



**DEPARTMENT OF THE ARMY  
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY  
PICATINNY ARSENAL, NEW JERSEY 07806-5000**

REPLY TO  
ATTENTION OF

01 September 2020

Army Contracting Command – New Jersey  
ACC-NJ, Building 9  
Picatinny Arsenal, NJ 07806

**SUBJECT:** Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-04, Objective TRE-20-04, Definitization of “Treatment of COVID-19 Using Convalescent Plasma and (b) (4) Anti-SARS-CoV-2 Immune Globulin” (Grifols Therapeutics, LLC)

**REF:** Request for Updated Proposal Submitted in Response to RPP 20-04 under OTA W15QKN-16-9-1002 for Objective TRE-20-04, dated 06 April 2020

Advanced Technology International  
ATTN: (b) (6), Sr. Contracts Manager  
315 Sigma Drive  
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-04 on 19 March 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Grifols as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Grifols to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 07 April 2020, and reviewed the costs and documentation accordingly. Based on the acceptable ROM proposal update, the Government issued an Undefinitized Project Action (UPA) on 08 April 2020. In order to definitize the UPA, the Government finalized an analysis of the cost proposal on 31 August 2020, which focused on evaluation of the cost components and documentation. Based upon the acceptable update of Grifols’ proposal for “Treatment of COVID-19 Using Convalescent Plasma and (b) (4) Anti-SARS-CoV-2 Immune Globulin” and 1) The Project Agreement Recipient’s concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The Cost Proposal that has been analyzed and negotiated final by the Government, you are hereby directed to issue a Definitized Project Agreement to Grifols for the subject project. The total project value has been determined fair and reasonable and Grifols’ proposal has been selected IAW the above referenced Basis of Selection

The total approved cost to the Government for this effort is not to exceed (b) (4) [REDACTED]. The break-out of the costs is as follows: \$12,332,250.00 to perform project efforts included in the SOW and \$(b) (4) [REDACTED] for the Consortium Management Firm Administrative Cost. The effort is fully funded.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

In addition, ATI is advised of the implementation guidance for Section § 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year 2019 (Pub. L. 115–232), which prohibits executive agencies from entering into, extending, or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. While the interim rule and Defense Pricing and Contracting (DPC) implementation memorandum are directed to FAR-based contracts, the § 889(a)(1)(B) prohibition went into effect August 13, 2020, and applies to Other Transactions (OTs) for Prototype Projects under § 2371b of title 10, United States Code (U.S.C.). Any OT for Prototype Project agreement on or after August 13, 2020 must contain an article for the Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment that requires the offeror to represent if it uses any equipment, system, or service that uses covered telecommunications equipment or services.

ATI must receive § 889(a)(1)(B) Certification from the MCDC member prior to executing any new project agreements or modification to an existing project agreement. A copy of the certification should be provided to the undersigned.

**Points of Contact:**

Agreements Specialist:

(b) (6) [REDACTED]

E-mail: (b) (6) [REDACTED]

Phone: (b) (6) [REDACTED]

Agreements Officer:

(b) (6) [REDACTED]

E-mail: (b) (6) [REDACTED]

Phone: (b) (6) [REDACTED]

Regards,

X (b) (6)

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(b) (6)  
Agreements Officer

Signed by: (b) (6)

Attachments:

Attachment 1: Encl 3\_Grifols Finalized SOW (August 24 2020) - FINAL

**Statement of Work  
For  
Treatment of COVID-19 Using Convalescent Plasma and  
(b) (4) Anti-SARS-CoV-2 Immune Globulin (IG)**

**RPP #:** 20-04

**Project Identifier:** MCDC2004-008

**Consortium Member:** Grifols Therapeutics LLC

**Title of Proposal:** Treatment of COVID-19 Using Convalescent Plasma and (b) (4) Anti-SARS-CoV-2 Immune Globulin

**Requiring Activity:** Health and Human Services (HHS), Biomedical Advanced Research and Development Activity (BARDA)

## **1.0 INTRODUCTION, SCOPE, AND OBJECTIVES**

The focus of this project is on the plasmapheresis of Coronavirus Disease 2019 (COVID-19) convalescent donors, production of (b) (4) anti-SARS-CoV-2 (severe acute respiratory syndrome-coronavirus-2) immune globulin, and viral inactivation of convalescent plasma for (b) (4). The objective of this project is to rapidly advance treatment for COVID-19 in the clinic, based on polyclonal antibodies. Previous data indicates that polyclonal antibody treatments can be efficacious against COVID-19 with rapid clinical recovery. Production of a polyclonal antibody product with (b) (4) to COVID-19, is sought to be manufactured under Good Manufacturing Practices (GMP) and advanced to a COVID-19 efficacy study, likely through the National Institutes of Health (NIH) / National Institute of Allergy and Infectious Diseases (NIAID), or other adaptive randomized controlled study. This first-in-kind prototype must be produced at levels sufficient (b) (4) with scalable production (b) (4).

