

UNIVERSITY OF HAWAII NOTICE OF EXEMPTION CHAPTER 103D, HRS

The President, University of Hawaii, is in the process of reviewing the request from
University of Hawaii Cancer Center (Department/Campus)

for exemption from Chapter 103D, HRS, for the following goods and services:

Clinical trial management services from WCG, including ethical review, study startup, and post award services.

Ethical review includes IRB and IBC services.

Study startup includes contract and budget development and negotiations.

Post-award includes receivables management and financial audits.

Vendor: WCG Clinical, Inc.
(If known)

Address:
212 Carnegie Center, Suite 301
Princeton, New Jersey 08540

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|--|-----------|---------|-----------------------------------|
| Term of Contract: (If known) | From: TBD | To: TBD | Cost: \$500,000.00 (estimated) |
|--|-----------|---------|-----------------------------------|

Direct any inquiries to:
Department: University of Hawaii Cancer Center

Contact Name/Title: Daniel Han, Director of Fiscal Services

Address: University of Hawaii Cancer Center
701 Ilalo Street
Honolulu, Hawaii 96813

Phone Number:
(808) 586-2998

Fax Number:
N/A

Date Posted: November 4, 2022

Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, within seven (7) calendar days from the date posted to:

Office of Procurement Management
1400 Lower Campus Road, Room 15
Honolulu, Hawai'i 96822
email: OPM@hawaii.edu

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS

TO: OFFICE OF PROCUREMENT MANAGEMENT

FROM: University of Hawaii Cancer Center
(Department/Program)

Pursuant to APM Section A8.220, the Department requests a procurement exemption to purchase the following:

Description of goods, services, or construction:

Clinical trial management services from WCG, including ethical review, study startup, and post award services.

Ethical review includes IRB and IBC services.

Study startup includes contract and budget development and negotiations.

Post-award includes receivables management and financial audits.

* Estimated cost is purposefully stated as a large figure to ensure actual costs is unlikely to exceed the estimate. Actual cost is dependent on the number of trials contracted as services are rendered on a requirements-basis. For example, if only one trial is contracted, cost could be only a few thousand dollars.

Estimated Cost: \$ 500,000.00 *

(1) Explanation describing how procurement by standard competitive means is either not practicable or not advantageous to the University;

See attachment.

(2) Details of the process or procedures to be followed in selecting the vendor to ensure as fair and open competition as practicable;

See attachment.

(3) A description of the Department's internal controls and approval requirements for the exempted procurement; and

See attachment.

(4) A list of Department personnel, by position title, who will be involved in the approval process and administration of the contract:

Technical representative and contract administrator: Dr. Jonathan Cho, Director of Clinical Trials Office (CTO)

Fiscal representative: Ashley Ji, Fiscal Administrator for CTO

Executive oversight: Clifford Martin, Associate Director for Administration

Direct questions to: Dan Han Phone: 808-586-2998

I CERTIFY THAT THE INFORMATION PROVIDED ABOVE IS TO THE BEST OF MY KNOWLEDGE, TRUE AND CORRECT.

Clifford Martin
Full Name of Principal Investigator, Department Head, or Administrator

Clifford C. Martin Digitally signed by Clifford C. Martin
Date: 2022.10.28 18:11:20 -10'00' 10/28/22
Signature Date

Daniel Han
Full Name of Fiscal Administrator

Daniel Han Digitally signed by Daniel Han
Date: 2022.10.31 11:24:05 -10'00' 10/31/22
Signature Date

APPROVED:

David Lassner
Full Name of Vice President or Chancellor

David Lassner Digitally signed by David Lassner
Date: 2022.12.04 22:23:06 -10'00' 10/31/22
Signature Date

FOR OPM USE ONLY

OPM COMMENTS:

APPROVED DENIED

David Lassner Digitally signed by David Lassner
Date: 2022.12.04 22:23:06 -10'00'

12/02/2022

PRESIDENT, UNIVERSITY OF HAWAII

DATE

Attachment to Cancer Center's Form 138

(1) Explanation describing how procurement by standard competitive means is either not practicable or not advantageous to the University;

The University of Hawaii (UH) is seeking clinical trial management services to include ethical review, study startup, and post award services to develop the phase-1 clinical trial facility for the University of Hawaii.

