



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-084 for “Early Detection of COVID 19 with Wearables” to Fitbit, Inc., PAL Version 1

REF: Revised Request for Project Approval from ATI dated 17 September 2020 for 20-12-COVID19-Diagnostics-084 under OTA W81XWH-15-9-0001

EGS#: MT20012.084

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 Fitbit, Inc’s proposal (20-12-COVID19-Diagnostics-084) entitled, “Early Detection of COVID 19 with Wearables,” 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 Fitbit, 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-P00003. The Sponsor Office Technical Representative (SOTR) for this RPA is (b) (6)

The period of performance of the Research Project Award is (b) (4). 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 the performer to finalize negotiations. This additional time is intended to align the end dates for the Task Order and RPA.

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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.

Data Rights

The following Rights in Technology and Data reflect those that have been mutually agreed upon between the Government and Fitbit, Inc. for the prototype project proposal entitled, “Early Detection of COVID 19 with Wearables.” (b) (4)

[Redacted] Fitbit, Inc. (b) (4)

Ownership of Technology and Data. Fitbit (b) (4)
 [Redacted] Fitbit (b) (4)

Government’s Rights (b) (4) Fitbit (b) (4) . Fitbit (b) (4)
 [Redacted] Fitbit (b) (4)
 [Redacted] Fitbit (b) (4)
 [Redacted] Fitbit
 (b) (4) Fitbit’s (b) (4)

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
(b) (4) Fitbit’s (b) (4)	Specifically-negotiated data rights	Category D	Fitbit, Inc.	ALL
(b) (4) Fitbit’s (b) (4)	Specifically-negotiated data rights	Category D	Fitbit, Inc.	ALL
(b) (4)	Specifically-	Category D	Fitbit, Inc.	ALL

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(b) (4) Fitbit's (b) (4)	negotiated data rights			
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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) (b) (4) (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
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

Sincerely,

HOOD.THOMA
S.L.1267679009

Digitally signed by
HOOD.THOMAS.L.1267679009
Date: 2020.09.23 10:26:31 -04'00'

Thomas L. Hood
Agreements Officer

Enclosed:
Statement of Work with Milestones