



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-050 for “Wearable Diagnostic for Detection of COVID-19 Detection” to Philips North America LLC, PAL Version 2

REF: Request for Project Approval from ATI dated 30 July 2020 for 20-12-COVID19-Diagnostics-050 under OTA W81XWH-15-9-0001

EGS#: MT20012.050

The purpose of this revised PAL is to:

- Update the Data Rights section to incorporate the revised data rights assertions table

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 Philips North America LLC’s proposal (20-12-COVID19-Diagnostics-050) entitled, “Wearable Diagnostic for Detection of COVID-19 Detection,” 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 Philips North America LLC for the subject initiative. This approval is contingent upon the provision of funding via a separate Other Transaction Agreement (OTA) Task Order modification, W81XWH-20-9-0015-P00001. 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 OTA 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

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for the individual RPAs. This additional time is intended to align the end dates for the Task Order and RPAs.

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 Philips North America, LLC’s proposal entitled, “Wearable Diagnostic for Detection of COVID-19 Detection,” and the revised data rights assertions dated 15 September 2020, the following data rights assertions will apply to this prototype project. The applicable asserted rights for the table below is Restricted Government Rights as described below.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Task # Affected
(b) (4)	(b) (4)	Category A; Commercial	Philips North America, LLC	Task 1-30
(b) (4)	(b) (4)	Category A; Commercial	(b) (4)	Task 1-30
(b) (4)	(b) (4)	Category A; Commercial	(b) (4)	Task 1-30
(b) (4)	(b) (4)	Category A; Commercial	(b) (4)	Task 1-30

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Pre-Award Cost Authorization

The Agreements Officer has authorized pre-award costs for the RPA to Philips North America, LLC. As the Pre-Award Cost Authorization (PACA) letter was fully executed between ATI and Philips North America, LLC on 20 July 2020, the Government agrees to pay allowable costs accrued in the performance of this RPA starting on this date (20 July 2020) through the end of the period of performance in an amount not to exceed \$125,000.00.

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 the appropriate use of Section 815 prototype OTA authority. The total approved cost to the Government for this effort is Not-to-Exceed (NTE) **\$2,753,675.00**. 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
\$2,753,675.00	\$0.00	\$2,753,675.00	\$0.00	\$2,753,675.00

Sincerely,

HOOD.THOMA
S.L.1267679009

Digitally signed by
HOOD.THOMAS.L.1267679009
Date: 2020.09.23 10:30:35 -04'00'

Thomas L. Hood
Agreements Officer

Enclosed:
Statement of Work with Milestones