

BOARD OF SUPERVISORS AGENDA ITEM REPORT CONTRACTS / AWARDS / GRANTS

Requested	Board	Meeting	Date:	June 7	', 2022
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* = Mandatory, information must be provided

or Procurement	: Director Award $lacksquare$	_
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*Contractor/Vendor Name/Grantor (DBA):

Exact Sciences Corporation

*Project Title/Description:

Unrestricted Grant Agreement for colorectal cancer (CRC) prevention, screening and care coordination.

*Purpose:

This grant will provide funding to the Pima County Health Department (PCHD) to expand health promotion, screening and service coordination activities to improve CRC health outcomes in the County.

*Procurement Method:

This grant agreement is a non-Procurement agreement and not subject to Procurement rules.

*Program Goals/Predicted Outcomes:

Goal: Increase colorectal cancer awareness, prevention, screening referral and follow up in at least three higher risk communities and census tracts/zip codes with low screening rates in Pima County.

Objective 1: Increase community awareness in Pima County via community outreach, engagement and education by developing and implementing health promotion activities and health communication strategies.

Objective 2: Implement CRC initial patient screening questions, provide information and referral services at PCHD clinics for target population at 70%.

Objective 3: Improve access to services and care for people in higher risk groups and low screening uptake areas to reduce disparities to CRC screening and follow-up services through enhanced service coordination between PCHD and other cancer care provider networks and coalitions.

Objective 4: Evaluate effectiveness of strategies and disseminate findings.

*Public Benefit:

PCHD clinical staff will assess patients eligible for CRC screening and provide information and referrals as appropriate. This grant will enable PCHD to adopt evidenced based practices around CRC assessment and referrals and provide follow-up services as needed. In addition, PCHD will build on their existing capacity and infrastructure to focus on prevention education, awareness of the need for screening and services for high risk, under-served and under-represented populations.

*Metrics Available to Measure Performance:

The metrics for this grant are primarily activity based. Please refer to Exhibit A for detail.

*Retroactive:

Yes. The grant activities began April 1, 2022. However, the grant agreement was not received by PCHD until May 3, 2022. If not approved, PCHD will not be able to take advantage of these funds to strengthen CRC outreach and response.

BMI 468/30/32

Page 1 of 2

Contract / Award Information	
Document Type: Department Code:	
Commencement Date: Termination Date:	
Expense Amount: \$*	Revenue Amount: \$
*Funding Source(s) required:	
Funding from General Fund? CYes CNo If Ye	s \$ %
Contract is fully or partially funded with Federal Funds? If Yes, is the Contract to a vendor or subrecipient?	☐ Yes ☐ No
Were insurance or indemnity clauses modified?	☐ Yes ☐ No
If Yes, attach Risk's approval.	
Vendor is using a Social Security Number?	☐ Yes ☐ No
If Yes, attach the required form per Administrative Proced	ure 22-10.
Amendment / Revised Award Information	
	Contract Number (i.e.,15-123):
	AMS Version No.:
Commencement Date:	
	Prior Contract No. (Synergen/CMS):
© Expense or © Revenue © Increase © Decreas	
Is there revenue included? CYes CNo	If Yes \$
*Funding Source(s) required:	
Funding from General Fund? CYes C No	If Yes \$ %
Grant/Amendment Information (for grants acceptance	and awards)
Document Type: GTAW Department Code: H	D Grant Number (i.e.,15-123): 22-115
Commencement Date: 4/1/2022 Termination Da	 ate: 06/30/2023
Match Amount: \$	
*All Funding Source(s) required: Exact Sciences Corpora	
	If Yes \$ %
*Match funding from other sources? CYes • No *Funding Source:	If Yes \$ %
*If Federal funds are received, is funding coming dire Federal government or passed through other organiz	ectly from the zation(s)? N/A - not federal funding
Contact: Sharon Grant	
Department: Health	7 Telephone: 724-7842
Department Director Signature/Date:	5/19/22
Deputy County Administrator Signature/Date:	23 May 2022
County Administrator Signature/Date: (Required for Board Agenda/Addendum Items)) him 5/24/2012

UNRESTRICTED GRANT AGREEMENT

THIS UNRESTRICTED GRANT AGREEMENT (the "Agreement"), made and entered into as of April 1, 2022 ("Effective Date"), is by and between Exact Sciences Corporation ("Exact") and Pima County Health Department ("Recipient").

