

Institutional Biosafety Committee (IBC) Policy on Vaccinia Vaccination and Waiver Form

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to ensure that researchers working with vaccinia virus receive information about vaccinia vaccination and to provide a copy of the vaccinia vaccination form that must be completed by all such researchers.
- 2.0 Scope:** This policy applies to all members of the UW-Madison IBC, UW-Madison Office of Biological Safety (OBS), UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with any additional personnel listed on the Biosafety protocol, as applicable.
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website (www.biosafety.wisc.edu).
 - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website (www.biosafety.wisc.edu).
 - UW-Madison, Occupational Health Program, Document Control System, Considerations for use of Vaccinia virus (VACV) Guidance Document (OH-GUI-018).
 - UW-Madison, Occupational Health Program, Document Control System, Vaccinia Exposure Medical Response Guidance for the University of Wisconsin- Madison (OH-GUI-036).
 - UW-Madison, Occupational Health Program, Document Control System, Monkeypox Exposure Medical Response Guidance for the University of Wisconsin- Madison (OH-GUI-043).
 - UW-Madison, Occupational Health Program, medical response plans for infectious agents used in research on campus. The plans can be accessed on the UW-Madison Occupational Health Program webpage at: www.ehs.wisc.edu/occ-resources.htm (EH&S Home > Occupational Health > Resources > Medical Response Plans).
 - U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Emergency Preparedness and Response website, Smallpox (<http://emergency.cdc.gov/agent/smallpox/>).
 - U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) - Biosafety in Microbiological and Biomedical Laboratories (BMBL), current version and/or any subsequent revisions.
 - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, current version and/or any subsequent revisions.
 - [Virology](http://www.sciencedirect.com/science/article/pii/S0042682208007976), Risks Associated with Vaccinia in the Laboratory, Science Direct, [Volume 385, Issue 1](http://www.sciencedirect.com/science/article/pii/S0042682208007976), 1 March 2009, Pages 1–4 (www.sciencedirect.com/science/article/pii/S0042682208007976).

4.0 Definitions: Not Applicable.

5.0 Roles and Responsibilities: Not Applicable.

6.0 Policy: This policy requires researchers who conduct activities with vaccinia virus to consider IBC recommendations for vaccinia vaccination and to complete the vaccinia vaccination form (attached).

Additional information regarding vaccinia virus can be found in the UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website (www.biosafety.wisc.edu), Policy and Procedure No. 4.1.13, *Precautions for Work with Poxviruses that Infect Humans*; see also *Virology, Risks Associated with Vaccinia in the Laboratory*, Science Direct, Volume 385, Issue 1, 1 March 2009, Pages 1–4.

Also please see information pertaining to vaccinia under the UW-Madison, Occupational Health Program (OHP), “Considerations for use of Vaccinia virus (VACV) Guidance Document” (OH-GUI-018), Vaccinia Exposure Medical Response Guidance for the University of Wisconsin- Madison (OH-GUI-036), and OHP Medical Response Plans for Infectious Agents used in Research on Campus, accessed on the OHP webpage at: www.ehs.wisc.edu/occ-resources.htm (EH&S Home > Occupational Health > Resources > Medical Response Plans).

Original signed and dated Policies are retained by the Office of Biological Safety

Signature
Professor Susan West, IBC Chair

Date
06/05/2013



Attachment 1

Vaccinia Vaccination Form
University of Wisconsin-Madison

Form with fields: Employee Name, Employee ID#, PI, SC#, Protocol Title, Protocol Description, and Description of the vaccinia virus...

Please read the information below and check the appropriate boxes.

The research described in this protocol uses the vaccinia virus or an attenuated form of the vaccinia virus. The consequences of exposure to either high doses of virus or an unusual route of exposure that may be associated with a lab-acquired infection are largely unknown.

The vaccinia virus is the "live virus" used in the Vaccinia Vaccine for smallpox. The vaccinia virus is related to the smallpox virus. The Vaccinia Vaccine has been used in the past to vaccinate against smallpox. Worldwide use of the Vaccinia Vaccine has eliminated smallpox. Vaccination with the Vaccinia Vaccine may confer immunity to accidental exposure to the vaccinia virus or an attenuated form of the vaccinia virus.

