Appendix 5.1: Statement of Work
Proposal Number: MTEC-20-09-COVID19-078
Organization: Altimmune, Inc.
Title: Use of (b) (4) in the Prevention and Treatment of Ambulatory Patients with COVID-19
ACURO and/or HRPO approval needed: ACURO and HRPO Approval Needed
EGS #: MT20009.078
Altimmune, Inc will provide all FDA communications and documents related to this award for review if requested by SOTR and ORP.

Introduction/Background (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)

The aim of the project is to evaluate (b) (4) strategy for COVID-19 in a Phase 1/2 clinical trial of ambulatory patients with early onset infection. (b) (4) The proposed Phase 1/2 study is anticipated to commence in June 2020. Altimmune has been in active discussions the Office of Vaccines Research and Review (OVRR) at the Center of Biologics Evaluation and Research (CBER) at FDA to expedite an IND (submitted 5 May 2020) for the treatment of COVID-19.

(b) (4)

As a result of the extensive manufacturing, regulatory and clinical experience with the (b) (4), this strategy can be rapidly deployed for COVID-19. (b) (4) .(b) (4)

Scope/Project Objective (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)
This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

The technical objective is to develop an intranasal, single dose immunotherapeutic against COVID-19 and evaluate its clinical safety and efficacy.

Specific objectives are described as follows:

(1) Conduct and completion of an exploratory Phase 1/2 study to evaluate the safety and efficacy of currently available clinical grade vector in approximately 100 COVID-19 patients and sign-off of clinical study report. Outcome of the study will support a Go/No go decision for the product to enter

further clinical development for the treatment of COVID-19.

(2) (b) (4) [redacted] (b) (4) [redacted].

Requirements (To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective).

The technical objective is to develop (b) (4) [redacted] vention against COVID-19 and evaluate its clinical safety and efficacy.

Specific objectives, including tasks to achieve these objectives, are described as follows:

1. Conduct and completion of an exploratory Phase 1/2 study to evaluate the safety and efficacy of currently available clinical grade vector in approximately 100 COVID-19 patients and sign-off of clinical study report. Outcome of the study will support a Go/No go decision for the product to enter further clinical development for the treatment of COVID-19.

1.4-1 IND Acceptance
1.3-1 Phase 1/2 study protocol finalized
1.3-2 HRPO approval received
1.3-3 First patient enrolled
1.3-4 Last patient enrolled
1.3-5 Topline data results drafted
1.3-6 Final Phase 1/2 Study Report

2. Evaluate the innate immune response in relevant animal models. (b) (4) [redacted] (b) (4) [redacted].

1.2-1 Study protocol finalized
1.2-2 ACURO approval received
1.2-3 Study 1 - interim study report
1.2-4 Study 1 – final study report
1.2-5 Study 2 – interim study report
1.2-6 Study 2 – final study report
1.2-7 Study 3 – interim study report
1.2-8 Study 3 – final study report
1.2-9 Study 4 – interim study report
1.2-10 Study 4 – final study report

Deliverables (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)

Milestones	**Deliverable**
Conduct and completion of an exploratory Phase 1/2 study to evaluate the safety and efficacy of currently available clinical grade vector in approximately 100 COVID-19 patients and sign off of clinical study report. Outcome of the study will support a Go/No go decision for the product to enter further clinical development for the treatment of COVID-19.	1. Final Phase 1/2 study report
Evaluate the innate immune response in relevant animal models, to be (b) (4) [redacted]	2. Final study report of experiments 1 through 4

Milestone Payment Schedule (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture))

Altimmune proposes a fixed price milestone payment agreement with the following milestones and associated deliverables:

