

the related densitometry measurements based on the falsified Western blots, and falsified and/or fabricated data for experiments that were not performed or from unrelated experiments.

Specifically, Respondent falsified and/or fabricated data in the following:

- R01 HL107949–01 for:
- Figure 1B for Western blots of α -smooth muscle actin (α -SMA), Vimentin, Collagen I and Glyceraldehyde 3-Phosphate Dehydrogenase (GAPDH) expression in human cardiac fibroblasts isolated from failing left ventricles (HF) and non-failing heart controls (CF)
- Figure 2A for Western blots of G protein-coupled receptor kinase-2 (GRK2) and GAPDH expression in HF and CF, and the related densitometric analysis
- JBC 2011 for:
- Figure 1A for a Western blot of Vimentin expression in HF and CF, and the related densitometric analysis
- Figures 1D and 2D for Western blots of GAPDH expression in HF and CF, and the related densitometric analyses
- JBC 2010 for:
- Figure 7A for Western blots of phosphorylated Rhodopsin (Rho) and GRK2 expression in non-transgenic (NTG) (lanes 1–4) and Protein Kinase C α cardiac-specific activation (PKC α AC) transgenic (lanes 5–6) mice, and Figure 7B for the related densitometric analysis
- GC2006, Figure 7, HP2010, Figure 5, and CR2009, Slide 15 for:
- Western blots of phosphorylated Rho and GRK2 expression in NTG and PKC α AC transgenic mice, and the related densitometric analysis
- HP2010 for:
- Figure 5 for a Western blot of GRK2 expression in NTG and PKC α AC transgenic mice, and the related densitometric analysis

Dr. D'Souza has entered into a Voluntary Settlement Agreement with ORI, in which she voluntarily agreed to the administrative actions set forth below:

(1) Respondent agreed that for two (2) years beginning on May 6, 2016, any institution employing her shall submit in conjunction with each application for U.S. Public Health Service (PHS) funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a supervision plan to ORI. Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported

research, any institution employing her shall ensure that a plan for supervision of her duties is submitted to ORI for approval. The supervision plan must be designed to ensure the scientific integrity of Respondent's PHS-supported research contribution and include the specific elements as outlined below. Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI. Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of senior faculty members and officials at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for two (2) years beginning on May 6, 2016. The committee will review PHS-supported primary data from Respondent and submit a report to ORI at six (6) month intervals, setting forth the committee meeting dates, Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's PHS-supported research.

ii. The committee will conduct an advance review of any PHS grant application (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification that the data presented in the proposed application/publication is supported by the research record.

(3) Respondent agreed that for two (2) years beginning on May 6, 2016, any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI at that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract.

(4) Respondent agreed to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of two (2) years, beginning on May 6, 2016.

(5) As a condition of the Agreement, Respondent agreed to the retraction of the JBC 2010 publication.

FOR FURTHER INFORMATION CONTACT:

Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Kathryn M. Partin,

Director, Office of Research Integrity.

[FR Doc. 2016–13072 Filed 6–2–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service

AGENCY: Indian Health Service (IHS), Department of Health and Human Services.

ACTION: Notice of Tribal consultation and urban confer sessions on the state of the Great Plains Area IHS.

SUMMARY: Notice is hereby given that the Indian Health Service will conduct a 90 day tribal consultation and urban confer regarding the State of the Great Plains Area IHS. The IHS will conduct two telephone tribal consultation and urban confer sessions on June 22, 2016 and August 10, 2016. The IHS will also conduct two on-site tribal consultation and urban confer sessions on July 13, 2016 in Aberdeen, South Dakota and on August 30, 2016 in Rapid City, South Dakota.

DATES: The IHS will conduct two telephone Tribal consultation and urban confer sessions on June 22, 2016 and August 10, 2016. The IHS will also conduct two on-site Tribal consultation and urban confer sessions on July 13, 2016 in Aberdeen, South Dakota, and on August 30, 2016 in Rapid City, SD.

The on-site meetings in Aberdeen and Rapid City, South Dakota will be conducted at the addresses noted below. Written comments must be received on or before September 1, 2016 at the address below.

Conference Call Information: 1–800–369–1747; Pass Code: 1381519.

ADDRESSES: The meetings will be held at The Dakota Event Center located at 720 Lamont Street, Aberdeen, South Dakota; and at the Rushmore Plaza Holiday Inn Convention Center located at 505 N. Fifth Street, Rapid City, SD 57701, during the 13th Annual Direct Service Tribes National Meeting.