Other details:

- List of details regarding the disease Vaccinia, its symptoms, spread, and the safety of the ACAM2000 vaccine.

- Three checkboxes with statements: 'I have read the University of Wisconsin-Madison Institutional Biological Safety Committee Policy for Personnel Working with Pox Viruses.', 'I understand that inadvertent exposure to the vaccinia virus or an attenuated form of the vaccinia virus may lead to an unknown outcome but may include all of the effects listed below associated with the Vaccinia Vaccine (ACAM2000).', 'I understand that vaccination with the Vaccinia Vaccine (ACAM2000) may confer immunity if I am accidentally exposed to either the vaccinia virus or an attenuated vaccinia virus.'

Printed Date:

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Paper copies may be outdated and should not be relied upon as current, active IBC policy

The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu

I understand that the vaccine site must be properly cared for to avoid autoinoculation of other sites on my body with the vaccinia virus and/or inoculation of other individuals with the vaccinia virus.

I understand that vaccination with the Vaccinia Vaccine (ACAM2000) may cause side effects including:

Normal and Typically Mild Reactions (go away without treatment):

- The arm receiving the vaccination may be sore and red where the vaccine was given.
- The lymph nodes in the armpits may become large and sore.
- The vaccinated person may run a low fever.
- One out of 3 people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.

Serious Reactions (250-500 of every 1 million people vaccinated for the first time; not life-threatening but serious):

- Inadvertent self inoculation. This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person. It usually occurs on the genitals or face, including the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this inadvertent inoculation.
- A widespread vaccinia rash (generalized vaccinia). The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site.
- A toxic or allergic rash in response to the vaccine that can take various forms (erythema multiforme).

Rare reactions (14-52 of every 1 million people vaccinated for the first time; life threatening):

- Eczema vaccinatum. Serious skin rashes caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis.
- Progressive vaccinia (or vaccinia necrosum). Ongoing infection of skin with tissue destruction frequently leading to death.
- Postvaccinial encephalitis (inflammation of the brain).
- Myocarditis or pericarditis

I understand that vaccination with the Vaccinia Vaccine (ACAM2000) should not be used in the following circumstances:

- I have active eczema or a history of eczema or atopic dermatitis, or Darier's disease.
- I have other acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, varicella zoster, severe acne, or other open rashes or wounds), until the condition resolves.
- I am pregnant or intend to become pregnant within 4 weeks of vaccination or am breast-feeding.
- I am immunodeficient or immunocompromised (by disease or therapy), including HIV infection.
- I have a current moderate or severe acute illness.
- I am less than 18 years of age.
- I am undergoing topical steroid therapy for inflammatory eye diseases or undergoing therapy with systemic steroids (potential immune suppression increases risk for vaccinia-related complications).
- I have a history of allergy or serious reaction to prior vaccinia vaccination or any of the vaccine's components.
- I have known cardiac disease (e.g., previous heart attack, angina, CHF, cardiomyopathy, stroke or TIA) or have three or more known risk factors for cardiac disease (e.g., hypertension, hypercholesterolemia, diabetes, first degree relative with onset of cardiac complications prior to age 50, smoker).
- I have close household contacts with one or more of the conditions listed above.



Institutional Biosafety Committee - Office of Biological Safety

Title: IBC Policy on Vaccinia Vaccination and Waiver Form

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I have read the above facts and elect to receive the Vaccinia Vaccine (ACAM2000).

I have received an evaluation via the UW-Madison Occupational Health Service.

I have been vaccinated with a vaccinia vaccine within the last ten years.

Date of Vaccination: _____

**I have read the above facts and decline the Vaccinia Vaccine (ACAM2000) at this time.
I understand that I may change my mind and receive the vaccine.**

I have read the above facts and elect to not participate in this research project.

Employee Signature: _____

Date: _____

References: CDC Website <http://emergency.cdc.gov/agent/smallpox/>