MTEC Milestone Payment Schedule

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	1.4-1	IND acceptance	6/1/2020	$0	$0	$0
2	1.1-1	Kickoff Meeting Conducted	6/3/2020	$0	$0	$0
3	1.2-1	Study protocol finalized	6/5/2020	$33,928	$0	(b) (4)
4	1.3-1	Phase 1/2 study protocol finalized	6/5/2020	$53,247	$0	(b) (4)
5	1.3-2	HRPO approval received	6/5/2020	$0	$0	$0
6	1.3-3	First patient enrolled	6/29/2020	$973,203	$0	(b) (4)
7	1.1-2	Quarterly Report 1 (June, Technical and Business Reports)	7/25/2020	$0	$0	$0
8	1.2-2	ACURO approval received	8/24/2020	$0	$0	$0
9	1.3-4	Last patient enrolled	8/31/2020	$1,049,122	$0	(b) (4)
10	1.2-3	Study 1 Interim Study Report completed	9/29/2020	$65,312	$0	(b) (4)
11	1.2-5	Study 2 Interim Study Report completed	9/29/2020	$65,312	$0	(b) (4)
12	1.3-5	Topline Data results drafted	10/16/2020	$1,051,295	$0	(b) (4)
13	1.1-3	Quarterly Report 2 (July- Sept., Technical and Business Reports)	10/25/2020	$0	$0	$0
14	1.2-4	Study 1 Final Study Report completed	10/27/2020	$63,578	$0	(b) (4)
15	1.2-6	Study 2 Final Study Report completed	10/27/2020	$63,578	$0	(b) (4)
16	1.2-7	Study 3 Interim Study Report completed	10/28/2020	$73,890	$0	(b) (4)
17	1.2-9	Study 4 Interim Study Report completed	10/28/2020	$73,890	$0	(b) (4)
18	1.2-8	Study 3 Final Study Report completed	11/25/2020	$75,296	$0	(b) (4)
19	1.2-10	Study 4 Final Study Report completed	11/25/2020	$75,296	$0	(b) (4)
20	1.3-6	Final Phase 1/2 Study Report delivered	11/25/2020	$1,008,053	$0	(b) (4)
21	1.1-4	Final Reports (Business and Technical)	12/2/2020	$0	$0	$0
TOTAL				**$4,725,000**		**$4,725,000**

Shipping Provisions (The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)
NOT APPLICABLE

Reporting
Altimmune will prepare the required periodic reporting as stipulated below, and the reporting schedule for this project is listed in the milestone payment schedule above.

Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)

Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)

Appendix 5.2: Data Rights Assertions

Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights.

It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights. If this is not the intent, then the proposal should discuss data rights associated with each item, and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Please indicate your assertion:

☐ Unlimited Data Rights.

☒ Government Purpose Data Rights.

☒ Restricted Government Rights as described below.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Organization Asserting Restrictions	Milestone/ Deliverable Affected
(b) (4)	(b) (4)	(b) (4)	Altimmune	(b) (4)
(b) (4)	(b) (4)	(b) (4)	Altimmune	(b) (4)
(b) (4)	(b) (4)	(b) (4)	Altimmune	(b) (4)
(b) (4)	(b) (4)	Government Purpose	Altimmune	(b) (4)

ALTIMMUNE BACKGROUND PATENT RIGHTS DISCLOSURE
MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM
May 11, 2020

"RAPID AND PROLONGED IMMUNOGENIC THERAPEUTIC"

US Serial No. 61/568,054	Filed 07 December 2011	Expired
US Serial No. 61/454,819	Filed 21 March 2011	Expired
PCT/US2012/029927	Filed 21 March 2012	Completed
US Pat. No. 9,175,310	Filed 21 March 2012	Granted (03 Nov. 2015)
US Pat. No. 9,605,275	Filed 30 December 2013	Granted (28 March 2017)
US Serial No. 16/206,211	Filed 30 Nov 2018	Pending

"CORONAVIRUS IMMUNOGENIC COMPOSITIONS AND USES THEREOF"

US Serial No. 62/977,078	Filed 14 Feb 2020	Pending
US Serial No. 62/992,553	Filed 20 March 2020	Pending
US Serial No. 63/005,923	Filed 06 April 2020	Pending
US Serial No. 63/016,902	Filed 28 April 2020	Pending