



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

28 July 2020

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

Dear (b) (6):

SUBJECT: Project Approval Letter (PAL) for 20-09-COVID19-065 for “Treatment and Prevention of Acute Respiratory Distress Syndrome in Patients with COVID-19 using (b) (4) ”

REF: Request for Project Approval from ATI dated 19 June 2020 for 20-09-COVID19-065 under OTA W81XWH-15-9-0001

EGS#: MT20009.65

In support of the U.S. Army Medical Research and Development Command (USAMRDC), ATI, on behalf of the Medical Technology Enterprise Consortium (MTEC) issued RPP 20-09-COVID19 on 25 March 2020. Members of the MTEC submitted Enhanced White Papers in response to this RPP, in accordance with the terms of the RPP and the Proposal Preparation Guide (PPG). ATI received the white papers and completed an administrative compliance review. Subsequently, the Government evaluated technical proposals in accordance with the stated evaluation criteria; (b) (4).

Based upon the evaluation of (b) (4) ’ proposal (20-09-COVID19-065) entitled, “Treatment and Prevention of Acute Respiratory Distress Syndrome in Patients with COVID-19 using (b) (4) ” 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 (b) (4) for the subject initiative. This approval is contingent upon the provision of funding via a modification to the separate Other Transaction Agreement Task Order, W81XWH-20-9-0008. At no time shall the Government’s obligation exceed the funding provided for this RPA. 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-20-9-0008, includes additional time to account for the final negotiations between ATI and (b) (4). This additional time is intended to align the end dates for the Task Order and RPA.

SUBJECT: PAL for 20-09-COVID19-065 for “Treatment and Prevention of Acute Respiratory Distress Syndrome in Patients with COVID-19 using (b) (4)”

SPECIAL CONSIDERATIONS

External reviews and special considerations apply to this Research Project Award including use of human subjects. USAMRDC’s Office of Research Protections, Human Research Protections Office (HRPO) approval must be obtained prior to commencement of any work involving use of human subjects.

PATENT RIGHTS

For this Research Project Award, revisions to Article 10.1 of the base agreement are applied as follows:

The Offeror shall comply with the terms and conditions defined in Article 10: Inventions in the Base Agreement between MTEC and (b) (4) regarding Patent rights.

Patent Rights for work funded by this Agreement shall be substantially the same as FAR 52.227-11 (“Patent Rights – Ownership by the Contractor {May 2014}”), <https://www.acquisition.gov/far/>, which is hereby incorporated by reference with the following modifications. With respect to Patent Rights, the Government acknowledges and agrees that its rights will depend upon its financial contributions. If the Government contributes between 0-49% of the Research Project Award costs, the Government shall obtain a nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced for or on its behalf, for government purposes, throughout the world a subject invention that was first conceived and reduced to practice under this Agreement. If the Government contributes between 50%-100% of the Research Project Award costs, the Government shall obtain the same license rights with the ability to transfer the license for commercial purposes. Nothing in this Agreement transfers any ownership, right, title, or interest, or grants any license from Contractor to the Government in any intellectual property that Contractor owned prior to the Agreement, or in any patent or patent application that Contractor had filed prior to this Agreement. In addition, the following modification to FAR 52.227-11, Subclause (b) “Contractor’s rights” is made.

Patent Rights	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
<p>Compounds and uses of Drug Candidates to treat Covid Induced ARDS – Relevant Patents below:</p> <p>(b) (4)</p> <p>(b) (4)</p> <p>(b) (4)</p> <p>(b) (4)</p> <p>(b) (4)</p> <p>(b) (4)</p>	<p>Previously developed exclusively (b) (4) expense and owned prior to this agreement.</p>	<p>(b) (4)</p>	<p>(b) (4)</p>	<p>None</p>

SUBJECT: PAL for 20-09-COVID19-065 for “Treatment and Prevention of Acute Respiratory Distress Syndrome in Patients with COVID-19 using (b) (4)”

<p>(b) (4)</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>				
<p>New Patents first conceived and reduced to practice under this Agreement</p>	<p>Potential Method of Use intellectual property invented during period of performance</p>	<p>The Government shall obtain a nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced for or on its behalf, for government purposes, throughout the world a subject invention that was first conceived and reduced to practice under this Agreement with the ability to transfer the license for commercial purposes.</p>	<p>(b) (4)</p> <p>[REDACTED]</p>	<p>All</p>

PRE-AWARD COST AUTHORIZATION

The Government has authorized pre-award costs for Research Project Award for (b) (4) (b) (4) proposal 20-09-COVID-19-065 starting 27 May 2020 in an amount not to exceed \$511,166.00. The Government agrees to pay allowable costs accrued in the performance of this Research Project Award starting 27 May 2020 through the end of the period of performance.

SUBJECT: PAL for 20-09-COVID19-065 for “Treatment and Prevention of Acute Respiratory Distress Syndrome in Patients with COVID-19 using (b) (4)”

The total authorized value has been determined fair and reasonable and this proposal has been selected IAW 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) \$5,111,224.00 as follows:

Government Project Funding	ATI Fixed Fee (Gov't Funding)	Total Cost to the Government	Anticipated Non-Federal Contribution	Total Project Cost
\$5,111,224.00	\$0.00	\$5,111,224.00	\$0.00	\$5,111,224.00

Sincerely,

GONZALEZ.JONA
THAN.FORD.1392
612641

Digitally signed by
GONZALEZ.JONATHAN.FORD.
1392612641
Date: 2020.07.27 15:56:30
-04'00'

Dr. Jonathan F. Gonzalez
Agreements Officer

Enclosed:
Statement of Work with Milestones