

FIRST AMENDMENT TO AGREEMENT

THIS FIRST AMENDMENT TO AGREEMENT (hereinafter "Amendment") is made and entered into this 8th day of OCTOBER, 2021, by and between COUNTY OF FRESNO, a Political Subdivision of the State of California, Fresno, California (hereinafter "COUNTY"), and The Regents of the University of California, San Francisco, a public university, whose address is c/o Office of Sponsored Research, 490 Illinois Street, 4th Floor, San Francisco, CA 94143 (hereinafter "CONTRACTOR").

WITNESSETH:

WHEREAS, COUNTY and CONTRACTOR entered into Agreement number D-21-130, dated April 21, 2021 (hereinafter "Agreement"), pursuant to which CONTRACTOR agreed to provide on-call COVID-19 vaccination administration teams, including all necessary staffing, to conduct on-call vaccination clinics that will provide vaccinations and documentation (using the local immunization registry) to COUNTY residents; and

WHEREAS, COUNTY and CONTRACTOR now desire to amend the Agreement in order to add the provision of monoclonal antibody therapy, flu vaccine administration services, the addition of COVID-19 testing services, and increase the total compensation to accommodate the provision of new and existing services through and including April 14, 2022.

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, COUNTY and CONTRACTOR agree as follows:

1. That all references to "Exhibit A" in existing COUNTY Agreement number D-21-130 shall be changed to read, "Revised Exhibit A", attached hereto and incorporated herein by reference.

2. That all references to "Exhibit B" in existing COUNTY Agreement number D-21-130 shall be changed to read, "Revised Exhibit B", attached hereto and incorporated herein by reference.

3. That Section 5 of the Agreement, located on page 3, lines 8 through 19, is deleted in its entirety and replaced with the following:

"5. **COMPENSATION/INVOICING:** COUNTY agrees to pay CONTRACTOR and CONTRACTOR agrees to receive compensation for actual costs as identified in Revised Exhibit B, attached hereto and incorporated herein by reference. CONTRACTOR shall submit monthly invoices in triplicate to the County of Fresno, Department of Public Health, 6th Floor, P.O. Box 11867, Fresno,

1 CA 93775, Attention: Business Office or dphboap@fresnocountyca.gov. Invoices shall be
2 accompanied by supporting cost documentation such as payroll records, equipment/supply invoices,
3 lease payment, payment records for marketing/education/outreach costs, utility/janitorial payment,
4 mileage records if applicable.

5 In no event shall services performed under this Agreement be in excess of Seven Million Four
6 Hundred Five Thousand Eight Hundred Three and 67/100 Dollars (\$7,405,803.67) during the term of
7 this Agreement. It is understood that all expenses incidental to CONTRACTOR'S performance of
8 services under this Agreement shall be borne by CONTRACTOR. Invoice terms shall be Net forty-five
9 (45) days from date of receipt of invoice by COUNTY."

10 4. That Section 15.A of the Agreement, located on page 10, lines 12 through 16, is deleted
11 in its entirety and replaced with the following:

12 A. COUNTY and CONTRACTOR recognize that CONTRACTOR is a recipient of
13 Federal funds under the terms of this Agreement. By signing this Agreement, CONTRACTOR agrees
14 to comply with applicable Federal suspension and debarment regulations, including but not limited to:
15 29 CFR 97.35, 29 CFR 1470.35, 41 CFR 105-71.135, and Executive Order 12549. By signing this
16 Agreement, CONTRACTOR attests to the best of its knowledge and belief, that it and its principals:"

17 COUNTY and CONTRACTOR agree that this Amendment is sufficient to amend the
18 Agreement and, that upon execution of this Amendment, the Agreement and this Amendment together
19 shall be considered the Agreement.

20 The parties agree that this Amendment may be executed by electronic signature as provided in
21 this section. An "electronic signature" means any symbol or process intended by an individual signing
22 this Amendment to represent their signature, including but not limited to (1) a digital signature; (2) a
23 faxed version of an original handwritten signature; or (3) an electronically scanned and transmitted (for
24 example by PDF document) of a handwritten signature. Each electronic signature affixed or attached
25 to this Amendment (1) is deemed equivalent to a valid original handwritten signature of the person
26 signing this Amendment for all purposes, including but not limited to evidentiary proof in any
27 administrative or judicial proceeding, and (2) has the same force and effect as the valid original
28 handwritten signature of that person. The provisions of this section satisfy the requirements of Civil

1 Code section 1633.5, subdivision (b), in the Uniform Electronic Transaction Act (Civil Code, Division 3,
2 Part 2, Title 2.5, beginning with section 1633.1). Each party using a digital signature represents that it
3 has undertaken and satisfied the requirements of Government Code section 16.5, subdivision (a),
4 paragraphs (1) through (5), and agrees that each other party may rely upon that representation. This
5 Amendment is not conditioned upon the parties conducting the transactions under it by electronic
6 means and either party may sign this Amendment with an original handwritten signature.

