

13. Saudi Arabian Patent 8651 (HHS Reference E-042-2014-0-SA-13), issued 15 September 2021;

14. Singapore Patent 11201609960Q (HHS Reference E-042-2014-0-SG-14), issued 28 September 2021;

15. United States Patent 10,287,350 (HHS Reference E-042-2014-0-US-15), issued 14 May 2019;

16. Hong Kong Patent HK 1234420 (HHS Reference E-042-2014-0-HK-16), issued 4 June 2021;

17. United States Patent 11,236,161 (HHS Reference E-042-2014-0-US-17), issued 1 February 2022;

18. New Zealand Patent 764530 (HHS Reference E-042-2014-0-NZ-18), issued 8 October 2024;

19. European Patent Application 20197459.9 (HHS Reference E-042-2014-0-EP-25), filed 22 September 2020;

20. Australian Patent 2020267211 (HHS Reference E-042-2014-0-AU-26), issued 15 August 2024;

21. Japanese Patent 7004470 (HHS Reference E-042-2014-0-JP-27), issued 6 January 2022;

22. Mexican Patent Application MX/a/2021/006239 (HHS Reference E-042-2014-0-MX-28), filed 27 May 2021;

23. Israeli Patent 283423 (HHS Reference E-042-2014-0-IL-29), issued 2 July 2022;

24. Hong Kong Patent Application 42021038427.7 (HHS Reference E-042-2014-0-HK-30), filed 8 September 2021;

25. United States Patent Application 17/557,845 (HHS Reference E-042-2014-0-US-31), filed 21 December 2021;

26. Japanese Patent 7485650 (HHS Reference E-042-2014-0-JP-32), issued 6 January 2022;

27. United States Patent Application 17/696,249 (HHS Reference E-042-2014-0-US-33), filed 16 March 2022;

28. Israeli Patent Application 291292 (HHS Reference E-042-2014-0-IL-34), filed 13 March 2022;

29. Indian Patent Application 202248047256 (HHS Reference E-042-2014-0-IN-35), filed 19 August 2022;

30. South Korean Patent Application 10-2024-7016401 (HHS Reference E-042-2014-0-KR-01), filed 17 May 2024;

31. Japanese Patent Application 2024-074954 (HHS Reference E-042-2014-0-JP-01), filed 2 May 2024; and

32. Australian Patent Application 2024205043 (HHS Reference E-042-2014-0-AU-01), filed 24 July 2024.

The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

“The commercial development, production, and sale of a T cell-directed, non-viral, synthetic nanoparticle-based system comprised of lipids, polymers and/or lipopolymers that encapsulates an mRNA that encodes a chimeric antigen receptor (CAR) that binds to CD19 via the CDR polypeptide sequences of the anti-CD19 antibody known as Hu19, for the treatment or prevention of B cell mediated autoimmune diseases.

The following are specifically excluded from the Licensed Field of Use:

(1) anti-CD19 targeting CAR-based immunotherapy using CRISPR/Cas9-edited allogeneic (where donor and recipient are different) T lymphocytes.

(2) the development of CAR-expressing cells generated ex vivo (both autologous and allogeneic cell therapies).

(3) viral-based nucleic acid systems or viral vectors to express the CAR.”

This technology discloses the development of chimeric antigen receptors that recognize the CD19 cell surface protein. CD19 is expressed primarily on B cells, including autoreactive B cells which drive the development of autoimmune disorders such as System Lupus Erythematosus, Immune-mediated myositis, and Antisynthetase Syndrome. For many autoimmune diseases there are no FDA-approved therapies, underscoring that there is an unmet need. The development of a new anti-CD19 CAR-based therapy can potentially meet the needs of patients that currently do not have any treatment options.

The scope of exclusivity for this license will be limited to the development of a specific class of molecules (CARs) which use a specific binding domain (Hu19), wherein the CARs are transfected via a specific methodology (non-viral transfection, *in vivo*) into specific types of cells (T cells). The scope is further limited for autoimmune diseases. Other fields of use will still be available if this license is granted, including use of Natural Killer cells instead of T cells to express the CAR product.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 30, 2025.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2025-12409 Filed 7-2-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM).

SACATM is a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations. SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM.

This meeting will be held as a virtual meeting and open to the public. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below. TTY users should contact the Federal TTY Relay Service at 800-877-8339. All requests should be made at

least five business days in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: Scientific Advisory Committee on Alternative Toxicological Methods (SACATM).

