



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
820 CHANDLER STREET
FORT DETRICK MD 21702-5014

23 September 2020

Advanced Technology International (ATI)
ATTN: (b) (6), Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6):

SUBJECT: Project Approval Letter (PAL) for 20-12-COVID19-Diagnostics-010 for “Wearable Physiologic Monitor with Real-time Continuous Data Acquisition and Analysis for Early Detection of COVID 19 Infection” to Sempulse Corporation, PAL Version 1

REF: Request for Project Approval from ATI dated 14 September 2020 for 20-12-COVID19-Diagnostics-010 under OTA W81XWH-15-9-0001

EGS#: MT20012.010

In support of the U.S. Army Medical Research and Development Command (USAMRDC), ATI, on behalf of the Medical Technology Enterprise Consortium (MTEC) issued Request for Project Proposal (RPP) number MTEC-20-12-COVID19-Diagnostics on 1 May 2020. Both current and prospective members of the MTEC submitted Enhanced White Papers in response to this RPP, in accordance with the terms of the RPP. (b) (4). Subsequently, the Government evaluated those Enhanced White Papers that passed the Government’s initial screening process in accordance with the stated evaluation criteria. (b) (4).

Based upon the evaluation of Sempulse Corporation’s proposal (20-12-COVID19-Diagnostics-010) entitled, “Wearable Physiologic Monitor with Real-time Continuous Data Acquisition and Analysis for Early Detection of COVID 19 Infection,” and ATI’s request for PAL (which includes the Statement of Work (SOW), inclusive of an acceptable milestone schedule), ATI is hereby authorized to issue a Research Project Award (RPA) to Sempulse Corporation for the subject initiative. This approval is contingent upon the provision of funding via a separate Other Transaction Agreement Task Order modification, W81XWH-20-9-0015-P00003. The Sponsor Office Technical Representative (SOTR) for this RPA is (b) (6).

The period of performance of the Research Project Award is 9 months. Note, however, that the period of performance within the Other Transaction Agreement Task Order, W81XWH-20-9-0015, includes additional time to account for the final negotiations between ATI and all performers included under the “Wearable Diagnostic for Detection of COVID-19 Infection” Task Order to finalize negotiations for the individual RPAs. This additional time is intended to align the end dates for the Task Order and RPAs.

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Special Considerations

- a. The Government has not identified any national security restrictions that apply to this RPA.
- b. The following special research considerations are applicable to this award: use of human subjects. Approval from the MRDC Human Research Protections Office (HRPO) must be obtained prior to commencement of the tasks involving human subjects.

Data Rights

The Sempulse platform uses proprietary and patented hardware and software previously developed and funded exclusively at private expense and as such is Restricted in use. The technical data collected and used across the listed aims and milestones during this study will have Government Purpose Rights. The rights of IP held by other parties would continue to be held by respective parties and any technical data developed would have Government Purpose Rights.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions
(b) (4)	(b) (4)	Government Purpose Rights	(b) (4) (b) (4)
(b) (4)	(b) (4)	Government Purpose Rights	Sempulse Corporation

Pre-Award Cost Authorization

The Agreements Officer has authorized pre-award costs for the RPA to Sempulse Corporation. As the Pre-Award Cost Authorization (PACA) letter was fully executed between ATI and Sempulse Corporation on 8 July 2020, the Government agrees to pay allowable costs accrued in the performance of this RPA starting on this date (8 July 2020) through the end of the period of performance in an amount not to exceed \$351,863.08.

The total authorized value (as summarized in the table on the following page) has been determined fair and reasonable and this proposal has been selected in accordance with the RPP evaluation criteria. The Agreements Officer documented the appropriate use of Section 815 prototype OTA authority. The total approved cost to the Government for this effort is Not-to-Exceed (NTE) **\$1,841,478.00**.

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At no time shall the Government’s obligation exceed the funding provided for this RPA.

Government Project Funding	ATI Fixed Fee (Gov’t Funding)	Total Cost to the Government	Anticipated Non-Federal Contribution	Total Program Cost
\$1,841,478.00	\$0.00	\$1,841,478.00	\$0.00	\$1,841,478.00

Sincerely,

HOOD.THOMA Digitally signed by
HOOD.THOMAS.L.1267679009
S.L.1267679009 Date: 2020.09.23 10:14:47 -04'00'

Thomas L. Hood
Agreements Officer

Enclosed:
Statement of Work with Milestones