### **1.1 Introduction**

Following the global spread of COVID-19, the US Government has been working feverishly to, among other things, identify potential therapeutic candidates to address the pandemic. According to many estimates, upwards of 50% of the US population may become infected with COVID-19 in the coming weeks and months. With a hospital admissions rate of approximately 5%, and a mortality rate reported to be close to 1%, this disease presents an existential challenge to the US healthcare system and many other social institutions. Without adequate available testing, an effective vaccine or therapeutic, every effort must be taken to blunt the impact of the disease. This includes the development of clinical therapeutics that can be used to treat those suffering in extremis, to include the warfighter.

Using expertise and resources gained in connection with previous emerging virus outbreaks, such as the 2014 Ebola epidemic in West Africa, Grifols will collaborate with the US Food and Drug Administration (FDA) and NIH/NIAID to develop for clinical application, two (2) therapeutic approaches to COVID-19 that depend on the identification and plasmapheresis of individuals who have been infected with, and recovered from, COVID-19. The two (2) therapeutic approaches include, (1) the direct transfusion of human source plasma from convalescent donors after viral inactivation (b) (4), and (2) the administration of a (b) (4) Immune Globulin (IG) produced from convalescent donors, that is rich in SARS-CoV-2 antibodies.

With a network of more than 250 plasma donor centers in the US, Grifols will be responsible for COVID-19 convalescent donor screening and plasmapheresis, in accordance with relevant FDA guidelines and

GMP requirements. Similarly, with its vast experience in plasma fractionation and polyclonal IG production, Grifols will assume responsibility for the (b) (4) fractionation of convalescent plasma obtained from donors. Donor identification and referral will be performed (b) (4)

The goal of this project is to develop sufficient human subjects data which, if demonstrative of a clinically meaningful benefit to patients suffering with COVID-19, can be used to support the administration of these two (2) approaches in a more routine clinical setting. (b) (4)

As drafted, this scope of work assumes that Grifols bears responsibility for performing plasmapheresis of convalescent donors and either performing viral inactivation (b) (4) of plasma for transfusion or using that plasma to produce a (b) (4) anti-SARS-CoV-2 IG.

If successful, the availability of treatments derived from convalescent donor plasma, such as plasma for transfusion and (b) (4) anti-SARS-CoV-2 IG, can offer viable treatment options that can help maintain continuity of Government, military readiness, and front-line healthcare providers. As the number of COVID-19 cases in the US continues to grow exponentially, and healthcare systems already report strained resources, it is essential to move quickly to advance the development of treatments from convalescent donor plasma. By lending its expertise in GMP compliant plasma collection and production, Grifols offers the US perhaps the most expedient route to test these promising therapeutics.

## 1.2 Scope

The scope of this project as it relates to Grifols, consists of performing plasmapheresis of prescreened COVID-19 convalescent donors, and the subsequent production of a (b) (4) IG from that plasma. It also includes the collection and storage of COVID-19 convalescent plasma for transfusion following viral inactivation (b) (4). In its entirety, this project proposes a collaborative among Grifols, the FDA, NIH/NIAID, and the CDC, with a funding mechanism coordinated through the Biomedical Advanced Research and Development Authority (BARDA). Each member in the collaborative has predefined roles, with the ultimate objective of producing clinical therapeutics to treat COVID-19 infection.

The duration of the prototype project is not yet fully determined. However, pursuant to this agreement, Grifols agrees to make available for a period of not more than (b) (4), its plasma collection infrastructure and (b) (4) production facility in Clayton, North Carolina, to support National efforts to combat COVID-19 infection. Similarly, Grifols agrees to make available its (b) (4) virus inactivation technology for plasma, for transfusion to support the same objective of combating COVID-19 infection. Availability of Grifols plasma collection infrastructure, (b) (4) production facility, and (b) (4), is dependent on the demand for such products, as stated by US national authorities, including FDA, NIH/NIAID, CDC and others.

