



City of Ketchum

May 4, 2020

Mayor Bradshaw and City Councilors
City of Ketchum
Ketchum, Idaho

Mayor Bradshaw and City Councilors:

Recommendation To Retroactively Approve Agreement 20468 Between the City of Ketchum and Fred Hutchinson Cancer Research Center

Recommendation and Summary

Staff is recommending the council retroactively approve Agreement 20468 and adopt the following motion:

I move to retroactively approve Agreement 20468

The reasons for the recommendation are as follows:

- This Agreement was required by Fred Hutchinson Cancer Research Center in order to proceed with the antibody testing in Ketchum
- Under the Emergency Powers Ordinance, the Mayor approved the Agreement and is now seeking Council ratification

Introduction and History

As part of the COVID-19 antibody study occurring in Ketchum and coordinated by Fire Chief McLaughlin, Fred Hutchinson Cancer Research Center requested Agreement 20468 be approved by the City of Ketchum. The Agreement sets forth the general terms and conditions, protocols and assurances for the study.

In order to expedite the approvals for the study, the Mayor signed the Agreement under the terms granted to in the Emergency Powers Ordinance. The Council is being asked to ratify the approval.

Sustainability

There are no impacts to sustainability resulting from this action.

Financial Impact

There is no financial impact resulting from this action.

Attachment:

Participating Site Agreement 20468

Participating Site Agreement

COVID 19 Antibody Seroepidemiology Study in Blaine County, Idaho (“Study”)

This Agreement is entered into this 27th day of April, 2020, between Fred Hutchinson Cancer Research Center and the institution referenced below that has been selected to act as a participating site in the performance of the above-referenced Study (referred to herein individually as “Party” and collectively as “Parties”).

Coordinating Center (“Fred Hutch”)
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North
Seattle, WA 98109-1024
Seattle, WA 98109-1024

Participating Site (“Institution”)
City of Ketchum
POB 2315, 480 East Avenue
Ketchum, Idaho 83340

Fred Hutch Principal Investigator

Larry Corey, M.D.
Full Member
Vaccine and Infectious Diseases Division
(206) 667-6770
lcorey@fredhutch.org

Institution Principal Investigator

Bill McLaughlin
Fire Chief, City of Ketchum
480 East Avenue

bmclaughlin@ketchumidaho.org

General Terms and Conditions:

The parties agree as follows:

1. **Study Performance.** Fred Hutch is the coordinating center for the above-referenced research study (“Study”). Institution agrees to collaborate with Fred Hutch and to act as a performance site for the Study in accordance with the terms of the Study protocol (“Protocol”) (attached hereto and incorporated herein by reference as **Exhibit 1**). Fred Hutch may amend the Protocol from time to time during the term of the Study, and a copy of such approved amendments will be promptly provided in writing by the Fred Hutch Principal Investigator to the Institution Principal Investigator and such amended Protocol shall be deemed incorporated by reference. The Fred Hutch Principal Investigator shall be Dr. Larry Corey and the Institution Principal Investigator shall be Mr. Bill McLaughlin. Institution, on its own behalf and on behalf of the Institution Principal Investigator and all other Study team members under her supervision, agrees to conduct the Study in accordance with the Protocol, good clinical practice guidelines and applicable statutes, rules and regulations. By signing this Agreement, Institution agrees to the Special Terms in **Exhibit 2** to this Agreement and certifies compliance with the assurances in **Exhibit 3** to this Agreement. If Institution discovers at any time during the term of this Agreement that any one or more of these assurances is not true and correct, Institution agrees to promptly notify Fred Hutch.

2. **Institution Principal Investigator.** The Institution Principal Investigator for the Protocol shall be responsible for Institution’s performance of the Study and for supervising any individuals performing the Study

on behalf of Institution. Institution Principal Investigator assures Fred Hutch that all individuals performing the Study on behalf of Institution are duly qualified and licensed to perform the Study procedures under the terms of the Protocol.

3. Payment. Institution will not receive payment for its participation in the Study.

4. IRB. Institution acknowledges and agrees the Fred Hutch Institutional Review Board ("IRB") will review and approve Institution's participation in the Study; that Institution Principal Investigator will execute (on his own behalf and on behalf of all research study team members under his direct supervision and control) an Individual Investigator Agreement reflecting the oversight of the Study by the Fred Hutch IRB; and, that Institution will not enroll any participants in the Study until it has received approval from the Fred Hutch IRB. Institution and all Institution officers, agents, employees and contractors ("Institution Study Team") will comply with all applicable laws and regulations governing the conduct of human subjects research in the conduct of the Study.

5. Term and Termination. This Agreement will be effective on the date of the last signature by an authorized representative of both parties ("Effective Date"). This Agreement will terminate

- a) at the conclusion of the Study;
- b) on thirty (30) days written notice from either Party with or without cause; or
- c) immediately upon notice from Institution to Fred Hutch if one or more of the assurances in **Exhibit 3** is or becomes not true and correct.