7 The Agreement, as hereby amended, is ratified and continued. All provisions, terms,
8 covenants, conditions and promises contained in the Agreement and not amended herein shall remain
9 in full force and effect.

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1 IN WITNESS WHEREOF, the parties hereto have executed this Amendment I to Agreement as of
2 the day and year first hereinabove written.
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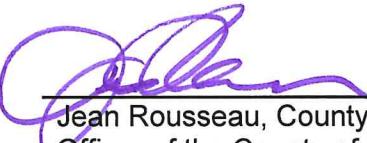
4 **CONTRACTOR**

5 **The Regents of the University of
6 California, San Francisco**

7 
(Authorized Signature)

8 Catherine Lagarde, Contracts Officer
9 Print Name & Title

10 **COUNTY OF FRESNO**

11 

12 Jean Rousseau, County Administrative
13 Officer of the County of Fresno

14 Mailing Address

15 FOR ACCOUNTING USE ONLY:

16 Fund: 0001

17 Subclass: 10000

18 ORG: 56201018, 56201019

19 Account: 7295

Revised Exhibit A

SCOPE OF WORK

The County of Fresno (County) Department of Public Health (DPH) is in need of temporary vendors to provide on-call COVID vaccine, **COVID testing, flu vaccine, and Monoclonal Antibody Therapy** administration teams, available for vaccination events. Licensed and unlicensed medical staff (Registered Nurses, Licensed Vocational Nurses and Medical Assistants or Certified Nursing Assistants with valid licensure and/or certification in the State of California) and clerical staff will be needed to conduct on-call vaccination clinics that will provide vaccination and documentation through the appropriate State system (e.g. MY Turn or Interface from allowed electronic medical record) to County residents. Clinics will be held through employers or through community medical clinic/vaccination events that may be open to the general public.

The vendor will work with County staff to determine the size, date and time of the clinic request. Lead time to clinic scheduling will be 5 days – 4 weeks. The County anticipates 20 to 30 clinics per month, providing services to up to 1,000 patients per clinic. Clinic times will vary as follows:

- Any day of the week, including weekends and evenings.
- Clinic hours will vary from 2 – 8 hours depending on size of event.
- Events may be held inside, outside or as a drive thru.
- Events may be located anywhere within Fresno County.
- Patients served will be dependent on which vaccine is being administered at the event. The Pfizer vaccine is authorized for use in individuals 16 years of age and older. The Moderna and Janssen vaccines are authorized for use in individuals 18 years of age and older. **The Monoclonal Antibody Therapy is authorized for use in individuals over 12 years of age and older with mild-to-moderate COVID-19 who meet criteria under the FDA's Emergency Use Authorization.** EUAs issued for each vaccine:
 - Pfizer EUA: <https://www.fda.gov/media/144412/download>
 - Moderna EUA: <https://www.fda.gov/media/144637/download>.
 - Janssen EUA: [Janssen COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers \(fda.gov\)](https://www.fda.gov/media/143893/download)
 - **Monoclonal Antibody Therapy EUA:** <https://www.fda.gov/media/143893/download>
 - Other vaccine requirements may vary. Vendor will be required to adhere to EUA for specific vaccines as additional vaccines are approved by the Food and Drug Administration (FDA).
- Vendor will be required to work with the venue host to determine if the vendor will need to provide tables, chairs, popup tents, etc.
- At County's request, vendor may be required to conduct a similar event at the same venue in order to administer required second doses of vaccine. Arrangements for both events shall be made at the same time. Timing of the second event will depend on the recommended second dose frequency: Pfizer is currently 21 days and Moderna is one month (see respective EUAs linked above and CDC clinical considerations linked here: <https://www.cdc.gov/vaccines/covid-19/>

Revised Exhibit A

19/info-by-product/clinical-considerations.html). Janssen vaccine is one dose only. Vendor should always check for CDC and/or vaccine manufacturer updates to these requirements prior to each event.

- When applicable, the requirement to conduct a second, similar event, and its timing, are subject to change depending on vaccine availability at the time of the second event and changes in recommended second dose administration timing.
- Any extra ancillary supplies not included with vaccine shipment must be supplied by vendor.
- The County prefers that the vaccine and ancillary supplies be shipped directly to the vendor rather than be held by the County prior to the clinic. This will be dependent on the vendor's ability to maintain vaccine at the appropriate temperatures (see Cold Storage Capacity, below) and the size of the event.

The County will provide the following:

- Venue and direct payment to venue for any rental costs.
- Clinic date, time, location and venue contact information.
- Vaccine and ancillary supplies as provided for by CDPH. Depending on vendor's cold chain capabilities and registered Provider status, vaccine and ancillary supplies may be shipped directly to vendor or picked up at the Department of Public Health.
- For Pfizer, Moderna, Janssen, flu and potentially other vaccines, as well as Monoclonal Antibody Therapy, we expect the following ancillary supplies to be provided with each 100 vaccine doses.
 - 105 needles
 - 105 syringes
 - 210 alcohol prep pads
 - 1 needle information card
 - 100 vaccination cards
 - 2 disposable face shields
 - 4 surgical masks

The vendor will be responsible for the following:

- County prefers vendors to enroll as a Provider in the federal COVID-19 Vaccination Program, utilizing the California Department of Public Health's (CDPH) COVIDReadi portal and agree and adhere to all requirements specified in the Provider agreement. If provider is not currently an approved California COVID vaccine provider then provider must adhere to all COVID vaccine handling and reporting requirements established by the State of California.
- Vendor shall administer the vaccine and enter all vaccinations into the appropriate State system within 24 hours of administration.
- Vendor is to provide all office supplies, ancillary medical supplies not included with vaccine, PPE, tables, chairs, tents, etc., when needed.