The initial term for this agreement is (b) (4), subject to extension by mutual consent. This agreement notwithstanding, nothing contained herein gives the US any ownership or interest in Grifols or its assets. Further, this agreement does not confer to the US any right to demand performance under this agreement in any respect and in particular, not to the detriment of Grifols day-to-day operations, except insofar as Grifols and the US mutually agree.

### 1.3 Objective

The objective of this project is to utilize Grifols expertise in plasma collection and manufacturing to provide virally in-activated convalescent plasma for transfusion, (b) (4) and (b) (4) anti-SARS-CoV-2 IG, for use in the clinical setting to combat the deadly effects of the COVID-19 pandemic.

Grifols will deploy its deep expertise and vast resources to support the collection of plasma from convalescent donors, from among any number of its existing FDA licensed plasma donor centers. Further, using (b) (4) production facility that operates under GMP, Grifols will produce (b) (4) anti-SARS-CoV-2 IG, using as the basis for its production methodology, the FDA licensed processes for manufacture of its commercially licensed polyvalent IG therapies.

The deliverables for this project include (b) (4) anti-SARS-CoV-2 IG ready for infusion in the clinical setting, and virally inactivated convalescent plasma ready for transfusion.

Initial performance timelines include:

- Providing virally inactivated (b) (4) convalescent plasma for transfusion (b) (4) as needed, beginning with a target start date of (b) (4).
- Clinical study support through, among other things, providing at least (b) (4) final maximum doses of (b) (4) anti-SARS-CoV-2 IG delivered to clinical study sites, with a target start date of (b) (4).

This is a prototype project because Grifols will develop virally inactivated convalescent plasma for transfusion (b) (4), and (b) (4) anti-SARS-CoV-2 IG, in order to evaluate the technical feasibility of using the treatment to combat COVID-19 infection and determine clinical efficacy. This first-in-kind prototype must be produced at levels sufficient to treat (b) (4), in order to ensure both (b) (4) feasibility.

In accordance with 10.U.S.C. §2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. *Currently, the extent of any follow-on production is not known.* This prototype project will be successfully completed if Grifols meets the key technical goals of the project, meets the success metrics established by this agreement or unilaterally by the Government for this project, or at the accomplishment of particularly favorable or unexpected results that justify transition to production. More specifically, this prototype project will be successfully completed if Grifols meets the initial production and timeline goals for this project, while demonstrating continuing proficiency in plasmapheresis of COVID-19 convalescent donors, and ongoing (b) (4) production of (b) (4) anti-SARS-CoV-2 IG.

If there is a conflict between the Project Agreement and the Base Agreement, the Project Agreement language will supersede and control the relationship of the parties.

### 2.0 APPLICABLE REFERENCES

- US Code of Federal Regulations Title 21, Sections applicable to Source Plasma collection, including Part 640.
- Currently in force and applicable FDA Blood Guidance documents.

- *Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies*, FDA Guidance, August 2006.
- Patent Application No (b) (4) filed (b) (4).

### 3.0 REQUIREMENTS

#### 3.1 Plasmapheresis of Convalescent COVID-19 Plasma Donors

Convalescent COVID-19 plasma will be obtained from individuals referred to Grifols for plasmapheresis at one of the Grifols network of US FDA licensed plasma donor centers. Individuals that requisite screening processes will undergo plasmapheresis (the donor may return multiple times). The resulting plasma donations will have samples drawn for any testing determined necessary for the convalescent COVID-19 program. Plasma donations will then be frozen to a core temperature of (b) (4) within (b) (4) hours and stored at (b) (4) until they are released and shipped to the (b) (4) that is US FDA licensed.

Once at the (b) (4), plasma donations will be placed into inventory and stored at (b) (4) until they are requested for further manufacture into anti-SARS-CoV-2 IG or requested for (b) (4) viral inactivation. Please refer to the following flowchart showing the potential process of convalescent plasma collection from individuals who have recovered from COVID-19 and are referred to a Grifols donor center.