WHEREAS, Exact, a molecular diagnostics company focused on earlier cancer detection to treatment guidance and monitoring, provides support for medical research and educational programs that are objective, unbiased, balanced, and scientifically rigorous; and

WHEREAS, Recipient hereby requests support from Exact for Colorectal Cancer (CRC) Prevention, Screening, and Care Coordination (the "Program") by means of an unrestricted grant in the amount of \$124,850 (the "Grant").

NOW THEREFORE, in consideration of the mutual covenants, agreements and representations set forth in this Agreement and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

- 1. <u>Term and Termination</u>. This Agreement shall be effective as of the Effective Date and shall continue in effect until June 30, 2023, unless otherwise terminated in accordance with the terms of the Agreement. Either party may terminate this Agreement upon thirty (30) days of written notice to the other party. The respective rights and obligations of the parties hereunder shall indefinitely survive the termination of this Agreement; provided, however, Exact's payment obligations will not survive termination.
- 2. <u>Financial Support</u>: Exact agrees to provide Grant to Recipient to support Program, as further described in the proposal attached as <u>Exhibit A</u> and incorporated herein by this reference.
- 3. <u>Statement of Purpose</u>: Recipient represents and warrants that the purpose of the Program is for scientific, educational or charitable purposes only and will not promote Exact or any other commercial entity's products, directly or indirectly. Any discussion of Exact products will be objective, balanced, and scientifically rigorous. Recipient is solely responsible for exercising full control over the Program and content of all presentations, publications and other work product ("Work Product") related to the Program and supported by the Grant, and Exact will not influence the content of the Program or any Work Product in any manner.
- 4. Regulatory Compliance. The parties acknowledge and agree that Grant is not being given in exchange for any explicit or implicit agreement to purchase, prescribe, recommend, influence or provide favorable formulary status for any of Exact or any other commercial entity's products and is not a solicitation, receipt, offer, payment or remuneration for referring business or purchasing or ordering products payable by any third party, including federal healthcare programs. This Agreement is not intended to influence the medical judgment of the Recipient, and Recipient shall not receive any compensation or remuneration for referrals, if any, to Exact or any Exact-affiliated entity. The parties agree and acknowledge that no compensation payable to Recipient is or will be based on the volume or value of any referrals to Exact or Exact-affiliated healthcare entity or other business generated by the Recipient for Exact or Exact-affiliated healthcare entity. Recipient further represents and warrants that (i) Recipient is not a referring physician for purposes of the Ethics in Patient Referrals Act, which

is codified at 42 U.S.C. Section 1395nn (commonly known as the "Stark Law"), and the regulations promulgated thereunder, and (ii) Recipient is not an employee, independent contractor, or owner of a group practice that refers healthcare business to Exact and does not "stand in the shoes" of any healthcare provider that refers to Exact, for purposes of the Stark Law, and the regulations promulgated thereunder.

5. Independence of Recipient in the Use of Grant Funds and the Conduct of the Program:

- a. Grant will be in the form of an unrestricted grant made payable to the Recipient. Exact's financial responsibility is limited to the amount of the grant set forth in this Agreement. Any other claims for payment are the sole responsibility of the Recipient.
- b. Recipient will ensure that the Program is independent, objective, fair, balanced and scientifically rigorous, so that it will not be viewed as nor in fact be promotional. Recipient is responsible for control of the Program, and Exact will not control in any way the planning or execution of any activity that is funded pursuant to this Agreement. Exact will not engage in "scripting," targeting points for emphasis, or other actions designed to influence content of the Program.
- c. If Exact products are mentioned in any way, the Recipient will ensure that data regarding Exact products (and competing products) are presented with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternate treatments. The title of the Program will fairly and accurately represent the scope of the presentation. The Program will present discussion of multiple treatment options, and will not focus on a single product or therapy.
- d. Recipient may only use the Grant for the Program. Recipient may not use the Grant or any portion thereof to pay travel, lodging, registration fees, honoraria or personal expenses or to subsidize recreational events, entertainment, meals or receptions.
- e. Recipient is responsible for the approval of all Work Product associated with the Program, and Exact will not have editorial or dissemination control of any Work Product associated with the Program.
- 6. <u>Disclosure of Financial Relationships:</u> To the extent required under applicable law, Recipient will disclose (a) Exact funding and (b) any significant relationship between the Recipient and Exact. The Recipient will acknowledge support from Exact Sciences Corporation in any material which describes the Program.
- 7. Sunshine Act Compliance. Recipient hereby acknowledges that Exact may be required to report all or a portion of the Grant as benefiting Recipient (if Recipient is a Teaching Hospital) or any other beneficiary of the Grant that is a US physician or Teaching Hospital, as and to the extent required by the US Physician Payment Sunshine Act (the "Sunshine Act"). If any portion of the Grant benefits a US physician or Teaching Hospital, including through Recipient's payment of honoraria, provision of food and beverage, provision of travel or lodging, or otherwise, Recipient shall provide Exact with all information Exact reasonably requires to comply with the Sunshine Act's reporting requirements, including the full name of each physician and/or Teaching Hospital receiving a benefit, their NPI number or TIN, and the value of the benefit received. Recipient hereby agrees that Exact reserves the right to withhold payment of the Grant until all such information has been provided to Exact, including after the conclusion of the Program (for example, if the required information includes the NPI numbers of Program attendees who actually partook of food and beverage paid for with the Grant). If Recipient has indicated on the Grant