Revised Exhibit A

- Vaccine will be transferred according to CDC or VFC recommendations, such as noted in the CDC's Vaccine Storage and Handling Toolkit, linked here:
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- Return unused/unopened vaccines to DPH the day of the event, or the day following, as directed by DPH when scheduling each event(to be determined prior to each event.) However, with County's permission, vendor may retain unused vaccine for use on the following clinic date provided vendor has appropriate cold storage capacity and the vaccine will not have expired per manufacturer guidelines.
- If vendor has vaccine that may expire before it can be used at an upcoming vendor event, vendor will work with the County to ensure any surplus or short-dated doses are transferred to an approved provider in a timely manner.
- Document and notify DPH of any wasted vaccine doses.
- Staff in charge of storage and handling, will complete the 7 EZIZ training modules at the following website: <https://eziz.org/eziz-training/>
- Per federal regulations, vendor is required to provide the appropriate EUA document to all vaccine recipients:
 - Pfizer: <https://www.fda.gov/media/144414/download>
 - Moderna: <https://www.fda.gov/media/144638/download>
 - Janssen: [Janssen COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers \(fda.gov\)](#)
 - **Monoclonal Antibody Therapy:** <https://www.fda.gov/media/143893/download>
- COVID-19 vaccination providers are required to report the following adverse events after COVID-19 vaccination, and other adverse events if later revised by CDC, to VAERS:
<https://vaers.hhs.gov/reportevent.html> or calling 1-800-822-7967.
 - Vaccination administration errors, whether or not associated with an adverse event
 - Severe COVID-19 illness (e.g., resulting in hospitalization)
 - Serious adverse events (AE) regardless of causality. Serious AEs are defined as:
 - Death
 - A life-threatening AE
 - Inpatient hospitalization or prolongation of existing hospitalization
 - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
 - A congenital anomaly/birth defect
 - Multisystem Inflammatory Syndrome
 - Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above
- Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).
- Vendor must make provision for patients with a history of anaphylaxis (due to any cause) to remain for observation for 30 minutes. For all other persons, observation period is 15 minutes.
- In the event of anaphylactic reaction, vendor must maintain appropriate emergency equipment at the event to manage anaphylaxis resulting from vaccination. See CDC recommended equipment

Revised Exhibit A

linked here: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>. Equipment supply should be sufficient to manage multiple patients experiencing anaphylaxis.

Cold Storage Survey (please check as appropriate):

- We have an ultra-low temperature freezer (temperature capability is -80°C to -60°C/-112°F to -76°F). Freezer make/model and cubic feet: SO-LOW MODEL U85-22 23.1 cubic ft - 3 units purchased. American Biotech Supply – ABT 115V-2186 17cubit ft. – 3 units purchased
- We have freezer storage capability (-25°C to -15°C/-13°F to 5°F). Freezer make/model and cubic feet: MCA Corporation MODEL HMCF7W4 – 7 Cubic Feet
- We have refrigerator storage capability (2°C to 8°C/36°F-40°F). Refrigerator make/model and cubic feet: American Biotech Supply PH-ABT-HC S16G 16 cubic ft.
*Current calibration certification will be required for freezers/refrigerators.
- We will pick up and return the vaccine the same day to the County and will make arrangements with County staff on pick up and drop off times.
- We have qualified container and packout for transport and digital data logger for continuous temperature monitoring during transport. We have purchased 6 transport containers for the purpose of transporting vaccines.
- We do not have qualified container and packout for transport and digital data logger for continuous monitoring during transport and will need to borrow from the Department of Public Health.

Per the CDC, a “qualified container and packout” are defined as “A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are ‘qualified’ through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.” (<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>) An example a qualified container is linked here: <https://www.vericormed.com/product/cooler-cool-cube-08-vaccine-transport-cooler-at-refrigerated-temperatures-fresh-vaccine-vt-08/>

Vendor shall submit invoices to:

County of Fresno Department of Public Health
1221 Fresno Street, 6th fl. (Business Office)
Fresno, CA 93721

DPHBOAP@fresnocountyca.gov

Revised Exhibit A

KEY RESOURCES

- [CDC's Storage and Handling Toolkit](#)
- [CDC's COVID-19 Vaccination Information Page](#)
- Phase Guidance:
 - [CDC's Phase 1A Powerpoint](#)
 - [Interim ACIP Guidance](#)
 - [Early NASEM Phase Guidance](#)

