



Dartmouth College

Institutional Biosafety Committee

Vaccinia Use Policy

IBC Policy # 140.1

Approved: 09/15/17



I. Purpose:

In the interest of providing a safe workplace and to comply with federal regulations, the Institutional Biosafety Committee (IBC) has developed this policy regarding working safely with vaccinia virus and other Orthopoxviruses in research laboratories. Recommendations for vaccination will be dependent upon on the strain used in the proposed research. This IBC policy follows national guidelines set forth by the CDC in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 5th Ed.) and the vaccinia vaccine recommendations of the Advisory Committee on Immunization Practices (ACIP) (*MMWR, Recommendations and Reports*, 50, 2001). This policy applies to all laboratory research staff with direct or indirect exposure to vaccinia virus, including animal handlers. This policy does not apply to custodians, maintenance staff, and other non-researchers who may enter vaccinia research labs but have very minimal likelihood of exposure to potentially infectious materials.

II. Background:

Researchers who engage in activities with non-highly attenuated strains of vaccinia virus are at increased risk for laboratory acquired infections, serious complications, and transmission to close personal contacts. From 1986-2009 there were 17 documented case reports of laboratory-acquired infections, involving needlestick or other sharps injuries, direct contact, and ocular exposure. Non-sharps exposures involved inconsistent biosafety practices and lack of personal protective equipment (PPE). Infections can include localized skin lesions at the site of exposure, including spread to other sites, as well as ocular infections.

III. Definitions:

- A. Direct exposure: defined as working with viral cultures, materials exposed to viral cultures, bodily fluids or tissues from infected animals or patients, and any other potentially vaccinia-infected material.
- B. Indirect exposure: includes laboratory research staff who do not directly work with cultures of vaccinia or vaccinia-infected fluids or tissues or animals as described above, but work in the same lab where vaccinia is used.
- C. Non-highly attenuated vaccinia strains: able to infect and replicate in human cells

Strain	Biosafety Level
Western Reserve (WR)	BSL2
New York City Board of Health (NYCBOH)	BSL2
Copenhagen	BSL2
Temple of Heaven	BSL2
Lister	BSL2
Cowpox	BSL2

- D. Highly attenuated vaccinia strain: able or unable to infect human cells; unable to replicate or replicate poorly in human cells; commonly used as vaccine strains and considered avirulent

Strain	Biosafety Level
Modified Vaccinia Ankara (MVA)	BSL2
NYCVAC (derived from Copenhagen)	BSL1
ALVAC (derived from canarypox)	BSL1
TROVAC (derived from fowlpox)	BSL1



- E. Recombinant vaccinia: viral vectors or recombinant/chimeric viruses containing vaccinia genome

IV. Scope:

- A. The Dartmouth IBC highly recommends that research personnel and students who work directly or indirectly with non-highly attenuated vaccinia viruses (see Section II), recombinant vaccinia viruses derived from non-highly attenuated vaccinia strains, or other non-highly attenuated Orthopoxviruses that infect humans, (e.g., monkeypox, cowpox, vaccinia and variola) receive the vaccinia vaccination, unless medically contraindicated.
- B. Vaccination is not recommended for research personnel or students whose work is limited to highly attenuated vaccinia strains (see Section II) and no other work with Orthopoxviruses is taking place.
- C. Custodians, facilities services, and visitors, who may have to enter the workspace where vaccinia virus is manipulated, will not require medical counseling and vaccination. Work space where vaccinia is manipulated should be decontaminated prior to entry, and activities with vaccinia should be suspended when non-lab personnel are in the room. If decontamination and suspension of work cannot be accomplished (e.g., in an animal room), non-lab personnel will be provided with appropriate PPE and receive information about the risks associated with entering these spaces.

