TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NEPA EID Checklist	1,500	1	1,500	1	1,500
Total	1,500		1,500		1,500

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–04267 Filed 2–28–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Chimeric Antigen Receptor T-Cell Therapies (CAR–T) That are Specific to CD22 and Other B-Cell Antigens 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 Syncopation Life Sciences Inc., (''Syncopation''), located in Palo Alto, California.

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 March 16, 2022 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 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–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:

''Development, manufacture and commercialization of chimeric antigen receptor T cell (CAR–T) immunotherapies for the treatment of B cell malignancies, wherein the T cells are:

1. Manufactured *ex vivo;*

2. Not engineered to overexpress CD47;

3. Engineered to express a CAR that targets CD22 via the m971 scFv in combination with both:

a. Binders, CARs, or other receptors targeting: CD19, CD20, CD79b, or any combination thereof; and

b. At least one of the following:

—A technology to activate CD2 signaling in the CAR T cell, and/or

—Manufacturing of the cell product using the Storage by Actuated Shuttling (StASh)

Where ''ex vivo'' specifically means where the cells or tissue are removed from a healthy donor (in the case of allogeneic therapy) or the patient (in the case of autologous therapy), modified *ex vivo* and then, implanted, transplanted, infused, or transferred into the patient.

For purposes of clarity, specifically excluded from these Fields of Use are the following:

1. Allogeneically-derived CAR–T immunotherapies that have been engineered to overexpress CD47;

2. CAR–T immunotherapies wherein the CAR–T cells are manufactured within the patient via gene therapy vectors delivered to the patient (*in vivo* CAR–T immunotherapies);

3. Autologously-derived CAR–T immunotherapies that have been engineered to be specific for CD19, CD20, and CD22 (via the m971 scFv) absent the engineering of the CAR–T therapies to activate CD2 signaling and/or StASh as described in the Fields of Use 3(b) above;

4. CAR–T immunotherapies wherein the CAR–T cells are engineered to express a bispecific CAR that is engineered to bind to CD19 and CD22, as described in HHS Ref. E–106–2015 and encompassing the m971 scFv and the CD22 CAR.''

The government-owned technologies that are contemplated in this proposed license are CAR therapies that target CD22 by utilizing the anti-CD22 binder known as m971 alone. The E–080–2008 technology encompasses the m971 binder, while E–291–2012 describes a CAR encompassing the m971 binder. Additionally, E–017–2017 describes a bicistronic CAR vector that encompasses the CD22-targeting m971 CAR and a CAR that targets CD19. CD22 is expressed on the surface of B cells in B cell malignancies and CD22-targeting CAR–T has shown early promise in clinical trials for ALL and NHL both as a monospecific and multispecific therapy. Targeting CD22 in combination with other B cell antigens (CD19, CD20, and/or CD79b in this instance) can lead to more effective CAR–T cell therapies.

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: February 23, 2022.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2022–04245 Filed 2–28–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Research Projects in Cancer Systems Biology (CSBC Research Projects) (U01).

Date: March 31, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W234, Rockville, Maryland 20850, 240–276–6368, *Stoicaa2@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–1 NCI Clinical and Translational R21 and Omnibus R03 Review.

Date: March 31, 2022.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Delia Tang, M.D., Scientific Review Officer, Resources Training and Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850, 240–276–6456, *tangd@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Social and Behavioral Intervention Research to Address Modifiable Risk Factors for Cancer in Rural Populations (R01).

Date: May 5, 2022.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room