October 28, 2020

Dear Project PREVENT Investigators,

Thank you for your interest in **PReventing Emerging Infections through Vaccine EffectiveNess Testing (Project PREVENT)**. We are really excited to be launching this new project to try to better understand the role of vaccination in stopping the COVID-19 pandemic. This will be a CDC-funded project that is being run through *EMERGE*ncy ID NET (https://www.emergencyidnet.org/), an emergency department-based network that has conducted ED-based infectious diseases research for over 25 years.

As you know, this project is moving very quickly. The project is not yet formally approved, but we anticipate that funding will be confirmed in the next 1-2 weeks. We are starting now, though, because of this incredibly tight timeline—we need to be ready to launch the overall project in 8 weeks. Our actual start date will be determined by vaccine availability, but once distribution starts this will move very quickly.

We rely on each of our sites to help us make this project stronger. That means that we will be looking for feedback on data elements, communication methods, and team structure. Because of the scope of this project, each of our sites will need to develop some creative solutions to data collection and management. Some of your sites will never have conducted a project like this before, so if you are running into barriers, please give us a call so that we can help you push toward a site readiness call ahead of schedule.

Here is our tentative timeline:

Oct 28 – All Site Call
Nov 18 – Case Finding and Recruitment Plan DUE
Nov 19-Dec 4 – Site Readiness Calls Scheduled (Site Readiness Checklist complete)
Dec 7 – Site Infrastructure Ready for Enrollment
Dec 7-11 – REDCap Training

Our actual launch date will be determined by vaccine availability and coverage.

In parallel with these activities, we have several additional procedures we will be asking you to complete:

1. Send Data Coordinating Center your institution's blank medical record release form (Due November 4)
2. Draft Case Finding and Recruitment Plan (Due November 18)
3. Submit documentation for local Institutional Review Board determination (this project will likely qualify as public health surveillance)
4. Finalize subaward with Olive View-UCLA

In this packet of information, you will find several documents that will be important as you prepare for your Site Readiness Call:

1. Draft Project PREVENT Protocol V0.8
2. Proposed IRB Determination Process
3. Case Finding and Recruitment Plan
4. Site Readiness Checklist
5. Site Coordinator Responsibilities
6. Project PREVENT Contact List

Project PREVENT is big, complex, and it needs to be done quickly. For those of you who participated in Project COVERED, the launch schedule for PREVENT will be familiar. The keys to being able to move quickly is to help us find the weak spots in the project methods early, solve problems at your own sites early, and to keep moving. There will be changes throughout this project, and good two-way communication will be critical for this project to be successful.

Please let us know if you have questions!

Sincerely,

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Proposed IRB Determination Process

For this project, we will be asking your local institutional review board to make a determination whether this project meets the definition of Human Subjects Research. In our opinion, it does **NOT** qualify as human subjects research, because we believe it meets the definition of public health surveillance.

To support that opinion, you will receive several documents from the coordinating center: (1) the CDC request that the study be performed (e.g., request from a qualified public health authority), (2) the human subjects research determination from the Olive View-UCLA, and (3) the human subjects research determination from the University of Iowa. We will also provide an up-to-date protocol that you will submit for your IRB's review as well.

Many centers have a process for an IRB to make a human subjects research determination. This determination is different from IRB approval, because if this project is not human subjects research, it is no longer subject to IRB oversight. Your center may have other approval processes that you need to follow, so please check with your institutional leadership and your IRB prior to human subjects research determination to see if you need to go through any additional approval processes.

Project PREVENT

PReventing Emerging Infections through Vaccine EffectiveNess Testing

UCLA

University of Iowa

EmergencyIDNet-COVERED@uiowa.edu

Case Finding and Recruitment Plan

Project PREVENT will be launched in 16 medical centers, and the function of each of those centers is different. Because of that, we need to learn about how your employee health clinics function, how you are testing employees for COVID-19, how you plan to do data sharing, and how your recruitment procedure will work.