V. Responsibilities

A. Principal Investigator (PI) Responsibilities:

- Will not store vaccinia or initiate research with vaccinia virus or vaccinia viral vectors without prior approval from the IBC
- Will not initiate research with vaccinia or vaccinia vectors in animals or human subjects without prior approval from the IBC and IACUC or the IBC for Clinical Gene Transfer (IBC-CGT) and the IRB, respectively
- Notify EHS of proposed vaccinia work for risk assessment consultation regarding lab space, decontamination procedures, etc.
- Report any lab accidents to EHS
- Ensure all personnel working with direct or indirect exposure to vaccinia have completed the mandatory confidential medical counseling with Occupational Medicine (OM) for vaccine screening prior to work
- Keep a copy of and follow OM recommendations provided through the Work Clearance (or Fit for Duty) Form when assigning duties to research staff.
- Notify EHS of new employees and make arrangements with OM for new employees to receive mandatory screening/counseling re: vaccination
- Provide annual, documented, lab specific training for all researchers in the lab (Section X)
- Report any exposures or potential exposures to the Biosafety Officer (EHS) within 24 hours

B. Researcher Responsibilities:

- Adhere to Dartmouth's policy on BSL2 practices, the BMBL, any other restrictions imposed by the IBC or PI for working with vaccinia
- Report any exposure or potential exposure to vaccinia to your PI or Supervisor immediately



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- Immediately seek medical attention for any exposure or potential exposure
- Report any exposure or potential exposure to the Biosafety Officer (EHS) within 24 hours

C. IBC Responsibilities:

- Review and approve all research involving non-highly attenuated vaccinia, highly attenuated vaccinia, and any recombinant vaccinia viruses
- Review and approve Biosafety Levels, personal protective equipment, any additional work practice controls, and training

D. EHS Responsibilities

- Perform regular lab inspections to verify that researchers are following appropriate practices and procedures
- Review BSL2 and lab specific training records
- Assist PI with performing a risk assessment with working with vaccinia
- Provide recommendations to the IBC on any additional work practice controls that may be warranted

VI. Policy:

- A.** PIs who plan to work with vaccinia in a research lab must complete a Pathogen Registration Form or Viral Vector Registration Form, as appropriate, in his/her BioRAFT Biological Registration and submit it to the IBC for approval prior to storing vaccinia or beginning any work with vaccinia.
- B.** Clinical researchers must have approval through the IBC for Clinical Gene Transfer (IBC-CGT) and IRB before using vaccinia-based vectors in gene therapy.
- C.** Animal researchers must have approval through the IBC and the IACUC before using vaccinia or vaccinia viral vectors in animals.
- D.** All proposed work with vaccinia must be reported to Environmental Health & Safety (EHS) and approved by the Dartmouth Institutional Biosafety Committee (IBC) prior to commencement.
- E.** All laboratory personnel who have direct or indirect exposure to vaccinia or other pox viruses will receive **mandatory confidential medical counseling** through Occupational Medicine (OM) before beginning work with the virus. These individuals will be counseled on the risks and benefits of the vaccine and medically screened for contraindications to vaccinia exposure or vaccination. If work duties change from indirect to direct exposure to vaccinia, unvaccinated employees must have additional counseling from OM and be offered the vaccine.
- F.** After medical counseling, the vaccine will be offered to individuals who OM has determined meet acceptable criteria to receive the vaccine. These individuals must complete a **vaccination acceptance/declination form** provided by OM. This form will be kept by OM.
- G.** Based on the risk assessment and medical review, some staff may be excluded from working with vaccinia.

