DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0475]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 12, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0475–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: ASPA COVID–19 Public Education Campaign Evaluation Surveys.

Type of Collection: Extension.

OMB No. 0990–0475.

Abstract: The Office of the Assistant Secretary for Public Affairs (ASPA), U.S. Department of Health and Human Services (HHS) is requesting an extension on a currently approved collection including two components: 1. COVID–19 Attitudes and Beliefs Survey (CABS), and 2. Monthly Outcome Survey (MOS). Throughout execution of the campaign, this information will primarily be used by ASPA to determine whether the campaign is having the intended impact on target audiences' (*e.g.,* parents, young adults, 65+) knowledge, attitudes, and beliefs as they relate to COVID–19, COVID–19 vaccination, and adherence to preventative behaviors. It will also keep key stakeholders informed of the Campaign's progress. Ultimately, the data will inform a thorough evaluation of the efficacy of the campaign and its impact on vaccine uptake.

COVID–19 Attitudes and Beliefs Survey (CABS)

The CABS is a longitudinal survey that will be fielded tri-annually to 4,000 U.S. adults for the duration of the Campaign via NORC at the University of Chicago's AmeriSpeak Panel. The survey will be fielded online, and each fielding period will last between 3 and 6 weeks. Those that respond to wave 1 of the survey will be recontacted in each wave, facilitating a comparison of COVID–19 behavior change over time for a representative sample and evaluation of U.S. adults. Panel members selected to participate in the study will receive one pre-invitation postcard in the mail, one email invitation, and three email reminders to complete the survey in each wave.

Monthly Outcome Survey (MOS)

The MOS is a shorter, cross-sectional survey that will be fielded monthly to 5,000 U.S. adults for the duration of the Campaign via the Ipsos KnowledgePanel 5K Omnibus Survey. The survey will be fielded online, and each fielding period will last between 7 and 10 days.

ANNUALIZED BURDEN HOUR TABLE

	CABS	MOS
Hours to complete survey	0.58	0.17
Participants (per wave)	4,000	5,000
Number of waves (per year)	3	12
Total respondents per year	12,000	60,000
Total burden hours per year	6,960	10,200

Sum of Both Studies

Total respondents per year: 72,000.

Total burden hours per year: 17,160.

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–19681 Filed 9–10–21; 8:45 am]

BILLING CODE 4150–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Allogeneic T Cell and Gene Therapy Vector Chimeric Antigen Receptor (CAR) Therapies Targeting CD22 Alone or in Combination With CARs Targeting CD19 for the Treatment of B-Cell Malignancies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Sana Biotechnology Inc. Life Sciences Inc., (''Sana''), located in Seattle, Washington.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before September 28, 2021 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer Manager, at Telephone: (240)–276–7856; or at Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–080–2012–0: Human Monoclonal Antibodies Specific for CD22

1. US Provisional Patent Application 61/042,329, filed April 4, 2008 (E–080–2008–0–US–01);
2. International Patent Application PCT/US2009/039,080, Filed April 1, 2009 (E–080–2008/0–PCT–02);
3. US Patent Application: 12/934,214, filed September 23, 2010 (E–080–2008–0–US–03);
4. US Patent Application 13/959,061, filed August 5, 2015 (E–080–2008–0–US–04);
5. US Patent Application 15/012,023, filed February 1, 2016 (E–080–2008–0–US–05);
6. US Patent Application 15/424,238, filed February 3, 2017 (E–080–2008–0–US–06).

E–291–2012–0: M971 Chimeric Antigen Receptors

1. US Provisional Patent Application 61/717,960, filed October 24, 2012 (E–291–2012–0–US–01);
2. International Patent Application PCT/US2013/060332, filed September 18, 2013 (E–291–2012–0–PCT–02);
3. Australia Patent Application No: 2019235926, filed September 2, 2020 (E–291–2012–0–AU–03);
4. Brazil Patent Application BR112015009003–6, filed April 22, 2015 (E–291–2012–0–BR–04);
5. Canada Application No: 2889055, filed September 18, 2013 (E–291–2012–0–CA–05);
6. China Application No: 201380061387.5, filed May 25, 2015 (E–291–2012–0–CN–06);
7. European Patent Application No: 13773468.7, filed September 18, 2013 (E–291–2012–0–EP–07);
8. India Patent Application No: 2344/CHENP/2015, filed September 18, 2013 (E–291–2012–0–IN–08);
9. Japan Application No: 539602/2015, filed April 24, 2015 (E–291–2012–0–JP–09);
10. Russia Patent Application: 2015117237, filed May 7, 2015 (E–291–2012–0–RU–10);
11. US Patent Application: 14/437,889, filed April 23, 2015 (E–291–2012–0–US–11);
12. Hong Kong Patent Application: 16101891.0, filed February 19, 2016 (E–291–2012–0–HK–12);
13. Russia Patent Application: 2018116582, filed May 4, 2018 (E–291–2012–0–RU–13);
14. Japan Patent Application: 2018–088908, filed May 2, 2018, (E–291–2012–0–JP–14);
15. Australia Patent Application: 2018204257, filed June 14, 2018 (E–291–2012–0–AU–16);
16. US Patent Application: 16/107,271, filed August 21, 2018 (E–291–2012–0–US–17);
17. Germany Patent Application: 13773468.7, filed April 22, 2015 (E–291–2012–0–DE–18);
18. Spain Patent Application: 13773468.7, filed April 22, 2015 (E–291–2012–0–ES–19);
19. France Patent Application: 13773468.7, filed April 22, 2015 (E–291–2012–0–FR–20);
20. Great Britain Patent Application: 13773468.7, filed April 22, 2015 (E–291–2012–0–GB–21);
21. Italy Patent Application: 13773468.7, filed April 22, 2015 (E–291–2012–0–IT–22);
22. China Patent Application: 201910500128.7, filed June 11, 2019 (E–291–2012–0–CN–23);
23. US Patent Application: 16/869,792, filed May 8, 2020 (E–291–2012–0–US–24).