(b) (4)

(b) (4)

[Redacted content]

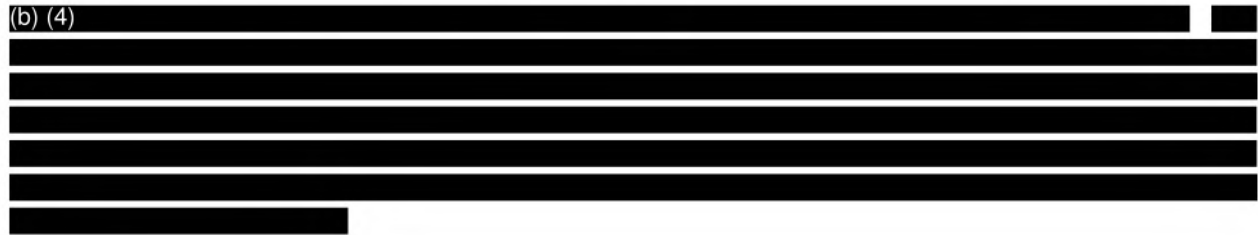
(b) (4)

[Redacted content]



3.2 Viral Inactivation of Convalescent Plasma (b) (4)

(b) (4)

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(b) (4)

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### 3.3 Production of Anti-SARS-CoV-2 IG

(b) (4) [Redacted text block]

[Redacted text block]

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[Redacted]	[Redacted]	[Redacted]	[Redacted]

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(b) (4)

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(b) (4)

(b) (4)



(b) (4)

(b) (4)

### **3.4 Regulatory Planning**

Collection of COVID-19 convalescent plasma will be done in accordance with FDA guidance, entitled *Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies*, August 2006. (b) (4) anti-SARS-CoV-2 IG will be produced under GMP, and in accordance with the protocols employed for the production of Grifols currently licensed polyclonal IG products. This work will be performed in accordance with the requirements of 21 CFR 640.

### **3.5 Clinical Trial Planning**

Currently, it is expected that clinical trial planning will be the responsibility of NIH/NIAID. However, if the responsibility for clinical trial planning falls to Grifols, the costs and timelines associated with this scope of work, will likely increase. Grifols has deep expertise in clinical trial planning and management, in connection with a number of licensed therapeutics. While these resources and expertise can be brought to bear on this project, it is not anticipated in this scope of work.

### **3.6 Regulatory Execution**

Currently, it is expected that regulatory execution will be the responsibility of NIH/NIAID. However, if the responsibility regulatory execution falls to Grifols, the costs and timelines associated with this scope of work, will likely increase. Grifols has deep expertise in regulatory execution and clinical trial management, in connection with a number of licensed therapeutics. While these resources and expertise can be brought to bear on this project, it is not anticipated in this scope of work.

### **3.7 Clinical Trial Execution**

Currently, it is expected that clinical trial execution will be the responsibility of NIH/NIAID. However, if the responsibility of clinical trial execution falls to Grifols, the costs and timelines associated with this scope of work, will likely increase. Grifols has deep expertise in clinical trial execution and management, in connection with a number of licensed therapeutics. While these resources and expertise can be brought to bear on this project, it is not anticipated in this scope of work.

### **3.8 Clinical Trial Close Out**

Currently, it is expected that clinical trial close out requirements will be the responsibility of NIH/NIAID. However, if the clinical trial close out requirements fall to Grifols, the costs and timelines associated with this scope of work, will likely increase. Grifols has deep expertise in clinical trial close out requirements, in connection with a number of licensed therapeutics. While these resources and expertise can be brought to bear on this project, it is not anticipated in this scope of work

### **3.9 Management and Reporting**

Management and reporting requirements will be mutually agreed upon among the project collaborators, i.e., Grifols, FDA, NIH/NIAID and CDC. It is anticipated that there will be a weekly management oversight teleconference among the collaborators to review:

- (b) (4) [REDACTED]
- (b) (4) [REDACTED]
- (b) (4) [REDACTED]

Each party will designate the appropriate representatives to participate on the weekly management oversight call. Minutes and action items from the management oversight calls will be recorded and circulated among the participants. Financial reporting will be done (b) (4) [REDACTED] and submitted to BARDA in a manner consistent with the requirements of this agreement.

### **3.10 Mandatory Reporting**

**Quarterly Reports:** The MCDC 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 MCDC Base Agreement.

**Annual Technical Report:** The MCDC awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one (1) year, in accordance with the terms and conditions of the MCDC Base Agreement. This may be combined with the concurrent quarterly report.

**Final Technical Report:** At the completion of the project, the MCDC 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, in accordance with the terms and conditions of the MCDC Base Agreement. Once the MCDC management firm has informed the MCDC awardee that the Final Technical Report has been approved by the Government, the MCDC awardee shall forward a copy to the Defense Technical Information Center, Attn. DTIC-O, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.

**Final Business Status Report:** At the completion of the project, the MCDC awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the project, in accordance with the terms and conditions of the MCDC Base Agreement.

