

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

Jane M. Lambert,

Project Clearance Liaison, National Institute of Environmental Health Sciences, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

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 Athenex, Inc. ("Athenex") headquartered in Buffalo, NY.

DATES: Only written comments and/or 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 application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5530; Email: suna.gulay@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

GROUP A:

E-237-2017-0/2: T Cell Receptors Recognizing Mutated P53

1. US Provisional Patent Application 62/565,383, filed September 29, 2017 (E-237-2017-0-US-01);

2. International Patent Application PCT/US2018/051285, filed September 17, 2018 (E-237-2017-2-PCT-01);

3. Australian Patent Application 2018342246, filed September 17, 2018 (E-237-2017-2-AU-02);

4. Brazilian Patent Application BR112020006012-7, filed September 17, 2018 (E-237-2017-2-BR-03);

5. Canadian Patent Application 3977024, filed September 17, 2018 (E-237-2017-2-CA-04);

6. Chinese Patent Application 201880074539.8, filed September 17, 2018 (E-237-2017-2-CN-05);

7. Costa Rica Patent Application 2020-0170, filed September 17, 2018 (E-237-2017-2-CR-06);

8. Eurasian Patent Application 202090757, filed September 17, 2018 (E-237-2017-2-EA-07);

9. European Patent Application 18780006.5, filed September 17, 2018 (E-237-2017-2-EP-08);

10. Israeli Patent Application 273515, filed September 17, 2018 (E-237-2017-2-IL-09);

11. India Patent Application 202047013911, filed September 17, 2018 (E-237-2017-2-IN-10);

12. Japanese Patent Application 2020-517556, filed September 17, 2018 (E-237-2017-2-JP-11);

13. Korean Patent Application 2020-7012344, filed September 17, 2018 (E-237-2017-2-KR-12);

14. Mexico Patent Application MX/a/2020/003504, filed September 17, 2018 (E-237-2017-2-MX-13);

15. New Zealand Patent Application 763023, filed September 17, 2018 (E-237-2017-2-NZ-14);

16. Singapore Patent Application 11202002636P, filed September 17, 2018 (E-237-2017-2-SG-15);

17. United States Utility Patent Application 16/651,242, filed September 17, 2018 (E-237-2017-2-US-16); and

18. Hong Kong Patent Application 62020021272.3, filed November 30, 2020 (E-237-2017-2-HK-17).

E-135-2019: T Cell Receptors Recognizing R175H or Y220C Mutation in P53

1. US Provisional Patent Application 62/867,619, filed June 27, 2019 (E-135-2019-0-US-01);

2. International Patent Application PCT/US2020/039785, filed June 26, 2020 (E-135-2019-0-PCT-02); and

3. Taiwanese Patent Application 109121744, filed June 26, 2020 (E-135-2019-0-TW-03).

E-173-2020: T Cell Receptors Recognizing R273C or Y220C Mutation in P53

1. US Provisional Patent Application 63/074,747, filed September 4, 2020 (E-173-2020-0-US-01).

E-098-2018: T Cell Receptors Which Recognize Mutated EGFR

1. US Provisional Patent Application 62/665,234, filed May 1, 2018 (E-098-2018-0-US-01);

2. International Patent Application PCT/US2019/030108, filed May 1, 2019 (E-098-2018-0-PCT-02);

3. Australian Patent Application 2019263233, filed May 1, 2019 (E-098-2018-0-AU-03);

4. Canadian Patent Application 3,099,106, filed May 1, 2019 (E-098-2018-0-CA-04);

5. European Patent Application 19723615.1, filed May 1, 2019 (E-098-2018-0-EP-05); and

6. United States Utility Patent Application 17/051,860, filed May 1, 2019 (E-098-2018-0-US-06).

E-165-2020: HLA Class II-Restricted DRB T Cell Receptors Against RAS With G12D Mutation

1. US Provisional Application 63/050,9131, filed July 13, 2020 (E-165-2020-0-US-01); and

2. International Patent Application PCT/US2021/041375, filed July 13, 2021 (E-165-2020-0-PCT-02).

E-172-2020: HLA Class II-Restricted DRB T Cell Receptors Against RAS With G12V Mutation

1. US Provisional Application 63/052,502, filed July 16, 2020 (E-172-2020-0-US-01); and

2. International Patent Application PCT/US2021/041737, filed July 15, 2021 (E-172-2020-0-PCT-02).

E-189-2020: HLA Class II-Restricted DQ T Cell Receptors Against RAS With G13D Mutation

1. US Provisional Application 63/086,674, filed October 2, 2020 (E-189-2020-0-US-01).

E-190-2020: HLA Class I-Restricted T Cell Receptors Against RAS With G12V Mutation

1. US Provisional Application 63/060,340, filed August 3, 2020 (E-190-2020-0-US-01) and U.S., PCT and foreign patent applications claiming priority to the aforementioned application.

GROUP B:

E-237-2017-1: Methods of Isolating T Cells Having Antigenic Specificity for a P53 Cancer-Specific Mutation

1. US Provisional Patent Application 62/565,464, filed September 29, 2017 (E-237-2017-1-US-01);

2. International Patent Application PCT/US2018/051280, filed September 17, 2018 (E-237-2017-1-PCT-02);

3. Australian Patent Application 2018342245, filed September 17, 2018 (E-237-2017-1-AU-03);

4. Canadian Patent Application 3080274, filed September 17, 2018 (E-237-2017-1-CA-04);