HRPP and IRB Application and Protocol (Version 1.12)

1.0 General Information

*Please enter the full title of your study:		
Team-Based Rapid Assessment of community-level Coronavirus Epidemics (TRACE)		
***Short Title:**		
COVID-19 Monitoring * This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.		
Anticipated study review level:		
Full Board		

2.0 Add Department(s)

2.1 Add the PI's primary department if you do not see it listed below:

Primary Dept?	Department Name
○	**OSU** - HHS - School of Bio & Pop Hlth Sci
◉	**OSU** - SZO - Integrative Biology

3.0 Study Team

3.1 *Name of Principal Investigator (FAQ: Who can be a Principal Investigator (PI):

Dalziel, Benjamin D

3.2 Additional Study Team Members:

Additional investigators:
(Do not list individuals who will receive IRB approval at their own external institution or whose institution has determined that they are not engaged.)

To remove a study team member prior to submitting the application, check the box next to their name and click the "remove" button.

Bethel, Jeffrey W
Faculty
Noakes, Aslan B
Staff
Peterson, Matthew R
Staff
Preece, Justin S
Faculty
Tyler, Brett

Faculty

Non-Research Support Staff:
(No access to participants, data, or specimens)

To remove a study team member prior to submitting the application, check the box next to their name and click the "remove" button.

3.3 *Please add a Study Contact:

Bethel, Jeffrey W
Dalziel, Benjamin D

The Protocol Contact(s) will receive all important system notifications. The Principal Investigator cannot be removed as a study contact, however, additional study contact(s) can be added. All protocol contacts must be listed in 3.2 above.

To remove a study team member from the "protocol contact" section, check the box next to their name and click the "remove" button.

3.4 If required by the PI's department, please select the Designated Department Approval(s):

Add the name of the individual required to approve and sign off on this protocol from your department (e.g. the Department Chair or Dean). Skip if none.

4.0 Help Text

4.1 Do you wish to see the application help text, examples, and links to additional information in this form?

(•) Yes ( ) No

5.0 Submission Type

5.1 Select One:

(•) New submission, not previously reviewed or approved by OSU
( ) Re-submission of previously approved protocol (expired or migration into iRIS)
( ) Request for .118 Determination
( ) Convert .118 Determination to a new application

6.0 Study Summary

6.1 Using lay language, briefly describe the study purpose or primary research question:

50 words or fewer. You will be asked for aims, background justification, and specific methods and procedures in later sections.

We propose to rapidly implement protocols to determine prevalence of SARS-CoV-2 in symptomatic and asymptomatic individuals in five Oregon communities (Corvallis, Bend, Newport, Boardman, and Hermiston), share results with public health officials for actionable response, and quickly scale up this approach through existing research university networks to expand capacity to communities across Oregon and the nation.

7.0 Determination of Whether the Project Requires IRB Review

7.1 "Research" is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Does the project involve research at OSU or elsewhere?

(•) Yes ( ) No

7.2 "Human subject" is defined as obtaining data about, or specimens from, one or more living individuals through intervention, OR interaction, OR the collection of identifiable private information. Does the project involve human subjects at OSU or elsewhere?

(•) Yes ( ) No

7.3 OSU Engagement:

Are any of the following true?

- OSU is the only institution participating in this study
- OSU is the primary awardee on the funding
- OSU employees or students are obtaining consent from participants
- OSU employees or students will have access to individually identifiable data or samples

(•) Yes ( ) No

8.0 Extent of the Review Required by OSU

8.1 Are OSU-affiliated individuals the only people conducting study activities; including recruitment, obtaining consent, data collection, data analysis, data or sample sharing or storage?

( ) Yes (•) No

8.2 Name(s) of the external site:

We are working with a few organizations that employ Traditional Health Workers (THWs) or other allied or community or health worker with an equivalent skill set who will be involved in recruitment, obtaining consent, and collecting data. These individuals will serve as team leads.

We are also partnering with a local CLIA-certified private laboratory where the samples will be tested. The lab is Willamette Valley Toxicology (WVT) Laboratory.

8.3 Name(s) of non-OSU researcher(s) at that site:

While it need not be described for the IRB, researchers should have a plan for maintaining communication between research sites that includes a method for assuring all participating sites:

- have the most current version of the protocol
- are made aware of any adverse events and unanticipated problems involving risks to participants or others

The specific team leads will be identified by the organizations with whom they work.

