Ontario

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

REPORT TO LOCAL MEDICAL OFFICER OF HEALTH

Protected when completed

A. PATIENT : **Name :** **Parent's/Guardian's name (if a child) :** **Address (**Street, City, Postal code)**:** **Home phone #** **Work phone #**	**DATE OF BIRTH** _____/____/____ **YYYY / MM / DD** AGE _____	**SEX** ☐ Male ☐ Female **DATE OF VACCINE ADMINISTRATION** _____/____/____ **YYYY / MM / DD**

Reason for Reporting: *Check all that apply*. **(1, 2, AND 3 must apply to meet AEFI reporting criteria)**
For additional guidance on completing form, call your local public health unit. Return completed form to your local public health unit.

- ❑ 1.Event temporally associated with immunization
- ❑ 2. Event has no other proven explanation
- ❑ 3. Event meets at least one of the following criteria:
  - ☐ Serious nature i.e. fatal, life-threatening, required hospitalization or resulted in residual disability ☐ Required medical attention
  - ☐ Was expected, but has been observed to occur with greater than usual frequency ☐ Was unusual or unexpected event

B. VACCINE (S) GIVEN (Trade name preferred)	**DOSE NUMBER (if applicable)**	**SITE**	**ROUTE**	**DOSAGE**	**MANUFACTURER**	**LOT NUMBER**

C. Information on Reporter

- Name of Individual submitting report _____
  - Telephone Number: _____
  - Professional Status: MD ___, RN ___, Pharmacist ___, Other *(specify)*_____
  - Address (Institution, Street, City, Province, Postal code) _____
  - Signature _____

Date reported (yyyy/mm/dd)

D. Case status at time of report

Choose only one

- ☐ Fully recovered
- ☐ Not yet recovered
- ☐ Residual effects *(please describe under Supplementary Information)*
- ☐ Fatal
- ☐ Unknown

E. Medical Attention
(Provide details in Supplementary Information)

Check highest level of care required as a result of AEFI.

- ❑ None
- ❑ Telephone advice from a health professional
- ❑ Primary care visit
- ❑ Emergency Room (*describe under Supplementary Information)*
- ❑ Hospital admission date _____/___/___ Total hospital days _____
  yyyy/mm/dd

F. Medical History Prior to Onset of Adverse Event

Check all applicable boxes and provide details in Supplementary Information section

- ❑ Medication(s) _____
- ❑ Acute Illness / Injury _____
- ❑ Known medical conditions/allergies _____

G. Public health Recommendations
(Provide additional information in the Supplementary Information section)

Name_____ Phone:_____
Signature_____ Date: (yyyy/mm/dd)_____

Recommendations: (*Check all that apply*)

- ❑ Controlled setting for next immunization
- ❑ Expert referral (specify) _____
- ❑ Determine protective antibody level
- ☐ No change to immunization schedule
- ☐ Active follow-up for AEFI recurrence after next vaccine
- ☐ No further immunizations (specify) _____
- ☐ Other (specify) _____

H: AEFI: Complete the event details section (1-5) that best describes the AEFI (can tick >1), and provide detail about fever, investigation, therapy and other information as appropriate in the Supplementary Information section of this form.
Events marked with an asterisk (*) require a physician diagnosis. Attach supporting documentation.

1. LOCAL REACTION at or near injection site. Symptoms/ signs. C*heck all that applies.*

Temporal characteristics

Choose the single most appropriate period of time (either Min, Hrs, or Days)

- ☛ Time from immunization to 1st symptom/sign onset: __Min __Hrs __Days
- ☛ Time from onset of 1st symptom/sign to resolution of all symptoms/signs: __Min __Hrs __Days

- ❑ **Swelling - Severe**
  - o Extending past nearest joint(s)
  - o Lasting fewer than 4 days o Lasting 4 days or more
- ❑ **Infected Abscess**
  - o Purulent discharge
  - o Positive gram stain or culture
  - o Erythema,
  - o Resolution on antimicrobial therapy
- ❑ **Pain – Severe**
  - o Lasting fewer than 4 days
  - o Lasting 4 days or more
- ❑ **Sterile Abscess**
  - o Non-purulent fluid
- ❑ **Nodule**
  - o Discrete, well-demarcated, firm soft tissue mass or lump

2. ANAPHYLAXIS OR OTHER ALLERGIC REACTION: *Choose the one that best fits the AEFI and provide details in Supplementary Information section.*

