

FDA to develop patient-focused drug development guidance to address a number of areas, including how a person seeking to develop and submit a proposed draft guidance relating to patient experience data for consideration by FDA may submit such proposed draft guidances.

In FDA's "Plan for Issuance of Patient-Focused Drug Development Guidance," (the Plan) available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM563618.pdf>, the Agency proposed issuing a guidance addressing this topic described in section 3002 during the second quarter of 2018. FDA recognizes that, like the other patient-focused drug development guidances described in the Plan, developing this draft guidance will also benefit from public input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders prior to FDA's drafting of the guidance. Accordingly, the Agency is scheduling this public workshop. After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public docket, and publish a draft guidance by the end of fiscal year 2018.

II. Purpose and Scope of Meeting

FDA is announcing a public workshop to convene a discussion on topics related to developing and submitting proposed draft guidance relating to patient experience data by an external stakeholder. The purpose of this public workshop is to obtain input from stakeholders on considerations for development and submission of proposed draft guidance relating to patient experience data submitted by an external stakeholder, including: (1) Defining the scope of the proposed draft guidance, (2) developing the proposed draft guidance, and (3) submitting the proposed draft guidance to FDA, including the process and format. The Agency is seeking information and comments from a broad range of stakeholders, including patients, patient advocates, academic and medical researchers, expert practitioners, drug developers, and other interested persons. FDA will publish a background document outlining the topic areas that will be addressed in the draft guidance approximately 2 weeks before the workshop date at the following website: <https://www.fda.gov/Drugs/NewsEvents/ucm582081.htm>.

After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public

docket, and publish a draft guidance by the end of fiscal year 2018.

III. Participating in the Public Workshop

Registration: Interested parties are encouraged to register early. To register electronically, please visit <https://pfdd-proposeddraftguidance.eventbrite.com>. Persons without access to the internet can call 240-402-6525 to register. If you are unable to attend the public workshop in person, you can register to view a live webcast. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public workshop will be based on space availability. If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the public workshop.

Open Public Comment: There will be time allotted during the public workshop for open public comment. Sign-up for this session will be on a first-come, first-serve basis on the day of the public workshop. Individuals and organizations with common interests are urged to consolidate or coordinate, and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Transcripts: As soon as a transcript is available of the public workshop, FDA will post it at <https://www.fda.gov/Drugs/NewsEvents/ucm582081.htm>.

Dated: December 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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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: Dr.

Natalie Greco, 301-761-7898;

Natalie.Greco@nih.gov. Licensing

information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at 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 patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Monoclonal Antibody Specific for DNA/RNA Hybrid Molecules

Description of Technology

NIAID has a hybridoma available for non-exclusive licensing that produces a monoclonal antibody specific for DNA/RNA hybrids. This antibody, which has been extensively characterized by NIH researchers, is already a widely-used research tool. It is currently the only monoclonal antibody available that is specific for DNA/RNA hybrids, making it a unique reagent. It is used in immuno-fluorescence (IF) microscopy, where it can be used to detect sites of transcriptional activity and potentially sites of viral replication. It has also been used in DNA/RNA immunoprecipitation (DRIP) experiments by a variety of researchers.

Aside from its use as a research tool, this antibody has potential to be used in diagnostic kits for viral/bacterial infections, cancers, and a variety of other human diseases. DNA/RNA hybrids arise during normal cellular function, but they are typically present in cells at low levels. When DNA/RNA hybrids are found at high levels in a cell, it indicates that the cell is "abnormal". For example, the cell may be cancerous or infected with a virus. NIH researchers have also incorporated the antibody into a micro-array platform, expanding its potential for use in diagnostic devices.

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

- Research tool:
- Detection and visualization of DNA/RNA hybrids, “R-loops”, or sites of viral replication in cells
 - DNA/RNA immunoprecipitation (DRIP) studies
 - Antibody based micro-arrays
- For use in diagnostic kits that detect:
- Viral/bacterial infections
 - miRNA biomarkers of disease (*i.e.* certain cancers)

Competitive Advantages

- Only available monoclonal antibody specific for DNA/RNA hybrids
- Binding properties extensively characterized by NIH researchers
- Widely-accepted as a key research reagent
- Antibody based micro-arrays are inexpensive, efficient, and increase detection of small or structured transcripts, as well as transcripts present at low levels

Development Stage

- *in vitro* data available

Inventors

S. Leppla, C. Leysath, D. Phillips, D. Garboczi, L. Lantz (all of NIAID).

Publications

- Phillips DD, et al. (2013)—PMID: 23784994—PMCID: PMC4061737—The sub-nanomolar binding of DNA–RNA hybrids by the single-chain Fv fragment of antibody S9.6
- Hu Z, et al. (2006)—PMID: 16614443—PMCID: PMC1435976—An antibody-based microarray assay for small RNA detection

Intellectual Property: HHS Reference No. E–738–2013

Licensing Contact: Dr. Natalie Greco, 301–761–7898; Natalie.Greco@nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize antibodies produced by the S9.6 hybridoma. For collaboration opportunities, please contact Dr. Natalie Greco, 301–761–7898; Natalie.Greco@nih.gov.

Dated: December 1, 2017.

Suzanne Frisbie,

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

[FR Doc. 2017–26937 Filed 12–13–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Special Volunteer and Guest Researcher Assignment (Office of Intramural Research, Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Arlyn Garcia-Perez, Assistant Director, Office of Intramural Research, Office of the Director, National Institutes of Health, 1 Center Drive MSC 0140, Building 1, Room 160, MSC–0140, Bethesda, Maryland 20892 or call non-toll-free number (301) 496–1921 or (301) 496–

1381 or Email your request, including your address to: GarciaA@od.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on September 15, 2017, page 43394 (82 FR 43394) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of Intramural Research (OIR), Office of the Director, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Special Volunteer and Guest Researcher Assignment—0925–0177, exp., date 08/31/2017—Reinstatement without Change of, Office of Intramural Research (OIR), Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Form Number: NIH–590 is a single form completed by an NIH official for each Guest Researcher or Special Volunteer prior to his/her arrival at NIH. The information on the form is necessary for the approving official to reach a decision on whether to allow a Guest Researcher to use NIH facilities, or whether to accept volunteer services offered by a Special Volunteer. If the original assignment is extended, another form notating the extension is completed to update the file. In addition, each Special Volunteer and Guest Researcher reads and signs an NIH Agreement.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 527.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual hour burden hours
Special Volunteer and Guest Researcher Assignment.	Special Volunteers and Guest researchers.	2,870	1	6/60	287
NIH Special Volunteer Agreement	Special Volunteers	2,600	1	5/60	217