

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Veteran Health Administration (VHA), Service Area Office (SAO) – East, 323 North Shore, Suite 500, Pittsburgh, PA 15212. The requesting facilities are Department of Veterans Affairs, VISN 18, Phoenix VA Health Care System 644 and the Milwaukee VAMC Research Departments.
2. **Nature and/or Description of the Action Being Processed:** Purchase of a Leica laser-scanning confocal microscope (LSCM). This system will permit imaging of fine details within defined thin planes of thicker specimens, including fixed cells and tissues, live tissue biopsies, and live cells grown in vitro. Critical to the request is a spectral scanner capable of distinguishing between, and measuring the fluorescent light emission of, multiple fluorescent dyes or tags in the same location, in the same sample, at the same time, to permit experiments in which focus on whether different proteins or organelles have joined together into an active configuration.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
 The Phoenix VA Health Care System and Milwaukee VAMC Research Services have had a longstanding need to purchase a LSCM system to advance a number of funded research projects. The LSCM will be used to investigate intracellular signaling pathways within cells, small organelles and other fine structures within cells, fluidity of the cell membrane in living cells, specific structures and cell locations within small tissue biopsy samples, etc. Unique to our needs is a confocal microscope with full control capabilities for experienced users, with software integration to permit use by less experienced and even novice confocal microscopists with minimal supervision. Also unique to our needs is a spectral scanner capable of distinguishing between at least three fluorescent dye colors in the same exact place at the same time.

Although confocal microscopes are nominally "products" that most manufacturers give model designations and catalog numbers, those refer to only to the core around which the instrument will eventually be built, and do not represent a functional instrument. A completed confocal microscope from any manufacturer is a highly specialized, custom-designed and custom-built laboratory instrument containing an exacting selection of specific parts, chosen through consultation between the manufacturer and the end users of the instrument. Which parts are needed is complicated decision based upon highly technical details of the experiments which the end users intend to run using the microscope. Two microscopes with nominally similar specifications may not be comparable instruments, since differences in the spectral characteristics of different manufacturers' lens glass, size and geometry of the confocal pinholes, efficiency of the mirrors, brightness of the illumination lasers, length and geometry of the microscope's optical paths, speed of the raster scan heads that aim the laser(s) pixel-by-pixel over the viewing area, sensitivity and spectral characteristics of the photomultiplier tubes (PMTs) that detect the fluorescence excited by the laser, etc., all interact in complicated ways that are not easily predicted from raw specifications. Due to the nature of similar research these hospitals required confocal microscope's with the same characteristics. The price per complete system of the Leica TCS SP8 Spectral Confocal System [REDACTED]

As can be inferred from the complexity of a confocal microscope's many carefully-selected parts, actually operating a laser-scanning confocal microscope is also a very complicated task. The settings of almost every part of the microscope must be specified for each experiment, and the physical and mental ergonomics of

the automation required to exactly set numerous tiny parts with nanometer precision many times per second are critical to producing a usable confocal microscope. Many of our intended users are not experienced confocal microscopists, so the software needs to be simple enough to let these users do their experiments as well, with prior guidance from, but unsupervised by, more experienced users. These ergonomic considerations are a critical, but unquantifiable, factor, and a microscope with the software and layout desired by the end users must be obtained if the microscope is to be usable. Past experience of PVAHCS staff familiar with the instruments has been that a confocal microscope with "unpleasant" hardware and software is practically unusable, regardless of its specifications, and represents hundreds of thousands of dollars wasted. There is also a safety factor with a microscope that does not adequately control its various components through well-tested, fully-integrated software and hardware. A confocal microscope has the capability to focus a significant amount of laser energy into the user's eyes, potentially resulting in permanent partial or complete blindness. Integrated controls should lock these modes out of casual availability, to prevent the possibility of accidental eye exposure.