Request that the Grant will not be used to benefit any US physician or Teaching Hospital, directly or indirectly, Recipient will not use the Grant to benefit a US physician or Teaching Hospital without informing Exact and providing all information as described above.

- 8. Reconciliation of Expenses: Within nine (9) months of the Effective Date, Recipient will provide a midpoint report to Exact's Health Equity Team. Recipient will furnish Exact within sixty (60) days of completing this Program: (i) a final project report that includes relevant data and outcomes related to specific goals, objectives and interventions outlined in the proposal (template will be provided), (ii) a certified report concerning the expenditure of funds associated with this Program and budget reconciliation, and (ii) a copy of all Work Product created as a result of the Program and/or supported by the Grant. In the event that the Program is: (a) cancelled through no fault of Exact; or (b) the Grant funds provided by Exact are not used for the Program, Recipient will notify Exact in writing of such cancellation or non-use of funds and then Recipient will return to Exact all funds not used for the Program described above, within sixty (60) days of the date of the Program.
- 9. Compliance with all Applicable Laws and Industry Standards: The Recipient agrees to abide by all applicable and relevant laws and standards including (a) all applicable standards relating to scientific publications; (b) U.S. Food and Drug Administration's Guidance for Industry; Industry-Supported Scientific and Educational Activities; (c) PhRMA Code on Interaction with Healthcare Professionals; (d) AMA guidelines; (e) AdvaMed guidance; and (f) the Health Insurance Portability and Accountability Act, as amended (HIPAA). Exact will not be responsible for any deviation or departure from relevant standards.
- 10. <u>Cancellation for Conflict of Interest.</u> This Contract is subject to cancellation for conflict of interest pursuant to A.R.S. § 38-511, the pertinent provisions of which are incorporated into this Contract by reference.
- 11. Compliance with all Institutional Policies: Recipient represents and warrants that the acceptance of the Grant funds is compliant with any and all policies, guidelines or directives, including all financial policies of Pima County, any institution where Recipient is engaged to practice medicine and any professional association of which the Recipient is a member. Recipient further represents and warrants that they have discussed this Agreement, as necessary, with Pima County administration and the Board of Supervisors and received any consents necessary to proceed with Recipient's obligations hereunder. Recipient agrees to immediately notify Exact in the event that this Agreement conflicts with any such policy or procedure. In the event of a conflict, Exact and Recipient agree to mutually work to reach an appropriate accommodation.
- 12. <u>Choice of Law:</u> The Parties agree that this Agreement will be governed by and interpreted under the laws of the State of Wisconsin without regard to its conflict of laws rules.
- 13. <u>Entire Agreement:</u> The Parties agree that this Agreement sets forth the entire understanding regarding the subject matter hereof, supersedes all prior agreements or understandings, whether written or oral, between the Recipient and Exact and may only be modified upon the mutual written agreement of the Recipient and Exact.
- 14. <u>List of Excluded Individuals/Entities:</u> Recipient represents and covenants that this Agreement does not conflict with Recipient's duties and obligations under any other agreement, whether oral or written, to which Recipient is or becomes a party. Furthermore, Recipient agrees (a) Recipient will not

enter into any agreement, whether oral or written, that conflicts with Recipient's duties and obligations hereunder, and Recipient will arrange to use the Grant funds pursuant to this Agreement in such a manner and at such times that no conflict will exist with any responsibilities or obligations of Recipient under any other agreement, arrangement or understanding, whether oral or written; (b) Recipient has not been (i) "debarred" by the United States Food and Drug Administration under 21 U.S.C. §335a or any foreign equivalent ("FDA"), (ii) excluded, debarred, suspended or otherwise ineligible to participate in Federal health care programs or in Federal procurement or nonprocurement programs; (iii) listed in the FDA's Disqualified and Restricted Lists for clinical investigations or (iv) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320-7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible nor will Recipient use in any capacity the services of any person or entity debarred by the FDA in performing under this Agreement and Recipient will notify Exact immediately if, during the term of this Agreement, Recipient or any person providing services in connection with the Program comes under investigation by the FDA for debarment or disqualification or is debarred or disqualified, excluded, suspended, restricted or sanctioned; and (c) when making a presentation for which Exact is providing Grant funding, Recipient agrees to disclose to the audience that the Recipient is receiving compensation from Exact and other such disclosures as may be required under this Agreement or applicable law.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto represent and warrant to each that each has the right and power to enter into this Agreement and have executed this Agreement in duplicate as of the date below written.