Temporal characteristics	*Choose the single most appropriate period of time (either Min, Hrs, or Days)* ☛ Time from immunization to 1st symptom/sign onset:__Min __Hrs __Days ☛ Time from onset of 1st symptom/sign to resolution of all symptoms/signs: __Min __Hrs __Days

❑ ***Anaphylaxis:** R*apid onset and involving at least 2 body systems.*
Check all involved systems below and list specific symptoms/signs for each checked box in the Supplementary Information section.
___Dermatologic/Mucosal ___Cardiovascular ___Respiratory ___Gastrointestinal

❑ **Other Allergic Reaction** *Describe in Supplementary Information section*

3. NEUROLOGIC REACTION: *Check all applicable boxes; provide details in Supplementary Information section.*

Temporal characteristics	*Choose the single most appropriate period of time (either Min, Hrs, or Days)* ☛ Time from immunization to 1st symptom/sign onset: __Min __Hrs __Days ☛ Time from onset of 1st symptom/sign to resolution of all symptoms/signs: __Min __Hrs __Days

❑ ***Encephalopathy / Encephalitis** *Check all that apply. Add details in Supplementary Information section.*
- o Depressed/altered level of consciousness, lethargy or personality change lasting for ≥24hrs
- o focal or multifocal neurologic sign(s)
- o CSF pleocytosis >5 wbc/mm^3
- o EEG consistent with encephalitis
- o Brain pathology consistent with encephalitis
- o Fever ≥ 38.0C
- o Seizures *(if present, provide details in seizure section below)*
- o Neuroimaging consistent with encephalitis

❑ ***Meningitis** *Record symptoms and CSF results in Supplementary Information section.*

❑ **Seizure(s)** *Check all that apply and provide a detailed description of the seizure in the Supplementary Information section (generalized, focal, or focal progressing to generalized; tonic, clonic, tonic-clonic or atonic motor manifestations; automatisms (e.g. drooling, lip smacking); loss of awareness (fixed stare, eye deviation, inability to communicate).*
- ❑ Sudden loss of consciousness *-if ticked was it:*
  - ❑ *Witnessed by healthcare professional OR* ❑ *By report only*
- ❑ Associated with fever ❑ History of seizures before immunization: o febrile o afebrile o unknown type

❑ ***Guillain-Barré Syndrome (***Indicate in Supplementary Information section whether EMG and/or LP done, and results, as well as any other relevant investigation including tests to look for possible causes, especially Campylobacter)*

❑ ***Bell's Palsy**

❑ ***Paralysis other than Bell's Palsy** *Describe in Supplementary Information section.*

4. OTHER DEFINED AEFIs OF INTEREST: *Complete temporal characteristics, check all applicable boxes and provide any important additional details in Supplementary Information section.*

Temporal characteristics	*Choose the single most appropriate period of time (either Min, Hrs, or Days)* ☛ Time from immunization to 1st symptom/sign onset: __Min __Hrs __Days ☛ Time from onset of 1st symptom/sign to resolution of all symptoms/signs: __Min __Hrs __Days

❑ **Hypotonic-Hyporesponsive Episode***: (NOTE: only if <2yrs old. If older, check "other severe or unusual event" and describe in Supplementary Information section)* ***Check all that apply***
- o Limpness o Reduced responsiveness / unresponsiveness o Pallor/Cyanosis

❑ **Persistent Crying** *(Crying which is continuous and unaltered for ≥ 3 hours)*

❑ **Rash** o Generalized o Localized at injection site o Localized at non-injection site

❑ **Arthritis** (*joint pain lasting at least 24 hours). **Check all that apply**:*
- o Joint swelling o Joint redness
- o Sensation of warmth over joint o Inflammatory changes in synovial fluid

❑ **Thrombocytopenia:** Lowest platelet count_____

❑ **Parotitis** (*parotid gland swelling with pain and/or tenderness)*

❑ **Oculo-respiratory syndrome (ORS)** *Bilateral red eyes AND at least one respiratory sign/symptom with or without facial edema, occurring within 24 hours of* **influenza** *vaccination*

5. OTHER SEVERE OR UNUSUAL EVENT(S) NOT LISTED in 1-4 ABOVE *Complete temporal characteristics below and describe the event in the Supplementary Information section.*

Temporal characteristics	*Choose the single most appropriate period of time (either Min, Hrs, or Days)* ☛ Time from immunization to 1st symptom/sign onset: __Min __Hrs __Days ☛ Time from onset of 1st symptom/sign to resolution of all symptoms/signs: __Min __Hrs __Days

SUPPLEMENTARY INFORMATION:

_____

_____

_____

_____

Please use additional pages if necessary