- An inverted binocular microscope operating as a laser-scanning pinhole confocal microscope, able to produce thin image sections through fixed and living cells, and small tissue samples.
- Brightfield, darkfield, phase contrast, interference contrast, polarization contrast, and combination contrast optics.
- All microscope parameters controlled through software, with hardware capable of fast-switching between modes, and with all settings visible on the control screen.
- Possessing two scan heads for simultaneous illumination of samples by two lasers moving in different patterns, which allows for measurements such as Fluorescence Recovery After Photobleaching (FRAP), Fluorescence Energy Resonant Transfer (FRET), and dual photon illumination of delicate samples, as well as the option to select the better scan head for collinear illumination with only one scan head.
- Possessing a spectral detector capable of distinguishing two similar fluorescent spectra.
- Possessing low-light capabilities for imaging faint signals.
- Stage with galvanic Z-motion controller, and mounting frames for slides (fixed cells and tissue sections) and standard tissue culture vessels (live cells and tissues).
- Plan-apochromatic lenses with immersion fluids, working ranges, and magnifications as specified in quote.
- Filters, mirrors, and prisms as specified in quote.
- Lasers emitting at 405 nm, 488, 514, 552 nm, and 638 nm with capability to add lasers at 355 nm and 425 nm.
- Vibration isolation air table included.
- Software-programmable control panel with multi-user memory.
- Computer and software to operate microscope and process confocal images obtained with microscope.

4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §253(g), as implemented by FAR 6.302. The specific paragraph must be cited. Most likely, only the -1 or -2 authorities will be cited. Please be aware that failure to adequately plan for future requirements does not constitute appropriate use of the unusual and compelling urgency statutory authority.

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR

6.302-3;

- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

The Leica TCS SP8 quoted includes lenses, optical filters, dichroic mirrors, galvanic and resonant mirrors, lasers, Z-motion controlled stage, and a spectral scanner, which experienced confocal microscopists working at these two facilities have determined are capable of performing the experiments required by the research community.

Leica is the only manufacturer of LSCM systems offering a spectral scanner based on five wavelength-tunable photomultiplier tubes (see attached email from Leica Advanced Imaging Specialist). Other spectral scanners available from other manufacturers use either large numbers of fixed-wavelength tubes which are prohibitively expensive, or offer only two tuneable PMTs which cannot distinguish between three colors at the same time. The spectral scanner is included in the quote for the Leica TCS SP8 [REDACTED]

Unlike all other confocal scanners, the Leica X2Y scanner built into the Leica TCS SP8 uses three scan mirrors, one for the x and two for the y dimension. The second Y mirror of the X2Y scanner guarantees that the pivot point of the light beam in the Q1's back pupil is always centered. By this arrangement, the optimal $4f$ design can be maintained to avoid vignetting and loss of resolution.

Most confocal microscopes control the depth of the optical section with a precise stepper motor controlling the stage height in discrete increments. For the fastest recording speed in 4D experiments Leica uses a galvanometric stage insert that moves the sample up or down at a constant speed, avoiding stop-start motor steps that slow down scanning and risk photo bleaching or destruction of samples by the laser. No other manufacturer offers a comparable solution for imaging living cells.

Leica's tandem scanner allows the functionality of both a precision galvanic scanner and a fast resonant scanner. It allows for line scan frequencies of up to 12 kHz, which results in about 40 fps at a scan format of 512x512 pixels or 428 fps at 512x16 pixels. This is a significant increase of more than 30% over Leica's and other brand names previous implementation with 8 kHz line frequency which is still available. These high scan speeds are required for a number of biological questions posed by existing funded research at PVAHCS, including rapid imaging of calcium ion signaling, kinetic measurements of cell processes, fluid flow, or cell motility.

Leica's HyD hybrid detection photomultiplier tube combines features of standard photomultiplier tubes (PMTs) and avalanche photodiodes (APDs). The large dynamic range and reasonable noise level of PMTs have made them standard in confocal imaging. Leica uses unique hybrid photo detectors combining elements from both PMTs and APDs. Instead of a long cascade of dynodes as in pure PMTs, with potential for photon loss and noise propagation, they use a simple geometry with an electron bombardment step, producing large (10^9) gain in a single step. Unlike other LSCM systems, Leica scopes with HyD always count emitted photons precisely, not just low-light signals detected by specialty APD scanners, or by repurposing spectral scanners so that each PMT counts photons that are split randomly rather than by color. Thus, Leica is able to offer spectral scanning at lower light levels and faster scanning speeds than competing LSCM

