pdf](http://www.gov.mb.ca/health/publichealth/sri/docs/consent_form.pdf)

**Adverse Events Following Immunization (AEFI) (applies to all immunizations)**

- Adverse events following immunization must be reported under *The Public Health Act*. See link:  
<http://www.gov.mb.ca/health/publichealth/act.html>.
- **Serious adverse events** such as anaphylaxis and others noted in Appendix A, **must be reported within 24 hours** to regional MOHs by phone and by faxing the completed AEFI Form.
- Practitioners who become aware of other reportable adverse events, as listed in Appendix A (attached) **are to be reported within 7 days** by completing and faxing the AEFI Form to their regional Medical Officer of Health (MOHs). See Appendix C for list of MOHs.
- Cooperation from **medical specialists** is requested to report conditions requiring a physician's diagnosis, marked with an asterix ( \* ) in Appendix A, and all noted in Appendix B.
- A revised AEFI form and User Guide can be downloaded from the Manitoba Government website:  
[http://www.gov.mb.ca/health/publichealth/sri/docs/aeafi\\_manual.pdf](http://www.gov.mb.ca/health/publichealth/sri/docs/aeafi_manual.pdf)

Note: Paper copies of the H1N1 Pandemic Influenza Vaccination Informed Consent Form, the AEFI Form, and the AEFI Form User Guide will be available from the Material Distribution Agency (MDA) by mid November 2009. Send an order to [InformationResources@gov.mb.ca](mailto:InformationResources@gov.mb.ca) or call the warehouse directly at 204-945-0570.

**Health Links-Info Santé**

- **Health Links-Info Santé:** Health Links-Info Santé can be used by the public to inquire about adverse events following immunization with the pH1N1 vaccine. Health Links-Info Santé will triage, manage and refer calls for appropriate public health and medical follow up.

Thank you in advance for your cooperation.

Yours sincerely,

*"Original signed by Val Steeves"*

Val Steeves  
A/Director, CDC Branch