**SAMPLE Consent Form**

**IMVAMUNE (smallpox and monkeypox) vaccine for adults 18 years of age and older**

IMVAMUNE vaccine has been authorized by Health Canada for active immunization against smallpox, monkeypox and related orthopoxvirus infection and disease under the provision of the Extraordinary Use New Drug (EUND) regulations in adults 18 years of age and older determined to be at high risk for exposure. EUND vaccines are part of emergency preparedness in Canada where manufacturers may not be required to provide substantial evidence in humans demonstrating the safety and efficacy of the product before being authorized. Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect exactly what will be experienced in practice, including side effects that may not have been identified previously. This is why EUND vaccines are monitored closely for clinical safety and effectiveness in the post-market phase.

**Last name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **First name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Health card number / First Nations Status Card Number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Phone number**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Email address**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Street address**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **City:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Province:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Postal code**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of birth**: Month \_\_\_\_\_\_\_ Day \_\_\_\_\_\_ Year \_\_\_\_\_\_ **Age:** \_\_\_\_\_\_\_

**Gender/Sex:** (insert choice per data collection preferences)

How many doses of smallpox/monkeypox vaccine(s) have you had before? None [ ]  One [ ]  Two [ ]

If you have previously received a smallpox/monkeypox vaccine, specify the **name and date of the previous smallpox /monkeypox vaccine(s) you have received**, if known.

Name of vaccine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_ (month / day / year)

Name of vaccine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_ (month / day / year)

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| --- | --- |
| **Are you feeling ill today?** | No [ ]  Yes [ ]  If yes, please provide details |
| **Do you have or have you had a monkeypox infection?** | No [ ]  Yes [ ]  If yes, please indicate when the symptoms started, if known |
| **If you have had one or more previous orthopoxvirus vaccine (Smallpox vaccine; live (freeze-dried), Smallpox vaccine; live (frozen-liquid) and/or IMVAMUNE), did you have any side effects after any previous dose(s)** (including allergic reactions, hypersensitivity reactions or heart inflammation [myocarditis/pericarditis])**?** | No [ ]  Yes [ ]  If yes, please provide details |
| **Are you** **allergic to eggs or egg products?1***Allergic reactions are not a contraindication to immunization with vaccines that are manufactured using processes involving eggs. Ask your health care provider who may advise on extra precautions.* | No [ ]  Yes [ ]  If yes, please provide details |
| **Are you allergic or could you be allergic to tromethamine (trometamol, Tris)2, benzonase3, gentamicin4 or****ciprofloxacin4 which are contained in the vaccine?** | No [ ]  Yes [ ]  If yes, please provide details |
| **Have you had an allergic reaction to another vaccine (another type of smallpox/monkeypox vaccine or a non-smallpox/monkeypox vaccine) or other medication given by injection or intravenously in the past?** | No [ ]  Yes [ ]  If yes, please provide details |
| **Are you or could you be pregnant or are you breastfeeding?** | No [ ]  Yes [ ]   |
| **Do you have any problems with your immune system or are you taking any medications that can affect your immune system** (e.g., high dose steroids, chemotherapy, some arthritis medications)**?** *Ask the health care provider if you are not sure about your medical conditions* | No [ ]  Yes [ ]  Uncertain [ ]  If yes, please provide details |
| **Do you have skin conditions such as atopic dermatitis?** *Ask the health care provider if you are not sure about your medical conditions* | No [ ]  Yes [ ]  Uncertain [ ]  If yes, please provide details |
| **Have you recently received specific medications for monkeypox treatment** (e.g., immunoglobulins)**?** | No [ ]  Yes [ ]  If yes, please provide the date of the treatment |
| **Have you received another vaccine in the last 4 weeks or do you anticipate receiving a vaccine in the next 4 weeks?** *To minimize the potential risk of interactions, it is recommended to administer certain types of vaccines 4 weeks before or after administration of IMVAMUNE. Consult your health care provider.* | No [ ]  Yes [ ]  Uncertain [ ] If yes, please provide details |
| **Have you ever felt faint or fainted after a past vaccination or medical procedure?**  | No [ ]  Yes [ ]  If yes, please provide details |

1. In Canada, there are several vaccines, including IMVAMUNE, that are manufactured by processes involving hens' eggs or their derivatives, such as chick cell cultures.
2. Tromethamine (trometamol, Tris) may very rarely cause allergic reactions and is found in some medications injected to do tests (contrast media) as well as other medications taken by mouth or injection, and some creams and lotions. Note that this is not a complete list.
3. Benzonase is used for purification of viral vaccines, viral vectors for vaccine, cell and gene therapy, and oncolytic viruses, removing DNA/RNA from proteins and other biologicals; reduction of viscosity caused by nucleic acids; sample preparation in electrophoresis and chromatography and prevention of cell clumping.
4. Gentamicin and ciprofloxacin are used as antibiotics in the treatment of some bacterial infections.

**I have read (or it has been read to me) and I understand the “Information sheet for IMVAMUNE (smallpox/monkeypox) vaccine for adults 18 years of age and older”. I have had the opportunity to ask questions and to have them answered to my satisfaction. I consent to receiving the vaccine.**

Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Print name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Date of signature: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

If signing for someone other than yourself, indicate your relationship to that other person: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

[ ]  I confirm that I am the parent / legal guardian or substitute decision maker.

**For Clinic Use Only**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **VACCINE** | **DOSE/ROUTE** | **LOT NUMBER** | **EXPIRY DATE** | **SITE and ROUTE** | **TIME GIVEN** | **DATE GIVEN****Month/day/year** | **GIVEN BY****Name and designation** |
| **IMVAMUNE smallpox / monkeypox vaccine** | **0.5 ml/SC** |  |  |  |  |  |  |

**Comments:**