

**SUMMARY:** The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health is announcing the availability of three draft guidance documents titled, “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements,” respectively.

**DATES:** Submit written comments by August 24, 2018.

**ADDRESSES:** Submit written requests for single copies of the draft guidance documents titled “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements,” respectively, to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-453-6909. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS-OS-OPHS-2018-0012 (Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements), docket ID number HHS-OS-OPHS-2018-0013 (When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements), and docket ID number HHS-OS-OPHS-2018-0014 (Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements), respectively, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Enter the docket ID number and click on “Search.” On the next page, click the “Comment Now” action and follow the instructions.

- *Mail/Hand Delivery/Courier [For Paper, Disk, or CD-ROM Submissions]:* Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; email [Irene.Stith-Coleman@hhs.gov](mailto:Irene.Stith-Coleman@hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Overview*

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of three draft guidance documents entitled “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements.” The draft guidance documents, when finalized, will represent OHRP’s current thinking on these topics. OHRP obtained input from HHS agencies and the Common Rule departments and agencies in developing the draft guidance documents.

The “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements” draft guidance explains how certain scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected are deemed not to be research under the 2018 Requirements of the regulations for the protection of human subjects (45 CFR part 46), and consequently do not have to satisfy the requirements of those regulations. It is intended for IRB administrators, IRB chairpersons, relevant institutional officials, and investigators who may be concerned about whether scholarly or journalistic activities need to satisfy the 2018 Requirements of the regulations.

The “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements” draft guidance provides information on the HHS regulations for the protection of human research subjects at 45 CFR part 46 related to the circumstances in which continuing review of research is not required. In particular, this guidance applies to research that transitions to comply with the 2018 Requirements during the 6-month delay period from July 19, 2018 through January 20, 2019. This guidance only applies during the 6-month delay period. It is intended for

Institutional Review Boards (IRBs), investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS.

The “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements” draft guidance provides guidance on the elimination of the requirement in the pre-2018 Requirements (45 CFR 46.103(f)) that each application or proposal for research undergo IRB review and approval as part of the certification process. It is intended for Institutions, IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of nonexempt research involving human subjects conducted or supported by HHS.

**II. Electronic Access**

Persons with access may obtain the draft guidance documents on OHRP’s website at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>.

Dated: July 19, 2018.

**Jerry Menikoff,**

*Director, Office for Human Research Protections.*

[FR Doc. 2018-15908 Filed 7-24-18; 8:45 am]

**BILLING CODE 4150-36-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 jointly owned by an agency of the U.S. Government with Vanderbilt University, University of Alabama and University of Pennsylvania 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:** Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager,

National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301-827-7181, or email [sury.vepa@nih.gov](mailto:sury.vepa@nih.gov). A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:**  
Technology description follows.

**Thiazole Based Inhibitors of Lactate Dehydrogenase (LDH) for the Treatment of Cancer**

*Description of Technology:* Agents that target enzymes involved in cancer cell metabolism offer an attractive therapeutic route in view of the potential to preferentially target cancer tissue over normal tissue. While normal tissue typically uses glycolysis as a major cellular metabolic path only when the oxygen supply is low, cancer tissue relies heavily on aerobic glycolysis regardless of the oxygen supply level. In addition, metabolic switching to a more glycolytic phenotype is a required step with inflammatory cells and other pathologies which require activated glycolysis in their metabolism. Lactate dehydrogenase (LDH) is involved in the final step of glycolysis, in which pyruvate is converted to lactate and the conversion of NADH to NAD<sup>+</sup>. There are two different genes of LDH, LDHA and LDHB, but both proteins (subunits) have the same active site and catalyze the conversion of pyruvate to lactate or lactate to pyruvate. In cancer patients, serum total lactate dehydrogenase (levels are often increased, and the gene for LDH, is up-regulated. LDH inhibition is expected to reduce the ability of the cell to effectively metabolize glucose and reduce tumor cell proliferation and tumor growth and other pathologies which involve a glycolytic metabolic switch. Thus, compounds that inhibit LDH activity have potential for the development of anti-cancer therapeutics. Previously developed LDH inhibitors have significant drawbacks, including poor potency and/or poor bioavailability, limiting their utility as therapeutics. The present technology provides novel 1 H-PYRAZOL-1 -YL-THIAZOLE based LDH inhibitors with improved potency, selectivity, and/or bioavailability for the treatment of cancer.

This technology is available for licensing 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.

*Potential Commercial Applications:*

- Novel therapeutics for cancer AND indications which depend on a

metabolic switch to glycolysis (e.g., inflammation, autoimmune disease, etc.)

*Competitive Advantages:*

- Novel LDH inhibitors with improved potency, selectivity, and/or bioavailability for the treatment of cancer.

*Development Stage:*

- Optimized lactate dehydrogenase inhibitors are in pre-clinical development.

*Inventors:*

- David J. Maloney, Alex Gregory Waterson, Ganesha Rai Bantukallu, Kyle Ryan Brimacombe, Plamen Christov, Chi V. Dang, Victor M. Darley-USmar, Matthew Hall, Xin Hu, Ajit Jadhav, Somnath Jana, Kwangho Kim, William J. Moore, Brian T. Mott, Leonard M. Neckers, Anton Simeonov, Gary Allen Sulikowski, Daniel Jason URBAN, and Shyh Ming Yang.

*Publications:* This manuscript reports early compounds in the series: <https://pubs.acs.org/doi/10.1021/acs.jmedchem.7b00941>.

*Intellectual Property:* 1. SMALL MOLECULE INHIBITORS OF LACTATE DEHYDROGENASE AND METHODS OF USE THERE OF, PCT/US2015/067895 filed on December 29, 2015 and published as WO 2016/109559 on July 7, 2016 (HHS Ref. No. E-244-2014), and 2. 1 H-PYRAZOL-1 -YL-THIAZOLES AS INHIBITORS OF LACTATE DEHYDROGENASE AND METHODS OF USE THERE OF, PCP/US2017/040021 filed on June 29, 2017 and published as WO 2018/005807 on January 8, 2018 9HHS Ref. No. E-190-2016).

*Related Intellectual Property:* HHS Reference Number E-293-2011.

*Licensing Contact:* Sury Vepa, Ph.D., J.D., 301-827-7181; [sury.vepa@nih.gov](mailto:sury.vepa@nih.gov).

Dated: July 5, 2018.

**Lili Portilla,**

*Technology Development Coordinator,  
National Center for Advancing Translational Sciences.*

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**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under

OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930-0205)—Revision**

The Center for Mental Health Services awards grants each fiscal year to each of the states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101-645, 42 U.S.C. 290cc-21 *et seq.*, the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 *et seq.* of the Public Health Service (PHS) Act) and the 21st Century Cures Act (Pub. L. 114-255). Section 522 of the PHS Act and the 21st Century Cures Act require that the grantee states and territories must expend their payments under the Act solely for making grants to political subdivisions of the state, and to nonprofit private entities (including community-based veterans' organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act and the 21st Century Cures Act specify that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH Annual Report are as follows:

*1. Reporting on Contacts*

To ensure that all contacts made by PATH providers are reflected in the report, a new question has been added that reports out on all contacts provided during the reporting period. The previous PATH Annual Report only reported on contacts through the date of enrollment.