



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

10 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-095 for (b) (4) for COVID-19 ONset” to Empatica Inc., PAL Version 1

REF: Request for Project Approval from ATI dated 25 August 2020 for 20-12-COVID19-Diagnostics-001 under OTA W81XWH-15-9-0001

EGS#: MT20012.095

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 Empatica Inc’s proposal (20-12-COVID19-Diagnostics-095) entitled, (b) (4) for COVID-19 ONset,” 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 Empatica Inc. 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-P00002. The Sponsor Office Technical Representative (SOTR) for this RPA is (b) (6).

The period of performance of the Research Project Award is 8 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 and human anatomical substances. Approval from the MRDC Human Research Protections Office (HRPO) must be obtained prior to commencement of the tasks involving human subjects and human anatomical substances.

Data Rights

As stated in Empatica Inc’s proposal entitled, (b) (4) for COVID-19 ONset,” all items except those listed in the following table will be delivered to the Government with Government purpose data rights or unlimited data rights.

| Technical Data or Computer Software to be Furnished with Restrictions     | Basis for Assertion | Asserted Rights Category  | Name of Organization Asserting Restrictions | Milestone # Affected                    |
|---|---------------------|---------------------------|---|---|
| Software: AURA algorithm for early detection                              | (b) (4)             | Restricted                | Empatica Inc.                               | Milestones 1.1, 1.2, 1.3, 2.1, 2.2      |
| Software: (b) (4)   | (b) (4)             | Restricted                | Empatica Inc.                               | Milestones 3.2, 3.3, 3.4, 3.5, 3.6      |
| Software: Front end data visualization                                    | (b) (4)             | Government Purpose Rights | Empatica Inc.                               | Milestones 3.1, 3.4, 3.6                |
| Software: E4 Device Embedded Software                                     | (b) (4)             | Restricted                | Empatica Inc.                               | Milestones 3.3, 3.4                     |
| Software: EmbracePlus Device Embedded Software                            | (b) (4)             | Restricted                | Empatica Inc.                               | Milestones 3.5, 3.6                     |
| Technical Specification Data: Tooling, Testing procedures, Facility setup | (b) (4)             | Limited                   | Empatica Inc.                               | Milestones 4.1, 4.2, 4.3, 4.4, 4.5, 4.6 |

Pre-Award Cost Authorization

The Agreements Officer has authorized pre-award costs for the RPA to Empatica Inc. As the Pre-Award Cost Authorization (PACA) letter was fully executed between ATI and Empatica Inc. on 18 August 2020, the Government agrees to pay allowable costs accrued in the performance of this RPA starting on this date (18 August 2020) through the end of the period of performance in an amount not to exceed \$401,800.00. Additionally, the Agreements Officer authorized the allowance of costs incurred by Empatica Inc. as Cost Share (Anticipated Non-Federal Contribution) starting on this date (18 August 2020).

The total authorized value has been determined fair and reasonable and this proposal has been selected in accordance with the RPP evaluation criteria. The Agreements Officer documented

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the appropriate use of Section 815 prototype OTA authority. The total approved cost to the Government for this effort is Not-to-Exceed (NTE) \$2,483,189.00 (note that the “Total Program Cost” value listed in the table below of (b) (4) is inclusive of the Anticipated Non-Federal Contribution). 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 |
|----------------------------|-------------------------------|------------------------------|--------------------------------------|--------------------|
| \$2,483,189.00             | \$0.00                        | \$2,483,189.00               | (b) (4)                              | (b) (4)            |

Sincerely,

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Thomas L. Hood  
Agreements Officer

Enclosed:  
Statement of Work with Milestones