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- H. A **Vaccinia Clearance Form** (or Fit for Duty Form) will be completed by OM for each employee and returned to the PI indicating whether or not an individual should be allowed to work with vaccinia prior to the PI assigning any duties that may involve exposure to vaccinia. The PI must follow the recommendations on the clearance form when assigning duties to research staff.
- I. Personnel will sign and label (name of agent, biohazard symbol) areas and items where vaccinia virus is used, stored, or may be present. Access to these areas will be limited.
- J. Personnel will conduct manipulations of the virus, animal inoculations, and husbandry activities with infected animals inside a certified biosafety cabinet or similar HEPA-filtered containment device. Activities with live virus or infected animals outside of a containment device are prohibited.
- K. Other engineering controls and procedures will be incorporated, as appropriate. For example: use of sealed rotors or safety cups during centrifugation; loading and unloading of tubes and rotors inside a biosafety cabinet; use of a cup sonicator or performing sonication inside a biosafety cabinet; protecting vacuum lines with HEPA filters.
- L. Infected animals will be housed in ventilated microisolator cages or static microisolator cages with filter tops, and personnel will label cages with a biohazard cage card.
- M. Personnel will eliminate or minimize the use of sharps in laboratory manipulations, and the principal investigator will incorporate engineered sharps devices when possible.
- N. Personnel will wear appropriate PPE at all times when manipulating virus or infected animals, including:
 - A buttoned up lab coat with cuffed sleeves or solid front gown with cuffed sleeves
 - Double disposable nitrile gloves
 - Eye and mucous membrane protection (e.g., face mask and goggles, face shield)

VII. Risks of Exposure:

- A. Accidental exposure to vaccinia may occur through ingestion, parenteral inoculation, and droplet or aerosol exposure of mucous membranes or broken skin with infectious particles. Ocular exposure is of particular concern. Protective eyewear or other shielding must be used when working with vaccinia outside of a biosafety cabinet.
- B. Pre-exposure vaccination can prevent or minimize the impact of accidental laboratory exposure. The CDC recommends vaccination every 10 years for laboratory workers in the United States who have any contact with non-highly attenuated vaccinia strains. However, individuals who are pregnant, breastfeeding, have skin conditions such as eczema or atopic dermatitis, or those with altered immune systems are at increased risk from the vaccine, and should not be vaccinated.
- C. The following medical conditions may increase risk of exposure or risk of complications following exposure to vaccinia:
 - Diagnosis and/or history of eczema even if condition is mild and not presently active.
 - Household contacts with diagnosis and/or history of eczema.

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- Other acute or chronic skin conditions including atopic dermatitis, burns, impetigo, etc.
- Any diseases or conditions that cause immunodeficiency including leukemia, lymphoma, other malignancies, HIV infection, therapy with alkylating agents, antimetabolites, radiation, high dose steroids.
- Household contacts with immunodeficiency disease or therapy listed above.
- Pregnancy or planning to become pregnant within 1 month following vaccination or accidental exposure.
- Allergy to polymyxin B, streptomycin, tetracycline, neomycin.

VIII. Vaccine Screening Process:

- A.** Research and clinical personnel and animal care staff who **will work directly with non-highly attenuated vaccinia** virus and materials infected or potentially infected with vaccinia, such as infected animals or bedding, must be medically screened through OM prior to beginning work.. All staff working directly with vaccinia will be asked to complete the “Vaccinia Clearance Form” as part of this screening.
- B.** Research and clinical personnel and animal care staff with indirect exposure, i.e., those who will not directly work with cultures of non-highly attenuated vaccinia or animals infected with these strains, but who work in the same lab where non-highly attenuated strains are being used, will also be offered the same medical screening and counseling.
- C.** EHS will provide OM with the PI submitted Pathogen Registration Form or Viral Vector Form and other relevant documentation regarding the vaccinia strain(s) to which research staff may be exposed and a summary of the work to be performed that may expose staff to vaccinia.
- D.** OM staff will review with staff:
- Job tasks to be performed
 - Vaccinia strain to be used in project
 - Review of “Vaccinia Clearance Form” with staff, including review of medical history, allergies, and contraindications to vaccination.
 - Discussion of risks, benefits, and contraindications of vaccination.
- E.** Based on this review, a determination will be made regarding vaccination and exclusions from work with vaccinia based on contraindications to vaccination.
- F.** Contraindications to the vaccinia vaccination include those indicated in Section VII-B, VII-C.
- **Additionally, the following precautionary measure was added by the CDC on 3/31/03:** Anyone with a physician diagnosed heart condition, with or without symptoms should **not** get the smallpox vaccine at this time. These include conditions such as:
 - known coronary disease including: previous myocardial infarction, angina
 - congestive heart failure
 - cardiomyopathy
 - stroke or transient ischemic attack
 - chest pain or shortness of breath with activity
 - other heart conditions under the care of a doctor
 - **In addition, anyone with 3 or more of the following risk factors should NOT get**

