PERSONAL PROTECTIVE EQUIPMENT (PPE) DECONTAMINATION SERVICES AGREEMENT

WHEREAS, on March 12, 2020, the World Health Organization declared COVID-19 a pandemic. On March 13, 2020, the President of the United States declared a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak;

WHEREAS, the Food and Drug Administration on March 29th, 2020 issued an Emergency Use Agreement ("EUA") authorizing Battelle Memorial Institute to operate the Battelle Critical Care Decontamination System (CCDS)™ for use in decontaminating compatible N95 or N95-equivalent respirators ("compatible N95 respirators") for reuse by healthcare personnel (HCP)[1] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of Filtering Facepiece Respirators (FFR) during the COVID-19 pandemic;

WHEREAS, on April 10th, 2020 the Defense Logistics Agency, under authority of 10 U.S.C. 2304(c)(2), FAR Part 6.302-2, issued a contract to Battelle Memorial Institute to operate the CCDS™, in accordance with conditions of the EUA, to decontaminate compatible N95 respirators at site locations throughout the United States as directed by the U.S. Government (the "DLA Contract"). Under this program, qualifying customers can submit qualifying PPE to be decontaminated at a Battelle approved facility without cost to the customer;

WHEREAS, Client and Battelle acknowledge and understand that the provision of these services is intended to be within the scope of the Public Readiness and Emergency Preparedness Act ("PREP Act") and the PREP Act COVID-19 declaration by the U.S. Department of Health and Human Services, effective as of February 4, 2020;

WHEREAS, the EUA directs and requires Battelle to enter into agreements with customers requesting decontamination of compatible N95 respirators prior to providing such services to the facility; and

THEREFORE, now comes Battelle and Webb County (and at Client's option, its affiliates and/or subsidiaries) ("Client"), referred to herein individually as a "Party" and collectively as the "Parties", to set forth the terms and conditions under which a customer can elect to participate in this program.

1. DURATION OF AGREEMENT

This Agreement shall begin upon execution and last indefinitely until any one of the following occurrences:

a) The Client notifies Battelle in writing that it no longer wishes to participate in the program;
b) The DLA Contract under which this program operates expires or is terminated by the US Government;
c) The US Government directs Battelle to no longer operate at the site location used by Client and an alternate location is not available;
d) The EUA is revoked by the FDA pursuant to Section 564(b)(2) of the Federal Food, Drug, and Cosmetic Act;
e) The participating healthcare facility violates the terms and conditions of this agreement, or any applicable US law or regulation governing this program, or whose status changes so that it no longer qualifies as an eligible healthcare facility; or
f) Funding of the program is exhausted and is not available to continue processing N95 respirators.

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[1] Healthcare personnel ("HCP") refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel.

g) Battelle may terminate this agreement at its convenience for any reason.
h) Battelle is unable to continue to process PPE for decontamination due to a force majeure event as described in Section 9 below.

Battelle will notify Client upon occurrence of any of the preceding events as soon as practical. In no event will Battelle be responsible to process PPE submitted by Client after occurrence of any of the preceding events regardless of Client's expectations or reliance on the program. Battelle will not be liable for any costs of substitute decontamination services sought by Client subsequent to the end of this program.

2. SERVICES PROVIDED

Battelle will provide decontamination services to Client for hospital Personal Protective Equipment (PPE), limited to the PPE approved by the FDA as set forth in EUA for decontamination processing. Battelle will receive and store contaminated PPE prior to decontamination. Battelle will decontaminate and repackage PPE. Battelle will deliver a chain of custody form (or equivalent) indicating conditions of the decontamination implementation process in addition to chemical indicators which will be used to qualify each decontamination cycle will be provided for each decontamination cycle performed for all PPE upon retrieval. Battelle will comply with the terms and conditions of the EUA. If Client wishes to have Battelle assist in the transportation of PPE to and from Client, Client can request such assistance. In response, and at Battelle's sole discretion, Battelle may provide a subcontractor to coordinate transportation of PPE to and from the Battelle approved decontamination facility to Client location. These services will be provided to the Client at no cost.