To accomplish that, we would like each site to draft a ***Case Finding and Recruitment Plan***. This plan should detail how you plan to run Project PREVENT at your site, and any procedures you haven't worked out yet. This project will require close collaboration with others at your site.

If you have areas of your process that you are still working out at the time of the deadline, it is okay to just describe what you know and clarify what you are still working on.

Your answers to the questions in this document will help us with site selection and will help us identify areas to discuss on the Site Initiation Call. Please let us know if you have any questions. Please submit your Case Finding and Recruitment Plan to Anusha Krishnadasan, PhD at idnet@ucla.edu by November 18, 2020.

Project Prevent Case Finding and Recruitment Plan

1. **Site Name:**

2. **Site Principal Investigator(s) (Name(s), credentials, e-mail address(es)):**

3. **Site Coordinator(s) (Name(s), credentials, e-mail address(es)):**

4. **Employee Health/Occupational Health Collaborator (Name, credentials, e-mail address):**

5. **Director of COVID-19 Testing Center (if different from employee health) (Name, credentials, e-mail address:**

6. **Please describe the process for COVID-19 testing at your institution. Please include all possible pathways to testing for all employees.**

7. **Please estimate the proportion of employees with symptoms of COVID-19 who are tested outside your health system's testing center.**

8. **Please describe the structure of your employee health clinic(s) at your institution, especially as it relates to COVID-19 care. Please include details of how screening of employees is performed (to determine who is tested) and details of how vaccination and COVID-19 testing records are maintained.**

9. **Will you be enrolling from one hospital, or multiple hospitals? If more than one hospital, please list hospital names and detail the relationship between hospitals.**

10. **How many COVID-19 <u>tests</u> were performed in employees in your facility last week?**

11. **How many COVID-19 <u>positive</u> tests were resulted in employees in your facility last week.**

12. **How many total employees will be included in your surveillance plan in your health system? This could be the total number of employees, or it could be different if you are enrolling from multiple hospitals or if some employees are not tracked through your employee health clinic.**

13. **Does your site have a plan for COVID-19 vaccination? If yes, please describe that plan briefly (dates and timelines are not required).**

14. **Please describe your influenza vaccination requirements and procedures at your site.**

15. **Please describe how you plan to identify cases and controls for Project PREVENT? Please include all possible strategies for getting into the project cohort. Please include your plans for capturing employees tested in your employee health clinic, employees tested outside your health system, and employees diagnosed who are admitted to the hospital for severe illness. We <u>strongly</u> encourage project teams to use identified lists of all tested employees for participant selection.**

16. **Please describe your recruitment and enrollment strategy. The current data plan includes REDCap contacting selected employees 2 weeks after testing. After 2 reminders, though, sites are encouraged to have a plan to contact participants by at least one method (e.g., e-mail), with the ability to follow up using a second method (e.g., telephone).**

17. **Our current plan for informed consent is electronic consent documented through REDCap. We are currently planning to get completed Release of Medical Record forms, using DocuSign (your site form will be completed with data on the records needing release and the electronic authentication will be included on the signature line). Will this process be acceptable for release of employee health records and medical records at your site? If not, what is the specific barrier?**

18. **Please describe your strategy for getting source data from within your health system (e.g., vaccination records, testing records, medical records).**

19. **Please describe your strategy for getting source data from outside your health system (e.g., vaccination records, testing records, medical records). The project will get signed informed consent documents (electronic signature) as part of project-wide data collection activities.**

20. **Please list the people (with email addresses) who will be following up with participants, validating data sources, and conducting data tasks. If the person/people who will be doing this work have not yet been hired, please describe your plan to hire staff to accomplish these tasks.**

21. **Please describe any other aspects of your system that will be helpful in understanding how Project PREVENT will be conducted at your site.**

SITE READINESS CHECKLIST

This list details activities that need to be completed prior to initiating enrollment at your site. As you know, this project is important to start recruitment *very* quickly, so we appreciate your involvement in getting information/approvals collected.