#### 4.0 DELIVERABLES

Project deliverables include:

- Providing virally inactivated (b) (4) convalescent plasma for transfusion to clinical sites, as needed.
- Providing (b) (4) anti-SARS-CoV-2 IG to clinical study sites, as needed.
- Access to and right to use all (b) (4) administration of the virally inactivated (b) (4) convalescent plasma for transfusion
- Access to and right to use all (b) (4) administration of (b) (4) anti-SARS-CoV-2 IG.

Dates for project deliverables will be changed by mutual agreement of the Project Agreement Holder and the Government. Changes will be incorporated by modification to the agreement.

#### Deliverables

Deliverable Title	Format	Deliverable Schedule
Regular teleconferences	BARDA and Contractor to determine format	Conducted at a frequency to be agreed by the Contractor and BARDA
Meeting agenda and minutes for teleconferences	Contractor-determined format	Agenda – At least 1 day before teleconference; Minutes – Within 5 days of teleconference (COR may request edits to content)
Quarterly reports	MCDC-determined format	Quarterly, by end of month trailing close of quarter (not required in a month where an Annual Report is also due)
Annual reports	MCDC-determined format	Annually, by end of month trailing close of year
Final Technical and Business reports	MCDC-determined format	Within 30 days after provision of final material

Updates on (b) (4)	Contractor-determined format	Provided at a frequency to be agreed by the Contractor and BARDA
Manufacturing updates (b) (4)	Contractor-determined format	Provided at a frequency to be agreed y the Contractor and BARDA
Clinical updates (b) (4)	Contractor-determined format	Provided at a frequency to be agreed y the Contractor and BARDA
Manufacturing Reports (b) (4)	Contractor-determined format	Within 5 days of request by COR
Analytical Protocols	Contractor-determined format	Within 5 days of request by COR
Analytical Reports	Contractor-determined format	Within 5 days of request by COR
Validation Protocols	Contractor-determined format	Within 5 days of request by COR
Validation Reports	Contractor-determined format	Within 5 days of request by COR
Quality Agreements with Subcontractors	Contractor-determined format	Within 5 days of request by COR
Fill / Finish Reports	Contractor-determined format	Within 5 days of request by COR
Incident Reports	Contractor-determined format	Notification of incident within one week
Regulatory Submissions to FDA (e.g., meeting requests, briefing books, draft minutes, DMFs, IND, BLAs, etc.)	Contractor-determined format	Draft – As agreed to by the COR Final – Within one week after submission to FDA
Regulatory correspondence from FDA (e.g., meeting confirmations, preliminary responses, final meeting minutes, notifications)	Contractor-determined format	Within one week of receipt from FDA
Attendance at FDA Meetings	FDA-determined format; BARDA allowed to have at least three (silent) attendees	Attendance/dial-in information provided upon meeting confirmation from FDA
Information supporting Emergency Use Authorization (EUA) Request	BARDA-determined format	As agreed to by COR
Press Releases based on BARDA-sponsored activities	Contractor-determined format, with acknowledgement of BARDA funding	Draft – As agreed to by the COR
(b) (4) of pathogen-inactivated convalescent plasma made available for clinical use	Contractor-determined format	As agreed to by COR (precise date pending finalizing clinical development program).
(b) (4) of hyperimmune globulin (final drug product) made available for clinical use	Contractor-determined format	By (b) (4)

## 5.0 MILESTONE PAYMENT SCHEDULE

The below payment schedule reflects a fully fixed pricing structure for all portions of the project. The payment schedule contemplates fixed pricing for the startup expenses, manufacture of anti-SARS-CoV-2



hyper immune globulin, viral inactivation of convalescent plasma with (b) (4), and project management expenses.

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	Project Kick-Off	(b) (4)	\$0
5.2	Quarterly Technical and Business Status Report	(b) (4)	\$(b) (4)
5.3	Annual Technical and Business Status Report; (b) (4)	(b) (4)	\$(b) (4)
5.4	Quarterly Technical and Business Status Report; (b) (4)	(b) (4)	\$(b) (4)
5.5	Quarterly Technical and Business Status Report; (b) (4)	(b) (4)	\$(b) (4)
5.7	Final Technical and Business Status Report; (b) (4)	(b) (4)	\$(b) (4)
<b>Total (FFP):</b>			<b>\$12,332,250</b>
<b>Period of Performance:</b>			<b>(b) (4)</b>

## 6.0 SHIPPING PROVISIONS

Currently, no shipping provisions have been determined. It is anticipated that if a clinical trial is initiated, a third-party Contract Research Organization (CRO) will be engaged by the Investigational New Drug (IND) holder to manage shipping of clinical therapeutics to clinical trial sites. At that time, shipping details for the clinical therapeutic will be identified, and can be recorded.