3. CLIENT'S RESPONSIBILITIES

a. Client will be responsible for preparing PPE for transportation in the manner described in the instructions provided to Client

b. Client shall make available to HCP who are or may be using the decontaminated respirators the authorized Fact Sheet for Healthcare Personnel that is required to be provided by Battelle.

c. Client shall monitor HCP who use such respirators for the signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to Battelle, so that Battelle can provide a weekly report to FDA. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

d. Client shall inspect the decontaminated respirators upon receipt from Battelle. Any discoloration or other signs of degradation with a decontaminated respirator should promptly be reported to Battelle, and the healthcare facility should dispose of such respirator.

e. The maximum number of times a N95 respirator can undergo the decontamination cycle is twenty (20) and the Client shall not submit N95 respirators that have reached this limit for decontamination.

f. Client shall provide Battelle with a complete list of all subsidiaries and/or affiliates who utilize Services provided for in this Agreement. Client is responsible for obtaining a three-digit site code for each Client location that will be utilizing the Services provided for in this Agreement.

g. Client shall make the literature listed in Section 4 below available to all subsidiaries and/or affiliates who utilize the Services provided for in this Agreement.

h. Client shall certify that the personnel benefiting from the use of the Services herein are Healthcare Personnel as provided for in the EUA.

4. RECEIPT OF LITERATURE

Client acknowledges that it has received the following literature from Battelle related to this program.

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System ("Instructions for Healthcare Personnel");

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System ("Instructions for Healthcare Facilities"); and

- Labeling and instructions for use developed by Battelle that include the Fact Sheet, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities.

5. WARRANTY AND LIMITATION OF LIABILITY

ALL SERVICES ARE PROVIDED TO CLIENT AS-IS. BATTELLE MAKES NO OTHER WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR FOR ANY PARTICULAR RESULT.

Notwithstanding any other provision of this Agreement to the contrary, in no event shall either Party be liable to the other for any indirect, incidental, special, punitive, or consequential damages, arising from or in connection with this Agreement and regardless of the cause of action or theory of law asserted.

In no event shall Battelle's maximum cumulative liability, regardless of the cause of action or theories of law asserted, exceed the total amount paid by Client to Battelle under this Agreement.

6. LIABILITIES

Each Party agrees to be responsible for any liability, claim, loss, damage or expenses, including without limitation, reasonable attorney fees, arising from its negligent acts or omissions in connection with its performance of this Agreement, or its failure to comply with the terms of this Agreement, as determined by a court of competent jurisdiction.

7. COMPLIANCE WITH LAWS

The Parties agree to comply with all laws and regulations applicable to the performance of their respective obligations under this Agreement, including those related to export control, and neither Party shall export nor re-export any tangible goods, service or information related to this Agreement without first obtaining any required export licenses or other governmental approvals, if required by law. Each Party is responsible for its own compliance with this provision.

8. NON-ENDORSEMENT AND USE OF NAME

Client agrees that it will not use or imply Battelle's name or marks, or use Battelle's reports, for advertising, promotional purposes, raising of capital, recommending investments, or in any way that implies endorsement by Battelle without Battelle's prior written approval.

9. FORCE MAJEURE

Neither Client nor Battelle shall be liable for any expenses, losses or damages (except payment of monetary obligations) resulting from delay or failure to perform caused by acts beyond the control of the Party delayed or unable to perform including, without limitation, acts or failure to act of government, war, acts of terror, civil unrest, extreme weather conditions, and pandemics (a "Force Majeure Event"). In the event of any delay or failure to perform occasioned by the foregoing, the time for performance will be extended by a period of time equal to the time lost by reason of such delay or failure to perform and any other affected provision(s) of the Agreement including, without limitation, price, shall be equitably adjusted provided that the Party delayed or unable to perform provided the other Party with written notice of the occurrence and impact of the Force Majeure Event.

10. MISCELLANEOUS

Each Party is, at all times, acting as an independent contractor under this Agreement and not as an agent, employee, joint venturer or partner of the other.

This Agreement may not be assigned in whole or in part without the prior written consent of both Parties, which shall not be unreasonably withheld or delayed. This Agreement shall be binding upon, inure to the benefit of, and be enforceable by and against the successors and permitted assigns of each Party.

Battelle makes no commitments with regards the time necessary to complete the decontamination process once PPE is received from the Client. Processing time will be dependent on the amount of PPE received from numerous health care providers.