Date: September 11–12, 2025.

Registration is required to attend to view the webcast, and/or present oral comments. Written public comments will be accepted. Information about the meeting, registration, and how to submit public comments are available at <https://ntp.niehs.nih.gov/go/32822>.

Time: 10:00 a.m. to approximately 3:15 p.m. Eastern Time (each meeting day)

Agenda: The preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/32822>.

Address: NIEHS Research Triangle Park, NC 27709 (Virtual Meeting).

Meeting Format: Virtual Meeting.

Contact Person: Mary S. Wolfe, Ph.D., Director, Office of Policy, Review, and Outreach, Division of Translational Toxicology, National Institute of Environmental Health Science, National Institutes of Health PO Box 12233, MD A3–01 111 T.W. Alexander Dr, Research Park Triangle, NC 27709, wolfe@niehs.nih.gov.

Any member of the public interested in presenting oral comments may register at <https://ntp.niehs.nih.gov/go/32822>. Each public comment period allows for five oral commenters. Only one representative of an organization may be allowed to present oral comments per comment period and if accepted by the committee, presentations are limited to five minutes. Registration is on a first-come, first-served basis. If the maximum number of commenters per comment period is exceeded, individuals registering to submit an oral comment will be placed on a wait list and notified should an opening become available.

In addition, any interested person may file written comments with the committee. Information on submitting written comment is available at <https://ntp.niehs.nih.gov/go/32822>.

Responses to this notice are voluntary. No proprietary, classified, confidential, or sensitive information should be included in statements submitted in response to this notice or presented during the meeting. This request for input is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in

response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Additional information about SACATM, including link to the charter, roster, and records of past meetings, can be found at <https://ntp.niehs.nih.gov/go/advisory>.

Dated: July 1, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–12480 Filed 7–2–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Brian Bailey at 240–669–5128, or bbailey@mail.nih.gov. Licensing 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; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION:

Technology description follows:

Anti-Nucleoprotein Crimean-Congo Hemorrhagic Fever Virus Monoclonal Antibodies for Assay Creation

Description of Technology

Crimean-Congo hemorrhagic fever (CCHF) is the most widespread form of viral hemorrhagic fever, found in Eastern and Southern Europe, the Mediterranean, northwestern China, central Asia, Africa, the Middle East, and the Indian subcontinent. Typically beginning with non-specific fever,

myalgia, nausea, diarrhea, and general malaise, symptoms of infection with the tick-borne CCHF virus (CCHFV) can rapidly progress to hemorrhagic manifestations, with case fatality rates as high as 30–40% in some regions. Critically, there are no approved vaccines for CCHF, and prevention is limited to control of exposure to infected ticks and livestock.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Disease (NIAID) have recently demonstrated robust immunogenicity and significant protection in a Rhesus macaque model of CCHF following vaccination with a novel repRNA vaccine. Single memory B cells from peripheral blood mononuclear cells (PBMCs) were isolated from the vaccinated macaques to derive monoclonal antibodies that target the nucleocapsid protein (NP) of CCHFV, which plays a critical role in the replication and pathogenesis of the virus. This technology comprises mAbs with strong potential for the development of diagnostic tools, *in vitro* assays, research reagents, and other analytical methods for CCHFV NP recognition.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Development of diagnostic assays for rapid, accurate CCHFV detection in clinical and non-clinical settings.

Competitive Advantages:

- There are no readily available antibodies that bind to the NP protein of CCHFV.

Development Stage:

Relevant Publications: Hawman DW, et al. A replicating RNA vaccine confers protection in a rhesus macaque model of Crimean-Congo hemorrhagic fever. *NPJ Vaccines* 2024;9:86. <https://doi.org/10.1038/s41541-024-00887-z>.

Inventors: Daniel Douek, David Hawman, Leonid Serebryannyy, Noemia Santana Lima, Chaim Schramm, Sarah Smith (Kerscher), Amy Henry, Alicen Spaulding (all of NIAID)

Intellectual Property: HHS Reference No. E–129–2025.

Licensing Contact: To license this technology, please contact Brian Bailey at 240–669–5128, or bbailey@mail.nih.gov, and reference E–129–2025.

Dated: June 30, 2025.

Surekha Vathyam,

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

[FR Doc. 2025–12455 Filed 7–2–25; 8:45 am]

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