

C. Issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or compliance review for failure to comply with requirements of that section.

2. The authority under section 543 of the Public Health Service Act, as amended by section 3221 of the CARES Act, to administer the regulation, "Confidentiality of Substance Use Disorder Patient Records," at 42 CFR part 2, and to make decisions regarding the interpretation, implementation, and enforcement of these requirements.

General Provisions

This delegation supersedes any prior delegations.

This authority may be redelegated by the Director of OCR.

I hereby affirm and ratify any actions taken by the Director of OCR or their subordinates which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

Effective Date

This delegation is effective upon the date of signature.

Authority

42 U.S.C. 290dd-2; 42 U.S.C. 1320d-5; 42 CFR part 2.

Dated: August 25, 2025.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

[FR Doc. 2025-16391 Filed 8-26-25; 8:45 am]

BILLING CODE 4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: RFXP1 AGONISTS

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences (NCATS), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing opportunities for the inventions listed below, which are owned by an agency of the U.S. Government, Florida International University (FIU), and University of South Florida (USF). The NCATS has taken the lead in both

patenting and licensing via consolidation of rights under an Inter Institutional Agreement (IIA). The inventions are available for licensing and collaboration to achieve expeditious commercialization results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT:

Inquiries related to these licensing or collaboration opportunities should be directed to: Jasmine Kalsi, M.S., Licensing and Patenting Manager, Office of Strategic Alliances (OSA), NCATS, Email: jasmine.kalsi@nih.gov or Phone: 301-435-0129. Respondents will be required to submit an "Application for License to Public Health Service Inventions." An executed CDA will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: NIH seeks to ensure that technologies developed by NIH and its partners are expeditiously commercialized and brought to practical use. NCATS is actively seeking a licensing partner to facilitate the development and commercialization of a technology or small molecule compounds that are in an early phase of development for therapeutic interventions for cancers, fibrotic and vascular disease including but not limited to breast cancer, solid tumors, atherosclerosis, and liver fibrosis.

NCATS in collaboration with Florida International University (FIU) and University of South Florida (USF) has identified low molecular weight, highly potent, and efficient full RXFP1 agonists with low cytotoxicity. The identification and characterization of these compounds may lead to the development of a new class of cost-effective drugs for the treatment of numerous cancers, fibrotic, and vascular disorders.

It is well documented in literature that activation of RXFP1 by relaxin induces: (1) up-regulation of the endothelin system which leads to vasodilation; (2) extracellular matrix remodeling through regulation of collagen deposition, cell invasiveness, proliferation, and overall tissue homeostasis; (3) a moderation of inflammation by reducing levels of inflammatory cytokines, such as TNF- α and TGF- β ; and (4) angiogenesis by activating transcription of VEGF.

The present invention is directed to novel relaxin receptor (RFXP1 receptor) small molecule agonists useful for treating relaxin-related disorders including fibrosis, certain cancers, vascular calcifications, including atherosclerosis, and heart failure. The RFXP1 agonists of this invention

possess a number of advantages not found in earlier RFXP1 agonists. These properties include, for example, improved bioavailability, low toxicity, and better activity in RXFP1-dependent biological functional assays.

The development of small-molecule agonists of RXFP1 would have numerous benefits and will allow investigating additional therapeutic applications where chronic administration is required. NCATS has identified a series of small-molecule agonists of RXFP1 which are potent, highly selective, easy to synthesize, and with reasonable metabolic and physical properties. Our molecules display similar efficacy as the natural hormone in several functional assays. Mutagenesis studies have mapped the specific regions responsible for relaxin receptor activation by these compounds to an allosteric site on the receptor. Finally, these compounds display good in vivo pharmacokinetic properties and are currently being evaluated in vivo.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E-145-2024-0.

Product Type: Therapeutics.

Therapeutic Area(s): Reproductive Health, Pulmonology, Oncology, Geriatrics, Dermatology, Cardiology.

Potential Commercial Applications:

- Vascular health
 - Fibrotic diseases
 - Cancers
 - Human reproductive health
- Competitive Advantages:*
- Potent and highly selective
 - Bioavailable with excellent exposure

- Easy to synthesize and scale-up

Publication:

"Anti-apoptotic and Matrix Remodeling Actions of a Small Molecule Agonist of the Human Relaxin Receptor, ML290 in Mice With Unilateral Ureteral Obstruction." Ng HH, Soula M, Rivas B, Wilson KJ, Marugan JJ, Agoulnik AI. *Front Physiol.* 2021 Jul 7.

