DETAILED INCLUSION AND EXCLUSION CRITERIA FOR SYSTEMATIC REVIEW—Continued

Category	Include	Exclude
	KQ 3, 3a, 3b, 4, 4a, 4b: Eligible followup imaging for routine surveillance of kidney stones, no followup imaging.	
Outcomes	*All KQs:* Patient-centered health outcomes: Incident symptomatic stones, urinary tract obstruction with acute renal impairment, end-stage renal disease, urinary tract infection, stone-removal procedures/surgery, procedure-related morbidity, emergency department visits and hospitalizations, quality of life, missed school or work, preventive treatment-related adverse events, imaging-related adverse events, serious adverse events, discontinuations due to adverse events. *Intermediate outcomes:* Growth of existing stones, incident radiographic stones, radiation exposure, incidental imaging findings.	*KQ 1, 1a, 1b, 3, 3a, 3b:* Blood or urine chemistry measures, urine supersaturation measures, acute pain.
Timing	*KQ 1, 3:* Studies that measure outcomes at least 12 months after baseline. *KQ 2, 4:* Followup not limited.	*KQ 1, 3:* Studies of less than 12-months duration.
Setting	Outpatient clinical settings including primary care, urology, nephrology, or other specialty stone clinics; countries with HDI[12] of *very high* (Appendix B).	Inpatient settings; Countries with HDI other than *very high.*
Study Designs, Publication Types, and Language.	*All KQs:* Published in peer-reviewed literature, unpublished studies with enough information about methods to determine risk of bias; English language. RCTs; for comparisons lacking sufficient RCT evidence, NRSIs with concurrent comparator group and primary study aim/outcome to assess a dietary or pharmacologic intervention or surveillance imaging approach are eligible.	*All KQs:* Interrupted time series, case series, narrative reviews, editorials, and commentaries are not eligible; systematic reviews are not eligible but will be reviewed to determine whether any included studies are eligible. Studies with fewer than 30 participants at baseline per study arm. Studies published in languages other than English. *KQ 2:* Studies designed to report epidemiologic associations between dietary factors and stone incidence.

CT = computed tomography; FDA = U.S. Food and Drug Administration; HDI = United Nations Development Programme Human Development Index; KQ = key question; NRSI = nonrandomized study of intervention; OTC = over-the-counter; RCT = randomized controlled trial.

Dated: December 4, 2024.

Marquita Cullom,

Associate Director.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Materials; Availability for Access

AGENCY: National Institute of Allergy and Infectious Diseases, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The material listed below is owned by an agency of the U.S. Government and is available for transfer to achieve expeditious use and/or commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Access information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852 by contacting Benjamin Hurley at 240–669–5092 or *benjamin.hurley@nih.gov.*

SUPPLEMENTARY INFORMATION:

Royalty-Free Starting Material (MVA-clone 1) for the Clinical Development, Evaluation, and Commercialization of a Viable Mpox Vaccine

Worldwide, leading health authorities have cited the growing need for a commitment to equitable vaccine access and its role in curtailing future epidemics—a vision that cannot be realized without significant improvements in the speed, scale, and access of vaccine manufacturing and deployment in historically underserved regions. For at-risk populations and those with contraindications to commonly deployed vaccines, such initiatives are even more vital.

Modified vaccinia virus Ankara (MVA), developed more than 30 years ago as a highly attenuated candidate smallpox vaccine, was recloned at the U.S. National Institute of Allergy and Infectious Diseases (NIAID) (referred to here as ''MVA clone-1'') from a 1974-originating passage and evaluated for safety and immunogenicity in both normal and partially immune-deficient animals. Subsequent studies verified the protective ability of this attenuated vaccine against mpox in non-human primates, and clinical efforts since have resulted in FDA approval and availability of a two-dose MVA vaccine in the U.S.

In support of the global humanitarian effort to achieve equitable vaccine access and in light of the current public health emergency of international concern (PHEIC) declared by the World Health Organization in 2024—which has resulted in more than 500 deaths in the Democratic Republic of the Congo since the beginning of this year—the National Institute of Allergy and Infectious Diseases (NIAID) is seeking inquiries from parties interested in independent R&D and/or collaborative research to further develop, evaluate, and commercialize a viable mpox vaccine for distribution (particularly in developing nations/regions currently having minimal access to mpox vaccines) using NIH-provided starting material (MVA clone-1). While traditional licensing opportunities related to mpox detection are also available (*e.g.,* antibodies, neutralization assays), NIAID will transfer the MVA clone-1 material in question on a royalty-free basis to qualified partners in an effort to combat the current PHEIC. In the event that NIAID has limited ability to distribute material, or if supply approaches exhaustion, priority will be given to collaborators with a proposed plan demonstrating, in

NIAID's sole judgment, the ability to develop a viable vaccine. Potential collaborators considered equally competitive in terms of capacity will also be evaluated based on their plans and intent to distribute in areas with immediate need, followed by the likelihood of the proposed plan contributing to the achievement of a self-sustaining vaccine ecosystem in developing nations.

This material is available for access for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration agreement.

Potential Commercial Applications:

- Prophylaxis against mpox in normal or high-risk populations
- Vaccine research

Competitive Advantages:

- MVA clone-1 material is believed to be functionally and genetically similar to FDA-approved vaccine material
- Identification of vaccine candidates that can elicit protective antibodies against mpox in normal or high-risk populations
- Royalty-free access for vaccine development and/or research

Development Stage:

- Pre-clinical

NIH Contributor: Bernard Moss, MD, Ph.D.

Publications:

- Earl PL, et al. (2004) Immunogenicity of a highly attenuated MVA smallpox vaccine and protection against monkeypox. *Nature.* 428:182.
- Wyatt LS, et al. (2004) Highly attenuated smallpox vaccine protects mice with and without immune deficiencies against pathogenic vaccinia virus challenge. *Proc Nat Acad Sci USA.*101:4590.
- Earl PL, et al. (2003) Development and use of a vaccinia virus neutralization assay based on flow cytometric detection of green fluorescent protein. *J Virol.* 77:10684.

Intellectual Property: N/A.

Technology Transfer Specialist: To discuss access to this technology, please contact Benjamin Hurley at (*benjamin.hurley@nih.gov*).

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking inquiries from parties interested in independent R&D and/or collaborative research to further develop, evaluate, and commercialize a viable mpox vaccine for distribution using this material. Please contact Benjamin Hurley at 240–669–5092 or *benjamin.hurley@nih.gov.*

Dated: December 4, 2024.

Jeremiah D. Mitzelfelt,

Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2024–28924 Filed 12–9–24; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ430000.L12200000.PM0000; OMB Control No. 1004–0217]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Surveys and Focus Groups To Support Outcomes-Focused Management (Recreation Survey and Focus Groups)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) has submitted an information collection request (ICR) to the Office of Management and Budget (OMB) for review.

DATES: Interested persons are invited to submit comments on or before January 9, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Matt Blocker, Outdoor Recreation Planner, by email at *mblocker@blm.gov,* or by telephone at (385) 341–3403. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1)), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on July 5, 2024 (89 FR 55653). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Information will be collected from visitors of public lands and community members near public lands. Information gathered from visitors and local community residents will be used to inform planning decisions in support of BLM's Planning for Recreation and Visitor Services Handbook H–8320–1. This request is for OMB to renew these surveys and focus groups for three (3) years.

Title of Collection: Surveys and Focus Groups to Support Outcomes-Focused