EXACT SCIENCES CORPORATION

Signature:	
Title:	
Print Name:	
Date:	
RECIPIENT	
Signature:	
Title: Chair, Board of Supervisors	
Print Name: Sharon Bronson	
Date:	
ATTEST	
Clerk of the Board	
Date	
APPROVED AS TO FORM	APPROVED AS TO CONTENT
Tipponylon	
Deputy County Attorney Tiffany Tom	Department Representative
Print DCA Name	Date
6/10/000	



Exhibit A (4 pages)

Pima County Health Department proposal to Exact Sciences to expand Colorectal Cancer Prevention, Screening, and Care Coordination in the County for individuals in high risk and low CRC screening uptake communities

Background

Target Populations and Health Disparities

Pima County is one of 15 counties in Arizona. It encompasses 9,189 square miles and shares 124 miles of international border with Sonora, Mexico. The Tohono O'odham Nation, the second largest tribe in Arizona by population and land mass and occupies much of the western side of the county. The City of Tucson accounts for 92% of Pima County's 1,068,730 population. Pima County has a Social Vulnerability (SVI) index of .8828 and a COVID-19 Community Vulnerability Index (CCVI) of .30. Nearly one in five (17.8%) of all Pima County resident lives below 100% of the federal poverty level, and one in four (25.1%) of Pima County children under 18 years of age lives under 100% of FPL. Poverty level and unemployment are highest in the areas with high Hispanic, Native American and African American residents.¹ Pima County has significant disparities in health outcomes across its diverse populations. Over two-thirds (65.3%) of people aged 50-75 in Pima County received colon cancer screenings in the past ten years. The 2030 Healthy People Target is 74.4%. (PCHD Community Health Needs Assessment, 2019).

PCHD has served historically marginalized communities to promote health equity for decades and is well-positioned to expand health promotion, screening and service coordination activities to improve colorectal cancer health outcomes in the County. PCHD has successfully accomplished community based programming, coalition development, public health interventions, and evaluation, pivoting to culturally, linguistically, and geographically targeted outreach campaign to combat a range of chronic diseases and more recently, COVID-19 response. PCHD's Community Outreach, Prevention and Education (COPE) Division is responsible for programs involving community outreach, engagement and collaboration to impact chronic disease prevention and management. Community/Clinical Linkages utilizes Public Health Nurses, Community Health Workers, the WIC program, prenatal education and home visitation, tobacco prevention and smoke-free compliance, and Healthy People Healthy Communities initiative focused on policies, systems and environmental change. PCHD has three public health clinics sites in Tucson that provide a range of public health services including: immunizations, STD and HIV clinics, family planning, TB clinic, Well Women Health Check, teen mobile clinic, health education and promotion and a range of health screenings available through Title X. PCHD clinics currently assess those patients eligible for CRC screening, and provide information and referral as appropriate. PCHD would like to adopt evidenced based practices around CRC assessment, referrals and linkages to available screening services in the County, and follow-up services as needed.

¹ https://www.census.gov/library/visualizations/interactive/2014-2018-poverty-rate-by-county.html



PCHD will leverage existing capacity and infrastructure to perform the proposed activities, building on successes of previous initiatives including the Mitigating COVID-19 in Communities of Color (MC3). This program brings mobile COVID-19 testing to underserved areas, including immigrant and refugee communities, historically African American neighborhoods, and areas with high concentrations of Mexican American residents. MC3 also provides culturally and linguistically competent education and awareness, contact tracing, and care coordination. In our work over the past two years, the PCHD has strengthened its partnerships with community and faith-based organizations, including the Tucson Indian Center, Pima Council on Aging, Chicanos por La Causa and PPEP- Portable, Practical Educational Preparation, Inc., International Rescue Committee, Pascua Yaqui Health Department, Tohono O'odham Nation Department of Health and Human Services and our network of Federally Qualified Health Centers

The department is confident it can successfully implement the proposed plan to advance health equity, reduce disparities in screening rates, and improve access to care with the overall aim to reduce the prevalence of colorectal cancer in high risk, underserved and underrepresented populations.

