



Tissue sectioning, hematoxylin & eosin staining (H&E), and immunohistochemistry staining of formalin-fixed, paraffin-embedded (FFPE) tissues from COVID-19 patients

Intent to Sole Source

FDA – 1240971

Date Posted: April 23, 2021
Closing Date: May 4, 2021 09:00 AM Central Time
Classification Code: B504 – Special Studies/Analysis
NAICS Code: 541990 – All Professional, Scientific and Technical Services; with a Small Business Size Standard of \$16.5 M

The U.S. Food and Drug Administration (FDA)/Office of Acquisitions and Grants Services (OAGS) intends to negotiate on a sole source basis and potentially award a firm fixed price purchase order to Winship Cancer Tissue and Pathology Shared Resource (CTPSR) facility at Emory University, 1701 Uppergate Dr. NE, 5th Floor, Bench 14, Atlanta, GA 30322, under the authority of FAR 13.106-1(b)(1)(i) – Soliciting from a Single Source.

The U.S. Food and Drug Administration's (FDA), National Center for Toxicological Research (NCTR) has a requirement for tissue sectioning, hematoxylin & eosin staining (H&E), and immunohistochemistry staining of formalin-fixed, paraffin-embedded (FFPE) tissues from COVID-19 patients. The Winship Cancer Tissue and Pathology Shared Resource (CTPSR) facility has the skill and expertise in staining human disease tissues for immune cells including T cells, B cells and macrophages using both standard and fluorescent detection methodologies which are necessary to complete the characterization of resident immune cell populations responding to SARS-CoV-2 infection in vital organs such as lung, liver, kidney, spleen and heart as described in E0774501. The autopsy tissues reside at Emory; Emory is unwilling to release the autopsy samples to other facilities due to safety concerns; Emory CTPSR has direct access to the samples and has the expertise in histology and immunohistochemistry procedures in human diseased tissue, therefore CTPSR is the sole source option for performing this requirement.

This notice is being published in accordance with Federal Acquisition Regulation (FAR) Part 5.101(a)(2) requiring the dissemination of information on proposed contract actions. This is a notice of intent to award a sole source contract and is not a request for competitive proposals. The statutory authority for this sole-source procurement is FAR 13.106-1(b)(1)(i).

This notice of intent is not a request for competitive quotes. Interested parties may identify in writing their interest and capability to respond, may submit a capability statement to Suzanne Martella at suzanne.martella@fda.hhs.gov before May 4, 2021 at 09:00 am Central Time (CT). A determination not to compete this requirement, based upon responses to this notice, is solely within the discretion of the Government. If no responsive statements are received before the closing date and time, negotiations with and subsequent award shall be made to Emory University.