JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1
(OVER MICRO-PURCHASE THRESHOLD($3.5K) BUT NOT EXCEEDING THE SAT ($150K))

IAW FAR13.104, COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW FAR13.106-1(b), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW FAR13.106-3(b)(3),COs are required to include additional statements ***explaining the absence of competition*** (see 13.106-1 for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW FAR13.106-3(b) (3). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. ACQUISITION PLAN ACTION ID:	**1A. PROJECT/TASK No.**	**1B. ESTIMATED AMOUNT:**
589-16-3-8504-0055 KC Ultrasonicator	N/A	$137,705

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

Covaris is the sole manufacturer of the E220 High Performance Ultrasonicator and is the sole distributor in the USA.

Acoustic shearing of DNA using the Covaris E220 instrument, in contrast to nebulization with nitrogen gas, sonication, and hydroshearing (e.g. GenomicSolutions Hydroshear) produces fragments in a highly reproducible size range down to 100 bp; the fragment ends are easily blunt ended in a single enzymatic step; and sample volumes can be as low as 100 ul and sample mass as low as 100 ng. The process is isothermal, eliminating bias to G-C region shearing. Quail et al. (2008) reported up to 5 fold increase in fragments in the correct size range for Illumina sequencing (~200 bp) compared to other instruments. More importantly, there is no physical contact between the instrument and the sample DNA, thus no contamination of tubing, etc. that could lead to sample mixing or sample loss. Finally, the E220 model allows automated, batch processing of up to 96 samples, which is extremely important for applications such as multiplexed sequencing of small genomes (bacterial, virus, BACS, fosmid clones).

The key requirements for the apparatus are as follows:

1. Controllable time and acoustic energy transfer, and real-time monitored temperature, to ensure sample-to-sample sample reproducibility.
2. User-tunable, generated fragment size distribution (range: 150-bp to 5k-bp)
3. Closed tube, non-contact process producing a computer controlled focused acoustic field inside a closed vessel. This is essential to limit sample cross-contamination and attendant contamination by human pathogens. The focused field allows for faster, continuous sample treatment, whereas with unfocused devices, longer treatment times result in introduction of significant heat into the system and are unable to be operated isothermally.
4. The system frequency must be within the ultrasonic range (wavelengths on average less then 1mm in length), and thus outside the human audible range. This is essential so that the instrument can be operated in a general laboratory bench setting without extra expense for system enclosures to ensure proper ear protection.
5. Sample input flexibility: tubes, vials, for single sample processing; and sample shearing, solubilization/disruption or extraction applications.
6. The maximum system size cannot exceed 46 cm wide, 48 cm high, by 52 cm deep owing to space limitations.
7. System does not require hearing protection or segregation from the common laboratory environment.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

1. Covaris is patented technology --adaptive focused acoustics (AFA), adapted for biomolecules. AFA acoustic waves are the same focused wavelength waves as lithotripsy (which is the method used to break up kidney stones)—this is done without damage to adjacent tissue. Using AFA technology will not damage the DNA in the sample.

2. Comparing AFA technology to sonication, sonication energy is unfocused energy, and heat generating, which is damaging to tissues/samples. AFA (Covaris) is an isothermal process.

3. Covaris AFA technology eliminates GC bias in data analysis so there is less or non-existent error in data analysis. This is important relative to accurate patient data and also cost savings both for the VA and the patient. Sequencing runs on the NextSEq Illumina can run up to 7000$/run in reagents. Having to repeat the runs and extra testing on patients can be very costly.

4. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

Market research was conducted, but a determination was made that substituting equipment for this type of research with other than that specifically prescribed is beyond the role, competency and professional functions of the Contracting Officer, and would be detrimental to the treatment of the Veteran patient. Market Research determined this is proprietary equipment. No additional market research was performed beyond determining the authorized distribution for Covaris. Market Research determined this is proprietary equipment.

5. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. Note: COs are required to make a determination of price reasonableness IAW FAR 13.106-3. See the Commercial Supply and Service SOP for Price Reasonableness templates.*

Eric M MURRAY 346562

Digitally signed by Eric M MURRAY 346562
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