The failure by one Party to require performance of any provision or to exercise any right, remedy or option available under this Agreement shall not affect that Party's right to require performance or to exercise such right, remedy or option at any time thereafter, nor shall a waiver of any breach or default of this Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

If any part of this Agreement shall be held invalid or unenforceable, such invalidity or unenforceability shall not affect any other part of this Agreement.

This Agreement may be modified or amended only by mutual agreement in writing. Battelle may require additional conditions of participation at any time in order for client to continue participation. No course of dealing, usage of trade, waiver, or non-enforcement shall be construed to modify or otherwise alter the terms and conditions of this Agreement.

This Agreement represents the entire agreement of the Parties and supersedes any prior discussions or understandings, whether written or oral, relating to the subject matter hereof and neither Party makes any representations other than as expressly set forth in this Agreement. In the event of any conflict or inconsistency between these terms and conditions and those of any Task Order, these terms and conditions shall control.

This Agreement shall be construed in accordance with the laws and enforced within the jurisdiction of the State of Ohio, without regard to its conflicts of law principles.

Clauses 5, 6, 7, 8, 9, and 10 shall survive termination or expiration of this Agreement.

IN WITNESS WHEREOF, the terms and conditions of this agreement are accepted by Client.

BATTELLE MEMORIAL INSTITUTE

CLIENT

BY:  BY: Katelyn Murwin

NAME: Tano E. Tijerina NAME: Katelyn Murwin

TITLE: Webb County Judge TITLE: Contracts Representative

DATE: June 9, 2020 DATE: 05/22/2020

CLIENT INFORMATION (REQUIRED):

ADDRESS: 1000 Houston Street, 3rd Floor

CITY: Laredo

STATE: Texas

ZIP: 78040

PHONE: 956-523-4600

EMAIL: judge_tano@webbcountytx.gov

ATTESTED:

Margie Ramirez-Ibarra
Webb County Clerk

APPROVED AS TO FORM:

Nathan R. Bratton
General Counsel
Webb County Civil Legal Division *

*The General Counsel, Civil Legal Division's office, may only advise or approve contracts or legal documents on behalf of its clients. It may not advise or approve a contract or legal document on behalf of other parties. Our review of this document was conducted solely from the legal perspective of our client. Our approval of this document was offered solely for the benefit of our client. Other parties should not rely on this approval, and should seek review and approval of their own respective attorney(s).

Passed and approved by the Webb County Commissioners Court On June 8, 2020; item no. 29.

BATTELLE

Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (hereafter referred to as the "Battelle Decontamination System") operated by the Battelle Memorial Institute ("Battelle"), for use in decontaminating compatible N95 or N95-equivalent respirators ("compatible N95 respirators"), for reuse by healthcare personnel. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by Battelle using the Battelle Decontamination System.

- **Due to incompatibility, the Battelle Decontamination System is not authorized for use with respirators containing cellulose-based materials**
- **All compatible N95 respirators provided to Battelle must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup)**
- **If N95 respirators are soiled or damaged, they will be disposed of and not returned after decontamination**

On-Site Collection/Marking

1. Your organization should create a collection station at the point of generation (i.e. hospital floor/unit)
2. Each station should have a bag provided by the healthcare facility to collect compatible N95 respirators. **NOTE: Bags are for compatible N95 respirators only. Do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.**
3. With a permanent marker, the healthcare personnel should label their own individual compatible N95 respirators with a three-digit site code and a 2-digit location identifier (as shown below). The unique site code corresponds to the healthcare facility delivery address and will be assigned by Battelle. Your organization may designate the location identifier to correspond to a specific location/floor/unit within your site.
4. Healthcare personnel should follow the instructions provided by Battelle in Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination.

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Site Code (Assigned by Battelle Point Of Contact) **Site Location ID** (Assigned by Healthcare Facility)

Preparation for Shipment:

1. Bags containing the contaminated compatible N95 respirators to be decontaminated by Battelle ("primary collection bag") should be closed.
2. Place the primary collection bag into another bag ("secondary collection bag") (provided by the healthcare facility), which is then closed.
3. Decontaminate the secondary collection bag with alcohol or other suitable decontaminant.
4. Place the decontaminated bags into a rigid, closed box (supplied by the healthcare facility) clearly labeled with a biohazard symbol, and tape the box securely shut.
5. Label the outside of the box with the 3-digit site code and 2-digit location identifier.