The key to acquiring industry supported clinical trials, which are lacking in the University of Hawaii Cancer Center, Clinical Trials Office (CTO) portfolio, is knowledgeable representation in negotiating contracts with pharmaceutical companies. UH as a whole and CTO do not have the internal resources to perform these complex negotiations with pharmaceutical companies.

With no expertise in clinical trials negotiation, budget development, and clinical trials billing, WCG was seen as a potential source for all those services. WCG currently provides Institutional Review Board (WIRB) for the Hawaii Cancer Consortium (HCC), which is led by the University of Hawaii, and other services for HCC members including Queen's Medical Center and Hawaii Pacific Health. Services from WCG was sought by HCC to assist with standardized Medicare Coverage Analyses, an essential initial element of conducting clinical trials in a patient care environment.

In addition, WCG offers dozens of specialized services that are required when engaging with sponsors to establish clinical trials. Each of these services require combinations of niche and highly technical knowledge and experience. WCG has obtained these capabilities through internal development and acquisitions of companies over the course of its 50-year history, the result being a single company that can provide the full spectrum of clinical management solutions in an efficient, coordinated, and effective manner.

A standard procurement (i.e., invitation for bids or requests for proposal) is not practicable or advantageous to the University to acquire these services. For both methods, the development of a scope of work sufficient for the solicitation would require an inefficient and ineffective investment in time, effort, and funds. UH does not possess personnel with the expansive and holistic knowledge in the areas of clinical trial contracting and management needed to develop a descriptive and enforceable statement of work (SOW). Therefore, the development a SOW would require UH to contract with a consultant to assist in identifying and describing UH's needs into a SOW; which would require a separate procurement process. It is highly improbable that any individual or firm would have the scientific or technical background of all of these specialized areas. Furthermore, piecing together multiple individual consultants would be inefficient and would simply not be cost effective.

In addition, consideration of a lowest bid price may not provide the best value as it does not equate to lowest contract cost for UH. During budget negotiations, much of UH's upfront expenses for services rendered from WCG is built into the clinical trial budget. UH may pay WCG for services upfront, but those fees will ultimately be covered by the revenue earned from the clinical trial negotiated by WCG. This means that regardless of the service fees, the vendor providing the best value is the one that can effectively negotiate a budget with the sponsor that will cover the most expenses incurred by UH. WCG is the leader in clinical trial management and has worked with all major clinical trial sponsors, such as pharmaceutical companies. This lends to WCG's credibility and success in its ability to negotiate recuperation of costs for UH.

(2) Details of the process or procedures to be followed in selecting the vendor to ensure as fair and open competition as practicable;

Based on the services provided by WCG to HCC, it has been determined that directly contracting with WCG is the most advantageous to the University. UH Cancer Center has invested concerted effort and time to research potential vendors to provide such services and to ensure that the best qualified vendor would be engaged for the services sought.

Extensive discussions between the vendor and the UH leadership team have been conducted to ensure WCG understands UH's needs and can deliver services as required as the UH Cancer Center embarks on its novel project to develop the phase-1 clinical trial facility for the University of Hawaii.

(3) A description of the Department's internal controls and approval requirements for the exempted procurement; and

The Director of Clinical Trials Office shall monitor the performance of the contract. In the absence of the Director of Clinical Trials Office or a delegate, the Associate Director of Administration shall take its place of authority.

The Director of Clinical Trials Office, or his/her delegate, shall submit a requisition for a requirements-PO with an estimated cost maximum per clinical trial project. All associated POs under this proposed exempt contract shall reference the master contract number established by the Office of Procurement Management. The requisition shall be reviewed and approved by the funding account supervisor and fiscal administrator. Requisitions and PO amendments shall adhere to UH APs governing procurement approvals. The Director of Clinical Trials, or his/her delegate, shall certify respective invoices to confirm services have been received satisfactorily and approved for payment. The fiscal representative shall certify availability of funds prior to approving PO or payments.

(4) A list of Department personnel, by position title, who will be involved in the approval process and administration of the contract:

Technical representative and contract administrator: Dr. Jonathan Cho, Director of Clinical Trials Office (CTO)

Fiscal representative: Ashley Ji, Fiscal Administrator for CTO

Executive oversight: Clifford Martin, Associate Director for Administration