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the vaccinia vaccine:

- Anyone who has been told by a doctor that he/she has high blood pressure
- Anyone who has been told by a doctor that he/she has high blood cholesterol
- Anyone who has been told by a doctor that he/she has diabetes or high blood sugar
- Anyone who has a first degree relative (for example, mother, father, brother, or sister) who had a heart condition before the age of 50
- Anyone who smokes cigarettes now

Note: consult the CDC website for updates to this list:

<http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/smallpox.html>

- G.** If an employee consents to vaccination, OM will provide this service, including appropriate instructions for dressing and care of the vaccination site and all appropriate follow up.
- H.** OM staff will monitor research staff for development of rare complications to vaccination. Complications following vaccination include vaccinia necrosum, eczema vaccinatum, generalized vaccinia:

Vaccinia necrosum is a progressive destruction of the skin and tissues at the vaccination site.

Eczema vaccinatum is a severe and destructive infection of the skin affected by eczema or other chronic skin disorders caused by spread of Vaccinia virus.

Generalized vaccinia – vaccination lesions that develop away from the vaccination site.

- I.** Revaccination every 10 years is recommended for people working with non-highly attenuated vaccinia strains; more frequent revaccination may be required for more virulent orthopoxviruses.
- J.** Research staff who experience a change in medical condition, at the request of the employee, may return to OM for follow up confidential medical counseling which may change whether they have clearance to work with vaccinia or not.

IX. Work Restrictions

- A.** PI will maintain a copy of the Vaccinia Clearance form (or Fit for Duty form) provided by OM for each staff member that they supervise.
- B.** Following medical consultation the individual will either:
- sign a vaccinia vaccination consent form and receive the vaccine (this will require follow-up visits to monitor the vaccination site), OR
 - sign a declination form, OR
 - if OM determines that vaccination is contraindicated, OM may recommend restrictions on the employee's work in order to protect the health and safety of the employee and others. Such recommendations should be set out on the Vaccinia Clearance Form.
- C.** In cases where OM recommends work restrictions, and the PI is not willing or able to modify the duties of the employee, the PI must consult with Human Resources prior to



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making that decision.

- D. All work with vaccinia in research labs will be done following a minimum of Biosafety Level 2 practices and following the [Emergency Response and Biohazard Exposure Control Plan](#).
- E. The EHS office and the IBC, in consultation with the PI, may require additional work practices and exposure controls beyond BSL2 on a case by case basis dependent on the particular strain of vaccinia, the work to be performed, and the immunization status of lab personnel with direct contact with the virus.

X. Training

- A. As per Dartmouth EHS Policy, all staff working in BSL2 labs must complete BSL2 Training annually.
- B. In addition to this training, the PI is responsible to ensure that lab personnel are trained annually in the proper techniques for safely handling vaccinia virus. This training shall include lab specific information on what tasks, procedures and equipment in the lab involve the use of vaccinia; information on how to recognize signs and symptoms of exposure; the steps to take in case of accidental exposure; and medical conditions that would warrant caution when working with vaccinia. A record of this training must be retained and made available for review by EHS and the IBC.

XI. References

Vaccinia (Smallpox) Vaccination Recommendations of the Advisory Committee on Immunization Practice. MMWR 50 (RR 10); June 22, 2001; pp 1-25.

CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
<http://www.cdc.gov/od/ohs/biosfty/bmb15/sections/SectionVIII-E-ViralAgents.pdf>

Cornell University Institutional Biosafety Committee Policy and Procedures on Use of Vaccinia Virus in Research Applications (2012)

I have read and understand the above Vaccinia Use Policy and agree to abide by it.

Printed Name	Signature	Date