Written Comments: For Tribes: consultation@ihs.gov.

For Urbans: urbanconfer@ihs.gov.

FOR FURTHER INFORMATION CONTACT:

CAPT Chris Buchanan, Acting Director, Great Plains Area, Indian Health Service, 115 4th Ave. SE Suite 309 Aberdeen, South Dakota, (605) 226-7584, Fax (605) 226-7541.

SUPPLEMENTARY INFORMATION: These meetings are in follow-up to the April 5-7, 2016 IHS Tribal Leaders Briefing in Sioux Falls, South Dakota. The IHS would like to invite the Great Plains Area Tribal Leaders to participate in formal consultation and interested urban Indian organizations to confer with IHS leadership to discuss the state of the Great Plains Area IHS.

The purpose of these sessions are to receive feedback on the organization of the IHS Great Plains Area Office in an effort to continue to become more patient-focused in order to better meet the needs of the American Indians in the Great Plains Area. Specific topics will include geographic location of the Great Plains Area Office, centralization or further decentralization of area office services, staffing, budget, local involvement, transparency and oversight, partnerships, accountability, and monitoring.

Tribal leaders and designated representatives as well as urban Indian organizations that are interested in submitting written testimony for the on-site or telephonic consultation and urban confer sessions can provide written comments to the following: For Tribes—consultation@ihs.gov. For Urbans—urbanconfer@ihs.gov.

The Tribal consultation and urban confer sessions will be conducted with elected or appointed leaders of Tribal governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)], and recognized representatives from urban Indian organizations, as defined by 25 U.S.C. 1603(29). Representatives from other Tribal organizations and Native non-profit organizations are welcome to attend as observers. Those wishing to participate in the discussions must have a copy of a letter signed by an elected or appointed official or their designee, which authorizes them to serve as a representative of the Tribe. This should be submitted no later than three days in advance of the Tribal consultation and urban confer session to CAPT Chris Buchanan at (605) 226-7541 (fax).

A detailed report of all written comments and comments received through the Tribal consultation and urban confer sessions will be prepared and made available within 90 days of

the close of the comment period to all Tribal governments and interested urban Indian organizations within the Great Plains Area.

Dated: May 27, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016-13135 Filed 6-2-16; 8:45 am]

BILLING CODE 4165-16-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 owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

FOR FURTHER INFORMATION CONTACT:

Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below, may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention: Chimeric Antigen Receptors to CD276 for treating Cancer.

Description of Technology: Chimeric antigen receptors (CARs) are hybrid proteins consisting of an antibody binding fragment fused to protein signaling domains that cause T-cells which express the CAR to become cytotoxic. Once activated, these cytotoxic T-cells can selectively

eliminate the cells which they recognize via the antibody binding fragment of the CAR. By engineering a T-cell to express a CAR that is specific for a certain cell surface protein, it is possible to selectively target those cells for destruction. This is a promising new therapeutic approach known as adoptive cell therapy.

CD276 (a.k.a., B7-H3) is a tumor-associated antigen that is expressed on the cell surface of several cancers, including neuroblastomas, prostate cancer, ovarian cancer and some lung cancers. This technology concerns the development of CARs comprising an antigen-binding fragment derived from the MGA271 antibody. The resulting CARs can be used in adoptive cell therapy treatment for neuroblastoma and other tumors which express CD276.

Potential Commercial Applications:

- Treatment of cancers associated with expression of CD276.
- Specific cancers include neuroblastoma, prostate cancer, ovarian cancer, lung cancer and other solid tumors.

Value Proposition:

- MGA271 is a well characterized anti-CD276 antibody, making it a known quantity regarding safety issues.
- High affinity of the MGA271 antibody for CD276 increases the likelihood of successful targeting.
- Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients.

Development Stage: Discovery (Lead ID).

Inventor(s): Crystal Mackall.

Intellectual Property: HHS No. E-243-2015/0-US-01 U.S. Provisional Application 62/216,447 (E-243-2015/0-US-01) filed 9/10/2015 titled "Anti-CD276 Chimeric Antigen Receptors".

Publications: None applicable.

Collaboration Opportunity:

Researchers at the NCI seek licensing for chimeric antigen receptors to CD276 for treating cancer.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: May 31, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-13112 Filed 6-2-16; 8:45 am]

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