One of the TRACE PIs is serving as a liaison with WVT and will communicate any issues with WVT and field any issues or concerns from WVT and report to the TRACE PIs at our daily meeting.

8.4 What are the procedures for transferring data or samples between research sites and for storage once received by OSU or the external site?

Field teams which include OSU and non-OSU members. Field teams will transport the samples/completed interview forms back to campus in OSU Motorpool cars for data entry. The nasal swab specimens will be stored in a plastic box by each field team and the students will also transport them back to OSU to the Dalziel lab specifically for storage. In Bend and Newport, a designated person will transport the samples and completed interviews back to OSU after each day of data collection. In Boardman and Hermiston (4-5

hours from OSU), we will store samples and completed interviews in a secure location within the local Extension Office, which falls within the purview of the College of Public Health and Human Sciences. Project staff will transport interviews and samples back to OSU, per below.

Each weekend after data collection is complete, project staff transport nasal swab samples and interviews to the Dalziel Lab at OSU for storage and data entry (interviews). Note that the virus is deactivated upon the participant places the sample in the specimen collection tube. On Monday, project staff package nasal swab samples in accordance with BSL2 procotols and transport them to the OSU VetMed Lab (OVDL) for sample preparation. Barcoded interview data are stored on an OSU-approved, level 3 data storage mechanism and physically taken to WVT the same day. WVT needs the participants' personal information from the interviews to complete their mandatory reporting of test results to the local health department. After OVDL completes preparation of the samples including splitting them for sequencing, project staff again package nasal swab samples in accordance with BSL2 procotols and transport them to the WVT for testing. After WVT completes testing the samples, results are stored on an OSU-approved, level 3 data storage mechanism and project staff will again physically retrieve it and return to the the OSU Dalziel Lab. WVT will destroy any remaining nasal swab samples.

9.0 OSU will be the RESPONSIBLE Institution

9.1 Will OSU be asked to provide IRB review for non-OSU researchers?

(•) Yes ( ) No

9.2 Will one or more of these researchers be affiliated with an institution that has an IRB?

( ) Yes (•) No

9.3 Will one or more of these researchers not be affiliated with an institution that has an IRB?

(•) Yes ( ) No

Attach an **Individual Investigator Agreement** for *each* collaborator who is not affiliated with an institution that has an IRB. Attachments are uploaded in a single section at the end of this form.

9.4 Will anyone from the other research sites perform the following activities?

Check all that apply:
Note: If there are multiple sites that will be responsible for a portion of the activities, please ensure that this is specified in the question above describing the external site's involvement.

- [x] Recruit participants
- [x] Obtain informed consent from participants
- [x] Collect data or samples
- [x] Receive individually identifiable data or samples for analysis
- [ ] Receive de-identified or coded samples with an agreement prohibiting the release of the key to the investigators under any circumstances (note that the IRB will not review or approve this agreement)
- [ ] None of the above

9.5 The OSU study document(s) should describe the overall study. Please briefly describe each external site's involvement in this study:

See Methods and Procedures.

10.0 OSU will be the RESPONSIBLE Institution but Review External Documents

10.1 Will OSU be asked to approve this study based on review of documents that have already been approved by another IRB?

( ) Yes (•) No

11.0 Regulatory Flexibility

11.1 Instructions:

The requirement to comply with some regulations and policies can be waived for eligible studies. Your answers to the questions in this section will assist us in determining whether this study is eligible for a flexible application of the regulations.

If "no" to all of the questions in this section, the study may be eligible for "flex" review. Flex studies will not be assigned an exempt or expedited category. When applicable, subsequent sections will contain special instructions related to these studies.

If "yes" to one or more of the questions in this section, regulatory flexibility cannot be applied to this project and the study will be reviewed using an exempt, expedited, or full board process.

Information about Regulatory Flexibility

11.2 Does the study involve more than minimal risk to participants?

(•) Yes ( ) No

If the study involves more than minimal risk to participants, it cannot be reviewed as exempt or expedited, and is not eligible for regulatory flexibility. This study will be reviewed by the Full Board.

12.0 Conflicts of Interest and Competing Relationships

12.1 Does a researcher or family member have a financial or other business interest in an entity that is supplying funding, materials, products, equipment, research participants, or the site of data collection for the current research project?