Shipment under the healthcare facility's agreement with Battelle:

1. Gather all boxes; complete one chain of custody form (provided by Battelle) per shipment, noting the number of boxes.
2. Coordinate with your organization's courier service to arrange transfer to designated Battelle location.

Reuse Information:

Following decontamination, you will be provided **decontaminated compatible N95 respirators** that have been processed through a decontamination system for reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. Before reuse, the healthcare facility should review the chain of custody form, which indicates successful decontamination, accompanying the returned respirators. The healthcare facility should also inspect each returned, decontaminated compatible N95 respirator for:

1. Numeric indication of the decontamination cycle number. **NOTE: Compatible N95 respirators will be disposed of after 20 decontamination cycles.**
2. Visible damage or soiling. **NOTE: Compatible N95 Respirators should be discarded and not reused if visually damaged or soiled.**

Any problems should be immediately reported to Battelle.

Battelle Contact: 1-800-201-2011 or solutions@battelle.org

BATTELLE

Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (hereafter referred to as the "Battelle Decontamination System") operated by the Battelle Memorial Institute ("Battelle"), for use in decontaminating compatible N95 and N95-equivalent respirators ("compatible N95 respirators"), for reuse by healthcare personnel. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by Battelle using the Battelle Decontamination System.

Due to incompatibility, the Battelle Decontamination System is not authorized for use with respirators containing cellulose-based materials.

All compatible N95 respirators provided to Battelle must be free of any visual soiling or contamination (e.g. blood, bodily fluids, makeup).

Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and will be disposed of and not returned after decontamination.

N95 Respirator Marking and Collection

1. Label your own individual compatible N95 respirator using a permanent marker; do not label others' or ask others to label for you.
2. Labeling should be legibly written on the outside OR inside of each compatible N95 respirator, as shown below.
3. Label ALL compatible N95 respirators with the three-digit site code and 2-digit location identifier provided below.
4. Place your compatible N95 respirator in the collection bag provided by your healthcare facility at a designated collection station at your facility.

NOTE: Collection bags are for compatible N95 respirators only; do not throw other personal protective equipment (such as gloves), paper towels or waste in the collection bags.

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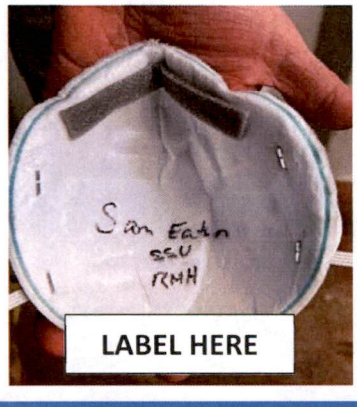
Site Code **Site Location ID**



potential exposure of healthcare personnel from breaks in or other damage to or degradation of the decontaminated N95 respirators.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings, Infection Control, and FAQ about PPE.*

Current information on COVID-19 for healthcare personnel is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of using decontaminated N95 respirators?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore risk of infection or illness
- Extends the usability of compatible N95 or N95-equivalent respirators by allowing for decontamination and reuse

Potential risks include:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Overview of the Battelle Decontamination System

The Battelle Decontamination System is a self-contained decontamination device that uses vapor phase hydrogen peroxide (VPHP) for decontamination of compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2. N95 or N95-equivalent respirators containing cellulose-based materials are incompatible with the Battelle decontamination process.

Each decontamination cycle in the Battelle Decontamination System consists of injecting VPHP into the decontamination chamber until achieving a saturated atmosphere indicated by micro condensation; maintaining the VPHP exposure for a 150-minute dwell time; and allowing the VPHP to off gas to a level of 1 ppm prior to post decontamination processing. A minimum of five calibrated chemical indicators are dispersed throughout the system to indicate a successful decontamination cycle. This decontamination system enables the reuse of compatible N95 or N95-equivalent respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

What is an EUA?

The United States FDA has made the emergency use of the Battelle Decontamination System to decontaminate compatible N95 or N95-equivalent respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The Battelle Decontamination System has been made available under an EUA, and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the Battelle Decontamination System may be effective at preventing healthcare personnel exposure to pathogenic airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per respirator, compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the Battelle Decontamination System is in effect for the duration of the COVID-19 declaration

MARGIE R. IBARRA
COUNTY CLERK
FILED

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WEBB COUNTY, TEXAS

BY _____ DEPUTY