Smallpox Vaccine Request Form and Use Agreement

Instructions: Vaccinia (smallpox) vaccine, ACAM2000™, may only be used to vaccinate laboratory and health care personnel in strict accordance with the guidelines established by the Advisory Committee on Immunization Practices (ACIP). These guidelines may be found in MMWR Recommendations and Reports, Volume 65, Number 10, published on 03/18/16. This document is accessible at: http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6510a2.pdf

Only individuals who fall into one of the categories below may be vaccinated with ACAM2000™:
1. Laboratory workers who directly handle cultures contaminated or infected with vaccinia, recombinant vaccinia, or other orthopoxviruses (such as monkeypox, cowpox, and others);
2. Laboratory workers who directly handle animals contaminated or infected with vaccinia, recombinant vaccinia, or other orthopoxviruses;
3. Other health-care workers (such as physicians and nurses) whose contact with these viruses is limited to contaminated materials (for example, dressings), but who adhere to appropriate infection control measures are probably at lower risk for inadvertent infection than laboratory workers. However, because a theoretical risk of infection exists, vaccination may be considered for this group.

The Principal Investigator (PI) of the research lab conducting vaccinia-related research will complete sections 1 and 3 below and attach an Executive Summary of the proposed research project that includes the following information:

1. The strains of vaccinia virus being utilized in the laboratory and in the research project.
2. A detailed description of the lab procedures involved that will be used by proposed vaccine recipients/laboratory workers.

The physician will submit a curriculum vitae along with their current medical license (THIS IS AN INITIAL REQUIREMENT THAT APPLIES TO FIRST REQUESTS ONLY) and complete section 2 below.

Both the physician and the PI will read and sign section 4.

Section 1: Laboratory Details

Last Name	MI	First Name	Date of Request

Institution Name

Street	Building	Suite

City	State	Zipcode	Email	Phone	Fax

Section 2: Physician Details (*This is the location the vaccine will be shipped and stored.*)

Last Name	MI	First Name	Email

Clinic Name

Street	Building	Suite

City	State	Zip Code	Phone	Fax

Section 3: Recipient Details

Name (Last, First, MI)	Age	Category: Healthcare/ Preparedness	Category: Laboratory	Indication: Position	Indication: Duties
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Smallpox Vaccine Request Form and Use Agreement (cont.)

Section 4: Use Agreement

The physician receiving the vaccine for the purposes of vaccinating personnel, as well as the Principal Investigator of the laboratory conducting vaccinia-related research hereby agree to the following conditions:

1. **ACAM2000™ MAY NOT BE USED FOR ANY PURPOSE OUTSIDE OF THE INDICATIONS FOR USE IN THE PACKAGE INSERT AND IN STRICT ACCORDANCE WITH THE ACIP GUIDELINES LISTED ABOVE.**

2. The receiving physician agrees to retain full control over ACAM2000™ while in their possession, and further agrees not to transfer the vaccine to any third party. Upon successful completion of all requested vaccinations, the receiving physician will destroy any remaining supplies and vaccine and document its destruction. Failure to return the form to CDC within 60 days of vaccine receipt may result in notification to FDA and denial of future vaccine requests.

3. ACAM2000™ vaccine is provided as a public health service for the vaccination of laboratory personnel who may have occupational-based exposure to vaccinia virus. It is the express responsibility of the receiving physician to immediately report any adverse events experienced by vaccinees by utilizing the VACCINE ADVERSE EVENTS REPORTING SYSTEM (VAERS). VAERS reports may be submitted online by visiting www.vaers.hhs.gov or by calling 1-800-822-7967.

4. By providing ACAM2000™ for vaccination of laboratory personnel, the Principal Investigator agrees not to claim, infer, or imply United States Governmental endorsement of the Research Project, the institution, or personnel conducting the Research Project or any resulting commercial product(s). Unless prohibited by law from doing so, the Principal Investigator agrees to hold the United States Government harmless and to indemnify the United States Government for all liabilities, demands, damages, expenses, and losses arising out of use of ACAM2000™.

5. By signing below, the Recipient warrants that all of the Recipient's statements and representations in this Agreement are true and accurate.

6. Any false or misleading statements made, presented or submitted to the U.S. Government, including any relevant omissions, under this agreement and made during the course of negotiation of this agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 USC § §3801-3812 (civil liability) and 18 USC §1001 (criminal liability including fine(s) and/or imprisonment).

Receiving Physician: I have read and understood the conditions outlined in this Agreement, and I understand that I must abide by them to receive and use vaccinia (smallpox) vaccine (ACAM2000™). I agree to the following:

1) That under no circumstances will the vaccine be used for research purposes, for human subject clinical trials/studies, nor for treatment of any condition in human subjects. All records of vaccination shall be stored by physician/ facility and available to CDC upon request.
2) I have viewed the Smallpox Vaccine Administration Video (located at: https://emergency.cdc.gov/agent/smallpox/vaccination/administration-video/)
3) I have informed the local public health department officials of my intentions to administer the vaccinia vaccine to personnel.
4) I will complete the Vaccine Accountability and Disposal Record and return to the Drug Service within 60 days of vaccine receipt.

Physician Signature	Physician Name (*printed*)	Physician Title	Date

Principal Investigator: I have read and understood the conditions outlined in this Agreement, and I understand that I must abide by them to have personnel in my lab vaccinated with vaccinia (smallpox) vaccine (ACAM2000™). I agree that under no circumstances will the vaccine be used for research purposes, for human subject clinical trials/studies, nor for treatment of any condition in human subjects.

PI Signature	PI Name (*printed*)	PI Title	Date