( ) Yes (•) No

13.0 Sources of Funding and Support for this Project

13.1 Is funding for the project pending/awarded?

(•) Yes (Internal or External)
( ) No (Unfunded)

13.2 Is there internal funding (example: PI's startup funds, departmental funds)?

( ) Yes (•) No

13.3 Is there external funding (example: OSU Foundation, OSU Agricultural Research Foundation, NSF, USDA, NIH)?

(•) Yes ( ) No

13.4 Are one or more sources of funding from a US federal agency?

( ) Yes (•) No

13.5 Details of external funding. This information enables OSRAA to match the HRPP/IRB notices to the information in Cayuse:

Add another entry for additional funding sources.

Entry 1

Funding Source:	○ NSF ○ NIH ○ USDA ○ DoD ○ OSU Foundation ○ OSU Agricultural Research Foundation ◉ Other **If Other, specify:** The David and Lucile Packard Foundation
Cayuse or index number(s):	20-1583
Name of PI on grant or contract:	Benjamin Danziel

Entry 2

Funding Source:	○ NSF ○ NIH ○ USDA ○ DoD ○ OSU Foundation ○ OSU Agricultural Research Foundation ◉ Other **If Other, specify:** PacificSource Health Plans
Cayuse or index number(s):	20-1869
Name of PI on grant or contract:	Benjamin Dalziel

Entry 3

Funding Source:	○ NSF ○ NIH ○ USDA ○ DoD ○ OSU Foundation ○ OSU Agricultural Research Foundation ◉ Other **If Other, specify:** Oregon Health Authority
Cayuse or index number(s):	20-2247
Name of PI on grant or contract:	Javier Nieto

Entry 4

Funding Source:	○ NSF

	○ NIH ○ USDA ○ DoD ○ OSU Foundation ○ OSU Agricultural Research Foundation ◉ Other **If Other, specify:** Oregon Health Authority
Cayuse or index number(s):	21-0297
Name of PI on grant or contract:	Javier Nieto

13.6 Is an external (non-OSU) organization or company providing material, equipment, drugs, supplements, or devices for this study?

○ Yes ◉ No

14.0 Study Overview

14.1 List the study aims or research questions and a general description of the participant population:

The objectives of the proposed study are to:

1. Rapidly estimate the prevalence of SARS-CoV-2 virus in Corvallis, Oregon, Bend, Oregon, Newport, Oregon, Boardman, Oregon, and Hermiston, Oregon;
2. Expand the study to numerous communities in Oregon (by collaborating with OSU Extension) and to numerous communities across the United States (by collaborating with other research universities).
3. Estimate how the prevalence of the virus differs across age groups and changes through time.
4. Estimate the fraction of infections that are asymptomatic.
5. Infer the importance of asymptomatic individuals in chains of transmission.
6. Estimate rates of transmission within and among specific cities, using viral genomic databases.
7. Acquire key epidemiological parameters for epidemic forecasts.
8. Monitor epidemic trends through time to enable public health officials to evaluate the efficacy of their strategies.

The study population will include all consenting/assenting individuals within randomly identified households in five Oregon cities (Corvallis, Bend, Newport, Boardman and Hermiston). Individuals of all ages are eligible to participate in this study to generate population-based estimates of infection.

Provide survey questions, questionnaires, interview and focus group guides, references/citations, etc., as separate attachments. Attachments are uploaded in a single section at the end of this form.

14.2 Provide details of where data will be collected:

A random sample of households will be identified in the five Oregon communities (Corvallis, Bend, Newport, Boardman, and Hermiston). These identified households (more detail on sampling scheme later) will be approached and, if the door is answered and participant(s) consents/assents, interviewers will administer a brief questionnaire (i.e. age, number in household, and symptom check) and proceed to obtain a nasal swab specimen for testing and sequencing. Interview teams will collect data over four weekends in Corvallis and over at least one weekend in Bend, Newport, Boardman, and Hermiston. The first weekend in Corvallis will serve as a pilot period.

14.3 Provide background justification:

Background justification should support the objectives of the research as well as the knowledge that is anticipated from the research results. Explain the need for the study and what gap in knowledge the results are expected to fill. Summarize relevant existing data, literature, past and ongoing studies, and how your study ties in with these.

Provide specific methods and procedures in a later section.

All evidence points to the likelihood that infected but asymptomatic people are transmitting SARS-CoV-2. A comprehensive strategy for combating SARS-CoV-2 must take this fact into account. Epidemiological models, public health strategies, and personal health strategies that ignore it are incomplete and prone to costly error.