6. Liability and Insurance. Each Party shall be responsible for its own acts or omissions and for those of its employees and agents to the extent permitted by applicable laws. Each Party agrees to maintain appropriate levels of comprehensive general liability and professional liability insurance or an appropriate self-insurance program for itself and its officers, employees, agents and contractors working on the Study and will provide the other party with written evidence of its insurance upon request.

7. Miscellaneous. The relationship of Fred Hutch to Institution is one of independent contractors, and neither party is the employee, agent, representative, partner or joint venture partner of the other party by virtue of this Agreement, nor shall either party have any express or implied right or authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by virtue of this Agreement. All notices, requests or other communications relating to this Agreement shall be given in writing and a) personally delivered, b) sent by fax or other electronic means, or c) sent by United States mail or express courier to the contacts listed on **Exhibit 3**.

FRED HUTCHINSON CANCER
RESEARCH CENTER

By *Gemmae J Sands*
Its DEPUTY GENERAL COUNSEL
Dated: 4/25/2020

INSTITUTION

By *Neil Bradshaw*
Neil Bradshaw, Mayor
Dated: April 24, 2020

Exhibit 1

Protocol

Researchers at the Albany College of Pharmacy and Health Services (Colleen McLaughlin, PI) are collaborating with Larry Corey's Lab at the Fred Hutch to sample blood from citizens of Blaine County, Idaho. Blaine County has one of the highest infection rates of COVID-19 in the country (18.1 cases per 1000 people, as of 4/6/2020). Blaine County elected officials and government employees have launched an initiative to collect blood samples from volunteer residents of Blaine County to test for the presence of antibodies to the SARS-CoV-2.

Participants will receive a link via email to the RedCap database by research staff at the Albany College of Pharmacy and Health Services (ACPHS) in Albany, NY. Both researchers from Albany College and lab staff from Larry Corey's lab at the Fred Hutch will have access and editing privileges to the database. A security statement about the database which was created by ACPHS is included in the submission.

Participants will read a consent statement hosted on the RedCap website and agree to their participation prior to completing a short intake form. A copy of the consent statement will be offered to the participant in the form of a pdf after they click the button to agree to participate. The intake form asks participants to report their basic demographics, potential sources of coronavirus exposure, history of coronavirus symptoms, and relevant clinical/risk factor data (survey included in submission). Collection of demographic and symptom data will allow Blaine County to better understand the infection rate and how to respond to the SARS-CoV-2 infection.

Upon completion of the survey, participants will be provided with an email that contains a unique study identifier to verify their participation at drive thru blood draw tents staffed by Blaine County employees (Bill McLaughlin, Fire Chief/PI – see separate Participating Site Application). Information regarding the time and location for the single blood draw of 10 mL (about 2 tsp) will also be provided to participants in this email. Participants will designate a password to retrieve their antibody test results from a RedCap database in the future. If participants forget their password, ACPHS staff can be contacted to help them retrieve it.

Participants will report to the designated location for blood collection where Blaine County staff will verify the Study ID # and email address entered into the RedCap database. Blood will be collected according to standard collection procedures, and collection tubes will be labeled with the participants unique study identifier and date of collection before being sent via overnight FedEx to Fred Hutch where lab staff will complete serology for SARSCoV-2 antibody testing. Participant results will be entered into the secure RedCap database. Following entry of lab results, RedCap will be used to send participants an email indicating that their results are available to view. Participants will be prompted to login to the RedCap database using the credentials they previously specified to access their serology results. All results will be accompanied by language to inform the participants that the presence of antibodies to coronavirus may not be a marker of protection to COVID-19, and that participants should continue to adhere to all precautions prescribed by their local, state, and federal health officials to protect themselves against contracting COVID-19 in their community. This is also stated repeatedly in the consent statement.

Participants who forget their password may contact ACPHS investigators, who will verify their identify and allow them to set a new password to retrieve their results. Contact information will be listed on the RedCap website for participants' reference.

Exhibit 2

Special Terms and Conditions

The following terms and conditions apply to this Agreement:

1. Confidentiality; Use of Study Data. Institution agrees to maintain the confidentiality of all Confidential Information and to use such information only for conducting the Study. "Confidential Information" means the Protocol, data collected from, or in relation to Study participants, data generated in the course of the Study, and any additional information related to the Study that is identified by Fred Hutch as confidential. Confidential Information does not include information which a) is or later becomes available to the public through no fault of Institution; b) is independently known by Institution prior to its receipt from Fred Hutch as shown by Institution's written records; or c) is obtained without an obligation of confidentiality from a third party who had the legal right to disclose the information to Institution. Institution may also disclose Confidential Information if required to do so by subpoena or other legal process and will provide to Fred Hutch prompt written notice of any such request or demand. Fred Hutch will use the data from the Study for any lawful purpose subject to applicable laws and regulations.