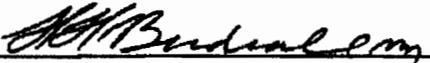
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systems, and precisely quantitate the brightness of every image pixel. That allows small differences between bright signals to be meaningfully compared between experimental conditions.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Three major manufacturers, Leica, Zess and Nikon have been contacted over the last several years. Their products information and quotes have been gathered and reviewed. Several research scientists and principle investigators [REDACTED] have carefully read all information, compared these three vendors and products and drew the conclusion, Leica's TCS SP 8 confocal is the only source to satisfy current research requirements with the Phoenix and Milwaukee VA Research Departments. [REDACTED]
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The only three devices even potentially suitable to the needs of PVAHCS (Leica, Zeiss, and Nikon) have been extensively explored over the past several years. Recent market research of GSA vendors found that Nikon has two FSS contracts for confocal microscopes that lack characteristics of the Leica; the FSS contract price for the available Nikon base models are [REDACTED] while the base price for the Leica is comparable [REDACTED]. As noted in (6) above, Leica is the one confocal microscope that meets the salient characteristics required, and based on market research, its price for scientifically advanced capabilities is reasonable and comparable to similar equipment.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Intent to sole source this request was established based upon the characteristics of the LSCM system required by both VA Research Departments, and the results of prior-years' market research that established that only Leica offered a LSCM system that met all requirements.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** As noted above, confocal microscopes are custom-designed, custom-built instruments that have to be designed by consultation between the manufacturer and the end-user. Their operation is extremely complex, and intangible factors like the layout and "feel" of both hardware (knobs, sliders) and software controls are critical factors in their capability to do the work for which they are purchased. It is not possible to publish a set of specifications to which competing suppliers can respond with mutually blinded proposals that can be objectively judged. The relevant criteria would be "match the exact capabilities of this Leica instrument which was already quoted," and even that would probably lead to submissions of quotes for instruments that are not actually usable by the Phoenix and Milwaukee research user base. Past experience has been that similarly-capable instruments from other manufacturers are not similarly-equipped instruments. They are instead much more complicated instruments which cost significantly more than Leica's design and require far more expertise to use successfully.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Only Market research was done and three manufacturers were found to produce confocal microscopes; Leica, Zeiss, and Nikon. Leica was the only manufacturer with salient characteristics noted above. GSA pricing was also used in the IGE for confocal microscopes on FSS contract. While one was similar in comparable price, the different manufacturer's were not comparable in characteristics, quality and performance.
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** At this time there is only one system that meets all of the needs for the approved research protocols. If future

developments in technology occur we will include all appropriate technology in any future purchase considerations.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Holly Birdsall, M.D., Ph.D.
Deputy Chief Research and Development Officer
VHA Office of Research & Development

6/25/2013
DATE

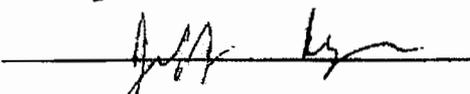
13. Approvals in accordance with FAR 6.304

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


CONTRACTING OFFICER'S SIGNATURE
Paula Stankovic, CO

6-25-2013
DATE

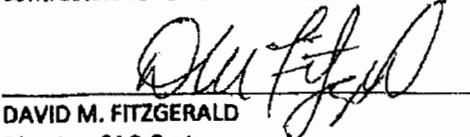
b. NCM/PCM/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


JEFFREY R. RYAN
Network Contract Manager, SAO East

6/25/13
DATE

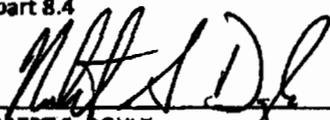
HIGHER LEVEL APPROVAL (Required For orders over \$500,000):

c. SAO: I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.


DAVID M. FITZGERALD
Director, SAO East

6-27-2013
DATE

d. **VHA HCA REVIEW AND APPROVAL (over \$500,000 to \$10 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4



NORBERT S. DOYLE
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

7/16/13

DATE