

JUSTIFICATION FOR AWARD WITHOUT COMPETITION

(To be completed and submitted by the Office of Procurement)

Based upon the following determination, the proposed procurement action described below is being procured pursuant to the authority of Section 11-35-1560 of the SC Procurement Code and 19-445.2105 of the Rules and Regulations, 1976 SC Code of Laws.

Why does the governmental body need this item or service: (description of the agency need that this procurement meets):

The College of Charleston submits more than 100 new protocol applications each year that must comply with federal regulations and protocols instituted by the Food and Drug Administration's (FDA) Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC). Review and approval of research protocols for human participants (IRB 45 CFR 46) and vertebrate animals (IACUC) is regulated by the Institutional Review Board (IRB). The Mentor e-Form system logs all protocol actions and notifications, sends automatic notifications and reminders to reviewers (new protocols available for review) and investigators (annual reports are due), and centralizes storage of all IRB protocol files, including consent forms.

Additionally, we periodically use the Financial Conflict of Interest (FCOI) and Biosafety forms to maintain our compliance with federal regulations and eligibility for federal grant funding through agencies such as National Science Foundation (NSF) and National Institutes of Health (NIH).

As a sole source procurement for \$ \$109,407.60 (5 year cost) from (name of sole source contractor): Sitero LLC. (formally Axiom Mentor)

Description of market research Agency has performed to determine the availability of products or services that would meet the Agency's needs:

Market research using Procurement IQ, GovSpend and Google found that Sitero, LLC. is the only vendor who can provide their Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC). There are no other resellers of Sitero's "Mentor Software" available in the market place.

Description of supplies, construction, information technology, and/or services Vendor will provide under the contract:

A intensive collaborative effort between the Office of Research & Grants Administration (ORGA), IT, Users, Faculty Sponsors, Committee Members, Admins, & our vendor Sitero (formerly Axiom), resulted in the Mentor system implementation that provides researchers with the following:

- Integrations between Mentor e-Forms w/ Banner/Shibboleth
- E-Form questions & logic
- Hundreds of notification templates
- Multiple IRB and IACUC instruction manuals
- Application testing

Detailed explanation why no other vendor's supplies, construction, information technology, and/or services will meet the needs of the Agency:

After completing the normal bid process in 2019, the College entered a 5-year contract with Sitero Mentor (formally Axiom Mentor) for use of their software to support our research compliance activities. We have spent hundreds of employee hours creating custom notifications, developing 16 custom training manuals & user documentation, training our users, & customizing the e-Forms to better suit our campus community & make the review process more efficient. We currently have hundreds of active protocols in the Mentor system, & we don't have the staff to commit hundreds of employee hours to move to a different solution. Additionally, any gaps in our ability to maintain compliance with federal regulations jeopardizes our ability for us to conduct research with humans or animals, publish new research, accept research funding, attract & maintain talented researchers at CofC. Evidence of IRB or IACUC approval is required to receive funding or publish scholarly work.

X

In accordance with the South Carolina Consolidated Procurement section 11-35-1560 - Sole Source, the College of Charleston announced the intent to award without Competition. No protests were received.

Solicitation# 24-57-SDM-SS-T5

Contract Expiration Date: 02/28/2029

DocuSigned by:



24420723170F4ED
Wendy E. Williams, CPPO, C.P.M., Director of Procurement

4/8/2024

Date

DocuSigned by:



24420723170F4ED
John F. Loonan, Executive Vice President for Business Affairs

4/8/2024

Date

If this procurement is \$50,000 or greater, the Drug Free Workplace Act(§ 44-107-10, et Seq. Code of Laws of SC) applies, the acceptance of a Purchase Order signifies the Vendor certification that they are in compliance with the Drug Free Workplace Act.

6-Digit Index Number: 110037

6-Digit Account Code: 710414

NIGP 3-Digit Commodity Code: 920

Buyer's Initials

DS
SDM