2. Inventions. Ownership of all inventions, improvements or discoveries which are conceived, reduced to practice, or developed in connection with or the performance of the Study and any patent rights related thereto ("Invention") shall be determined in accordance with United States patent laws. Institution will promptly notify Fred Hutch in writing of any Invention made by it or its employees or agents. Part 401 of Title 37 of the Code of Federal Regulations entitled "Right to Inventions Made by Non-Profit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements" and any further implemented regulations issued by the United States Department of Health and Human Services are made a part hereof by reference and Institution shall comply with the applicable provisions thereof.

3. Publications. Institution or its employees may publish the results from its participation in the Study. Institution shall submit a copy of any proposed publication or presentation by Institution personnel to Fred Hutch at least forty-five (45) days before submission of such proposed publication or presentation. During that time, Fred Hutch shall have the right to a) review the material for Confidential Information provided to Institution, and b) assess the patentability of any invention described in the proposed publication or presentation. If Fred Hutch decides that a patent application should be filed, the publication or presentation may be delayed an additional thirty (30) days or until a patent application is filed, whichever is sooner. The parties agree to give each other appropriate recognition for their respective scientific or financial contribution to the Study in any publication or presentation. Neither Institution nor Fred Hutch will use the other's name or the names of any of the other's employees or professional staff, in any publicity or advertising or for any other commercial purpose without prior written approval.

Exhibit 3 - Assurances

Institution certifies that the following assurances are true and correct to the best of its knowledge:

Human Subjects: Institution shall safeguard the rights and welfare of human subjects involved in sponsored research projects in accordance with Department of Health and Human Services (DHHS) regulations set forth at 45 C.F.R. Part 46 and FDA regulations set forth at 21 C.F.R. Parts 50, 56 and 312.

Conflict of Interest: Institution certifies that it has in place policies and procedures to implement financial conflicts of interest requirements under applicable law (45 C.F.R. Part 50, Subpart F) and that it will ensure that anyone responsible for the design, conduct or reporting of the research carried out in this Study discloses to Institution any significant financial interests and that any financial conflict of interest is managed, reduced or eliminated in accordance with Institution's Financial Conflict of Interest Policy that is as or more rigorous than that required under 45 C.F.R. Part 50, Subpart F.

Research Misconduct: Institution shall inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct and shall establish administrative policies and procedures that comply with 42 C.F.R. Part 50, Subpart A.

Debarment, Suspension and Other Sanctions: (A) Institution hereby certifies that it has never been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a(a) or (b), or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. § 1320 a-7b(f)), including, but not limited to, the federal Medicare or a state Medicaid program, or debarred, suspended, or excluded from any Federal agency or program. If, during the term of this Agreement, Institution (i) becomes debarred, suspended, excluded, or otherwise sanctioned, or (ii) receives notice of an action or threat of an action with respect to any such debarment, suspension, exclusion, or sanction, Institution agrees to immediately notify Fred Hutch. INSTITUTION also agrees that if it becomes debarred, suspended, excluded, or otherwise sanctioned, it shall immediately cease all activities relating to this Agreement.

(B) If INSTITUTION becomes debarred, suspended, excluded, or otherwise sanctioned, this Agreement shall automatically terminate, without any further action or notice by either party. If FHCRC receives notice from INSTITUTION or otherwise becomes aware that (i) a debarment, suspension, exclusion, or other sanction action has been brought against INSTITUTION, or (ii) INSTITUTION has been threatened with a debarment, suspension, exclusion, or sanction, then either shall have the right to terminate this Agreement immediately.

(C) INSTITUTION hereby certifies that it has not and will not knowingly use in any capacity the services of any Subcontractor, individual, corporation, partnership or association which has been debarred under 21 U.S.C. Sec. 335a(a) or (b), or listed in the DHHS/OIG Cumulative Sanctions Report or the General Service Administration's List of Parties Excluded from Federal Procurement and Non-Procurement Programs. If INSTITUTION becomes aware of the debarment, suspension, exclusion, or sanction, or threatened debarment, suspension, exclusion, or sanction of any individual, corporation, partnership or association providing services to INSTITUTION that directly or indirectly relate to the activities under this Agreement, INSTITUTION shall notify FHCRC immediately. Upon the receipt of notice by FHCRC, or if FHCRC otherwise becomes aware of such debarment, suspension, exclusion, or sanction, or threatened debarment, suspension, exclusion, or sanction, either shall have the right to terminate this Agreement immediately.

Exhibit 4

Contacts

Fred Hutch Contact

Rachael McClennen
Director, Regulatory Affairs, HVTN
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North M/S E3-300
Seattle, WA 98109-1024
Email: rmcclenn@fredhutch.org

Institution Contact

Bill McLaughlin, Fire Chief
POB 2315, 480 East Avenue
Ketchum, ID 83340
bmclaughlin@ketchumidaho.org

with a copy to

Suzanne Frick
City Administrator
POB 2315
Ketchum, ID 83340
sfrick@ketchumidaho.org

or

Grant Gager
Director of Finance and Internal Services
POB 2315, 480 East Avenue
Ketchum, ID 83340
ggager@ketchumidaho.org