E–106–2015–0: Chimeric Antigen Receptors Targeting Both CD19 and CD22

1. US Provisional Patent Application No.: 62/135,442, filed March 19, 2015 (E–106–2015–0–US–01);
2. International Patent Application PCTUS2016/023055, Filed March 18, 2016 (E–106–2015–0–PCT–02);
3. US Patent Application: 15/559,485. Filed September 19, 2017 (E–106–2015–0–US–03).

E–017–2017–0: CD19/CD22 Bicistronic CAR Targeting Human B-Cell Malignancies

1. US Provisional Patent Application No.: 62/135,442, filed May 15, 2017 (E–017–2017–0–US–01);
2. International Patent Application PCT/US2018/032,809, filed May 15, 2018 (E–017–2017–0–PCT–02);
3. Australia Patent Application No.: 2018269194, filed October 28, 2019 (E–017–2017–0–AU–03;
4. Canada Patent Application No: 3062433, filed May 15, 2018 (E–017–2017–0–CA–04);
5. China Patent Application No.: 201880032676.5, filed *Date:* May 15, 2018 (E–017–2017–0–CN–05);
6. European Patent Application No.: 18733012.1, filed May 15, 2018 (E–017–2017–0–EP–06);
7. Japan Patent Application No.: 2019–563082, filed November 13, 2019 (E–017–2017–0–JP–07);
8. Korea Patent Application No.: 2019–7017289, filed December 13, 2019, (E–017–2017–0–KR–08);
9. Singapore Patent Application No.: 11201910499V, filed November 11, 2019 (E–017–2017–0–SG–09);
10. United States Patent Application No.: 16/613,187, filed November 13, 2019 (E–017–2017–0–US–10).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

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

''Field 1: ''Ex vivo allogeneic CAR–T''

The development, manufacture and commercialization of chimeric antigen receptor T cells (CAR–T cells) for the treatment of B cell malignancies, wherein the CAR–T cells are engineered to express a CAR that comprises the m971 binder and is mono-specific for CD22, or is specific to both CD22 and CD19 (but are not engineered to bind to any other B cell antigen), and the engineered CAR–T cells are generated *ex vivo* using allogeneic T cells that are engineered to over-express CD47.

Field 2: ''In vivo gene therapy vector''

The development, manufacture and commercialization of gene therapy vectors encoding a chimeric antigen receptor construct (CAR construct), wherein the CAR construct comprises either (i) a CD22 binder m971 or (ii) the CD22 binder m971 and a CD19 binder, but, in each case (i) and (ii), comprises no other binder against a B cell antigen. For the avoidance of doubt, the field of use excludes development, manufacture and commercialization of genetically modified autologous T cells made by obtaining a patient's T cells via a standard leukapheresis procedure, genetically modifying the T cells *ex vivo,* expanding the T cells in cell culture, and formulating the T cells for later administration to the patient.''

This technology discloses CAR therapies that target CD22 alone or in combination with CD19 by utilizing the anti-CD22 binder known as m971. CD22 and CD19 are expressed on the surface of B cells in B cell malignancies and CAR–T utilizing binders targeting CD 19 and CD22 have shown early promise in clinical trials for B cell malignancies.

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.

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 from 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: September 7, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021–19618 Filed 9–10–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Division of Extramural Research and Training (DERT) Extramural Grantee Data Collection National Institute of Environmental Health Science (NIEHS)

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, to provide opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kristianna Pettibone, Evaluator, Program Analysis Branch, NIEHS, NIH, 530 Davis Dr., Room 3055, Morrisville, NC 20560, or call non-toll-free number (984) 287–3303 or Email your request, including your address to: *pettibonekg@niehs.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed 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) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Division of Extramural Research and Training (DERT) Extramural Grantee Data Collection, 0925–0757, Expiration Date 11/30/2021—REVISION, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: In order to make informed management decisions about its research programs and to demonstrate the outputs, outcomes and impacts of its research programs NIEHS will collect, analyze and report on data from extramural grantees who are currently receiving funding or who have received funding in the past on topics such as: (1) Key scientific outcomes achieved through the research and the impact on the field of environmental health science; (2) Contribution of research findings to program goals and objectives; (3) Satisfaction with the program support received; (4) Challenges and benefits of the funding mechanism used to support the science; and (5) Emerging research areas and gaps in the research.

Information gained from this primary data collection will be used in conjunction with data from grantee progress reports and presentations at grantee meetings to inform internal programs and new funding initiatives. Outcome information to be collected includes measures of agency-funded research resulting in dissemination of findings, investigator career development, grant-funded knowledge and products, commercial products and drugs, laws, regulations and standards, guidelines and recommendations, information on patents and new drug applications and community outreach and public awareness relevant to extramural research funding and emerging areas of research.

OMB approval is requested for 3 years. There are no costs to respondents, other than their time. The total estimated annualized burden hours are 700.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
NICHD Grantee	200	1	30/60	100
NIDCD Grantee	200	1	30/60	100
NIMH Grantee	200	1	30/60	100
NINDS Grantee	200	1	30/60	100
NCI Grantee	400	1	30/60	200
NIEHS Grantee	200	1	30/60	100
Total	1,400	1,400		700