- ☐ Send your site's Release of Medical Records form (blank) to EmergencyIDNet-COVERED@uiowa.edu (due November 4)
- ☐ Case Finding and Recruitment Plan (due November 18)
- ☐ Human Subjects Determination – Each institution will make a local determination on whether this project constitutes Human Subjects Research. We anticipate that many local IRBs will adopt the determination made by the University of Iowa and Olive View-UCLA that this activity constitutes public health surveillance and does not require human subjects research oversight.
- ☐ Provide Contracting Contact Information - We would like to streamline the subcontracting process so that we can promptly execute them and send initial payments for study startup. Please send your Federally Negotiated Indirect Cost Rate (FNICR) and contact information for the appropriate person at your site to whom we should send subcontracts (and who should be copied) for review and execution to Anusha Krishnadasan at idnet@ucla.edu.
- ☐ Confirm you can accept electronic consent for Release of Medical Records at your site.
- ☐ Employee Health Approval –Discuss this project with the Director of Employee Health/Occupational Health at each participating site. You will want to have identified a collaborator, who may be the clinic director (it's okay to provide salary support as appropriate). You will also have funding to support some staff time within the Employee Health Clinic as appropriate for your site's participation. Employee health approval is required before starting enrollment.
- ☐ Site-PI – The site PI will help with local approvals, identifying participants, and ensuring regulatory compliance. The site budget is flexible, but it can cover effort for the site PI.
- ☐ Site Coordinator – This project will require a lot of local coordination. The site budget is flexible, but it is anticipated to be sufficient to cover your coordinator's time for 12 months. Please identify a site coordinator to manage project activities. This person should join the site readiness call. Please see the attached "Site Coordinator Responsibilities."
- ☐ Provide Contact Information to Data Coordinating Center (DCC). Send the following information for the Site PI, Site Coordinator, and any other project members who will be reviewing project data, verifying records, uploading files, or any other project-related activities to EmergencyIDNet-COVERED@uiowa.edu as soon as possible. This information

will be used to generate usernames and passwords for data entry into REDCap. Login information will be sent to the listed e-mail address.

a. Name
b. E-mail Address
c. Job Title
d. Institution/Employer
e. Department
f. Phone Number

- ☐ Schedule Site Readiness Call. Note this call will be scheduled after the Clinical Coordinating Center (CCC) receives confirmation from the site that all of the above tasks have been completed or are at least in process with an expected date of completion.

Site Coordinator Responsibilities

- Act as a liaison to employee health clinic to ensure distribution of Project PREVENT invitation letters as feasible.
- Act as a liaison for staff-facing marketing around the medical center.
- Obtain a weekly list of employees with positive and negative COVID-19 tests from employee health (optimally including outpatient tests, inpatient admissions, and self-reported tests from outside your own clinic).
- Obtain facility-level data elements weekly (number of vaccines administered, etc.) and record on weekly facility form in REDCap.
- Upload Excel files of COVID-19 test results to the REDCap data portal.
- Check list every day of employees who have been invited to participate but not responded. If employees have failed to respond to several invitations over a 1-week period, attempt to follow-up by e-mail or telephone.
- Check list every day of enrolled participants who have not responded to the follow-up survey to encourage participation.
- For participants who do not want to or are unable to complete the electronic surveys, conduct telephone or in-person interview to collect relevant data and complete forms in REDCap.
- For participants who seek care during follow-up, request medical records from appropriate sources using the electronically signed Release of Medical Record consent forms.
- Process each record that has been returned and upload files into the REDCap portal
- Process testing, vaccination, and medical records to complete data verification documents in REDCap.
- Review data inconsistencies or errors twice weekly and follow up with participants to clarify responses.
- Respond to data queries from the Data Coordinating Center.
- Stay updated on REDCap training and Record Abstraction Training.
- Monitor performance of any data abstractors in your group.
- Communicate any issues or barriers encountered to the Clinical Coordinating Center as soon as possible.
- Participate in biweekly all-site calls.

PROJECT PREVENT CONTACT LIST

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Olive View-UCLA Medical Center

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