Goal, Objectives and Activities

Goal: Increase colorectal cancer awareness, prevention, screening referral and follow up in at least three higher risk communities and Census Tracts/Zip Codes with lower screening rates in Pima County by June 30, 2023

Objective 1: Increase community awareness in Pima County via community outreach, engagement and education by developing and implementing health promotion activities and health communication strategies

Activities/Timeline:

- 1. Develop social media, advertising and marketing campaign in English and Spanish targeting higher risk communities, including Native American audiences and groups.
- **April 1 2022- June 2023** Promote National CRC awareness month and CRC awareness day Saturday February 26th 2023.
- 2. Integrate CRC messaging into community outreach at health promotion events, health fairs, expos, community events and through PCHD's Healthy Shops Initiative including Barber, Beauty and Nail shops.

April 2022- June 2023

3. Implement a Train the Trainer curriculum on CRC prevention education and community engagement and deliver three trainings, reaching at least 75 key personnel, including Community Health Workers (CHW's), Public Health Nurses (PHN's), navigators, outreach specialists and community partners to provide culturally and linguistically appropriate CRC education, information, referrals and resources.

May 2022-March 2023

4. Engage with PCHD's Community Advisory Committee, on a quarterly basis, on outreach, messaging, health promotion and community engagement strategies

May 2022- June, 2023

5. Work with Tucson Indian Center to co-design tailored educational materials and products for the Native American communities in Pima County



Objective 2: Implement CRC initial patient screening questions, provide information and referral services at PCHD clinics for <u>target population</u> at 70%.

- 1. Update policies and procedures in PCHD clinics to reflect best practice CRC education, initial screening questionnaire and referral process for follow up care. **Target goal September 30, 2022**
- 2. Develop clinical report on current eligible screening criteria population served by PCHD clinics
 -Target goal June 30, 2022
- 3. Co-design CRC resources and toolkits for patients and providers with Exact Sciences Health Equity Team. **Target goal September 30, 2022**
- 4. Provide training to clinical, nursing, community education specialists and community partners on best practice CRC education and screening programs. May 2022- March 2023

Objective 3: Improve access to services and care for people in higher risk groups and low screening uptake areas to reduce disparities to CRC screening and follow-up services through enhanced service coordination between PCHD and other cancer care provider networks and coalitions.

- 1. Participate in, at least one, existing CRC and other cancer prevention coalitions in Pima County to enhance service coordination
 - Ongoing beginning April, 2022
- 2. Convene a working group to build prescribers and provider referral networks and linkages to affordable health care across provider networks, FQHC's and other groups. **Group will meet quarterly.**
 - May 2022- May 2023
- Provide at least 2 trainings to service providers in relevant areas such as trauma informed care, culturally sensitivity and humility practice, human centered design, health literacy
 August 2022-December 2022
- Create a system to link patients to care coordination resources as needed to remove barriers including transportation, child care, cost to access screening services and follow—up care June 2022- June 2023

Objective 4: Evaluate effectiveness of strategies and disseminate findings

- 1. Develop a work plan with key stakeholders April 2022-March 2022
- Work with Exact Sciences Health Equity team and PCHD public health informatics team to develop data informed approach to identifying target populations and communities April 2022-May 2022
- 3. Document activities and actions, capture success stories and evaluate effectiveness April 2022- June 2023
- 4. Share lessons learned and promising practice with community partners, community of practice, coalitions, publications etc.
 - January-June 2023



Budget for period April 1 2022 - June 30 2023

Communications support, media, advertising and marketing, including Product development tailored to Native American audiences (\$10,000)	\$20,000
Contracted curriculum tailoring and delivery	5,000
Tailor CRC toolkit and resources to target communities	5,000
Training delivery to CRC providers on best practice CRC services	5,000
Co-design education and training materials for Native American audiences In partnership with Tucson Indian Center	15,000
Healthy Shops CRC initiative - Funds to compensate small business owners for administrative and operational costs of hosting events. (10 shops at \$2,000/ea) 20,000
Promotional items for client participation in education, training, and health promotion activities	10,000
Care coordination/Provider network support and development – meetings costs, food and beverage, training, speakers	8,500
Patient assistance fund to remove cost barriers to screening and follow up Including transportation, translation, accommodation for rural clients,	
child care, lost wages etc.	25,000
Direct	113,500
Indirect Costs 10%	11,350
Total	\$ 124,850