Therapeutic effects of a small molecule agonist of the relaxin receptor ML290 in liver fibrosis. Kaftanovskaya EM, Ng HH, Soula M, Rivas B, Myhr C, Ho BA, Cervantes BA, Shupe TD, Devarasetty M, Hu X, Xu X, Patnaik S, Wilson KJ, Barnaeva E, Ferrer M, Southall NT, Marugan JJ, Bishop CE, Agoulnik IU, Agoulnik AI. *FASEB J.* 2019 Nov.

Optimization of the first small-molecule relaxin/insulin-like family peptide receptor (RFXP1) agonists: Activation results in an antifibrotic gene expression profile. Wilson KJ, Xiao J, Chen CZ, Huang Z, Agoulnik IU, Ferrer

M, Southall N, Hu X, Zheng W, Xu X, Wang A, Myhr C, Barnaeva E, George ER, Agoulnik AI, Marugan JJ. *Eur J Med Chem.* 2018 Aug 5.

ML290 is a biased allosteric agonist at the relaxin receptor RXFP1. Kocan M, Sarwar M, Ang SY, Xiao J, Marugan JJ, Hossain MA, Wang C, Hutchinson DS, Samuel CS, Agoulnik AI, Bathgate RAD, Summers RJ. *Sci Rep.* 2017 Jun 7.

Structural Insights into the Activation of Human Relaxin Family Peptide Receptor 1 by Small-Molecule Agonists. Hu X, Myhr C, Huang Z, Xiao J, Barnaeva E, Ho BA, Agoulnik IU, Ferrer M, Marugan JJ, Southall N, Agoulnik AI. *Biochemistry.* 2016 Mar 29.

Activation of Relaxin Family Receptor 1 from Different Mammalian Species by Relaxin Peptide and Small-Molecule Agonist ML290. Huang Z, Myhr C, Bathgate RA, Ho BA, Bueno A, Hu X, Xiao J, Southall N, Barnaeva E, Agoulnik IU, Marugan JJ, Ferrer M, Agoulnik AI. *Front Endocrinol (Lausanne).* 2015 Aug 17.

Identification and optimization of small-molecule agonists of the human relaxin hormone receptor RXFP1. Xiao J, Huang Z, Chen CZ, Agoulnik IU, Southall N, Hu X, Jones RE, Ferrer M, Zheng W, Agoulnik AI, Marugan JJ. *Nat Commun.* 2013.

Discovery, optimization, and biological activity of the first potent and selective small-molecule agonist series of human relaxin receptor 1 (RXFP1). Xiao J, Chen CZ, Huang Z, Agoulnik IU, Ferrer M, Southall N, Hu X, Zheng W, Agoulnik AI, Marugan JJ. 2012 Mar 10 [updated 2013 May 8].

Identification of small-molecule agonists of human relaxin family receptor 1 (RXFP1) by using a homogenous cell-based cAMP assay. Chen CZ, Southall N, Xiao J, Marugan JJ, Ferrer M, Hu X, Jones RE, Feng S, Agoulnik IU, Zheng W, Agoulnik AI. *J Biomol Screen.* 2013 Jul.

Patent Status: RFXP1 AGONISTS," U.S. Provisional Application No. 63/780,976 and NIH Reference No.: E-145-2024-0-US-02 filed 31 March 2025.

Development Stage: Preclinical (in vitro).

Date: August 20, 2025.

Joni L. Rutter,

Director, Office of the Director, National Center for Advancing Translational Sciences.

[FR Doc. 2025-16416 Filed 8-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: October 14–15, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 435-1042, cana2@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: October 16–17, 2025.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zachary Stephen Bailey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-4691, zach.bailey@nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Interventions to Prevent and Treat Addictions Study Section.

Date: October 16–17, 2025.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Izabella Zandberg, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-0359, izabella.zandberg@nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Cell Structure and Function 1 Study Section.

Date: October 16–17, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-3717, jessica.smith6@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 22, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-16371 Filed 8-26-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Translational Imaging Science Study Section.

Date: October 23–24, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.