The contractor shall submit Quarterly, Annual, and final reports in accordance with the Base Agreement to deliverables.mcdc.ati.org.

A copy of all data deliverables shall be sent to:

[usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil](mailto:usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil).

## 7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

Unless specified otherwise in this agreement, no party relinquishes rights to any background patents to any other party under this agreement. Additionally, no party to the awarded agreement shall enter into an agreement with any contract manufacturer or other third party whereby the third party will obtain rights in Subject Inventions or Subject Data, as those terms are defined in Other Transaction Agreement number W15QKN-16-9-1002, absent the mutual consent of the parties to the awarded agreement.

Any Subject Invention<sup>1</sup> that is Made by a party under this agreement will be owned by the party having Made the invention. For each Subject Invention Made solely by the Contractor, the Government will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. For any Subject Invention Made solely by the Government, the Contractor will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention or allow a third party to practice the invention for any purpose.

For each Subject Invention Made solely by the Contractor, the Contractor shall provide the Government a (b) (4)

. For each Subject Invention Made solely by the Government, the Government shall provide the Contractor a (b) (4)

for purposes of FDA licensure of the technology described herein, limited to the field of use described in the product indication, subject to a termination terms substantially similar to the events described below:

(b) (4)

of first refusal for an exclusive license to the subject joint invention upon terms identified above.

(b) (4)

<sup>1</sup> “Subject Invention” is hereby redefined as “any invention of the Government, PAH, or developed jointly by the parties, that was conceived or first actually reduced to practice in the performance of work under this Agreement.”

(b) (4)

If there is a conflict between this Section and Article X of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article X of W15QKN-16-9-1002, those sections remain operative.

Subject Data (defined as Technical Data under Article XI, §A(13), generated, directly or indirectly, related to the work performed under this agreement) shall be jointly owned by the Parties. Notwithstanding the foregoing, Contractor and Government shall have joint ownership of any and all data related to the donation of plasma which shall include but not be limited to (b) (4)

, Contractor and third party shall jointly own all Subject Data. Each party, including the third party, upon request to the other party, shall have the right to review and to request delivery of all Subject Data, and delivery shall be made to the requesting party (b) (4), except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party. All Deliverables, as described in the Deliverable Table within the Statement of Work, or mentioned elsewhere in this document, are considered Subject Data under this agreement.

Neither Party, as the Receiving Party, shall, directly or indirectly, divulge or reveal to any person or entity any confidential information of the other Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this agreement.

Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this agreement; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. FDA and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected this agreement will result in the FDA clearance and commercialization of product(s) (the "Technology"). The awardee may be the Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) pre-market notification filing (510(k) or another regulatory filing submitted to FDA) that controls research under this agreement. If the awardee is the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), they have certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

## **8.0 SECURITY**

The security classification level for this effort is UNCLASSIFIED.

## **9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)**

Grifols adheres to all relevant safety and environmental control laws and regulations in the jurisdictions where it operates. Further, work performed under or in accordance with this Statement of Work, shall be covered by the Secretary of Health and Human Services Declaration effective February 4, 2020, issued pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), to provide liability immunity for activities related to medical countermeasures against COVID -19 caused by SARS-CoV-2 or a virus mutating therefrom (the “Declaration”). Grifols, being a covered entity as defined by the Declaration, and engaging in countermeasures against COVID -19 caused by SARS-CoV-2 or a virus mutating therefrom, shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by any countermeasure developed by Grifols, as outlined in this scope. Per the Secretary of Health and Human Services, the Declaration shall be effective February 4, 2020, and shall cover Grifols through and including October 1, 2024.

#### **10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION**

Insofar, as this is a collaborative undertaking, involving multiple Government agencies in a variety of capacities, including as regulatory authority, as research coordinator, and testing service provider, it is not feasible to anticipate the many types of property/material/information that will be exchanged among and between the parties. As such, the provisions of this section will be developed as the project advances, and the roles and responsibilities of the various parties are better understood.

#### **11.0 AGREEMENTS OFFICER’S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION**

##### **AOR**

**NAME:** (b) (6)

**EMAIL:** (b) (6)

**PHONE:** (b) (6)

**AGENCY NAME/DIVISION/SECTION:** HHS/BARDA