Dr. Sandra Ciesek, Director of the Institute of Medical Virology in Frankfurt, published a letter in *The New England Journal of Medicine* in which she discussed two people who had recently returned to Germany from Wuhan, China. Both tested positive for SARS-CoV-2.[1] One of them had a rash and a mild sore throat; the other was asymptomatic. Both of their swabs infected cell cultures. She said, "We discovered that shedding of potentially infectious virus may occur in persons who have no fever and no signs or only minor signs of infection."

In work as yet unpublished, Dr. Ciesek tested 24 passengers as they arrived in Germany from Israel. Seven of the 24 tested positive for SARS-CoV-2. Four of the seven had no symptoms. But Ciesek found that the viral load of the specimens from the asymptomatic patients was higher than the viral load of the specimens of the symptomatic patients. This fact implies that asymptomatic carriers might be even more likely than symptomatic carriers to spread the disease to other people.

A team of researchers from Canada, Holland, and Singapore studied data from SARS-CoV-2 outbreaks in Tianjin and Singapore and discovered that the serial interval (the average time elapsed between successive cases in a chain of transmission) was shorter than the incubation period (the average time elapsed between exposure and onset of clinical symptoms).[2] Specifically, the serial interval was 2.55 days shorter than the incubation period in Tianjin and 2.89 days shorter in Singapore. These data suggest that infected people begin to transmit SARS-CoV-2 62 to 69 hours before they begin to experience symptoms. Another team of researchers from Belgium and Holland concluded that 48% of the 91 exposed people in the Singapore cluster and 72% of the 135 exposed people in the Tianjin cluster contracted SARS-CoV-2 from someone who was pre-symptomatic.[3]

1. S. Ciesek, Evidence of SARS-CoV-2 Infection in Returning Travelers from Wuhan, China, The New England Journal of Medicine, February 18, 2020, DOI: 10.1056/NEJMc2001899.

2. L.C. Tindale, M. Coombe, J.E. Stockdale, E.S. Garlock, W.Y.V. Lau, Manu Saraswat, Y.-H. B. Lee, L. Zhang, D. Chen, J. Wallinga, and C. Coljin, Transmission interval estimates suggest pre-symptomatic spread of COVID-19, medRxiv preprint https://doi.org/10.1101/2020.03.03.20029983.

3. G. Tapiwa, C. Kramer, D. Chen, A. Torneri, C. Faes, J. Wallinga, and N. Hens, Estimating the generation interval for COVID-19 based on symptom onset data, MedRxiv preprint doi: https://doi.org/10.1101/2020.03.05.2003181

14.4 Does the study involve any of the following?

Check all that apply:

- ☐ Education Records: Does the study involve the use of student education records?
- ☐ Food or Beverage: Does the study involve providing participants with commercially purchased food intended as a courtesy or compensation?
- ☐ Does the study involve participants ingesting, tasting, or smelling a food, a beverages, or a component thereof for the purpose of research?
- ☐ Drugs or Biologics: Are one or more drugs or biologics being studied as part of this project?
- ☐ Dietary Supplements: Are one or more dietary supplements being studied as part of this project?
- ☐ Devices: Are one or more medical devices being studied as part of this project?
- ☐ Radiation: Does the study involve exposing participants to radiation?
- ☑ Biological Samples: Does the study involve the collection or receipt of biological samples?

☐ Limited to chart review or analysis of large, pre-existing datasets.
☐ None of the above

15.0 Target Enrollment

15.1 What is the target enrollment number?

5280

☐ N/A

15.2 Provide scientific justification for the target enrollment number:

The previously approved target enrollment was 4800. The revised target number of participants across the 5 communities (Corvallis, Bend, Newport, Boardman, and Hermiston) is 5280, which is 10% more than the previously approved target enrollment number. This revised target enrollment number represents less than 800 per weekend of data collection. The actual number of participants per period of data collection has been close to 600, thus providing us to recruit in the two additional communities. These numbers represent the capacity that Dr. Benjamin Dalziel's laboratory in the Department of Integrative Biology can process during the five days that follow each weekend of data collection. Estimates of parameters for a formal sample size calculation are unavailable at this time; however, the target sample size for each community should be sufficient to produce a population-based estimate of infection.

16.0 Participant Demographics

16.1 Instructions:

Justification must be provided for excluded populations. Excluding certain categories of people may reduce generalizability. For example: Study results may not be applicable to the general population of adults in the US if pregnant women, people who do not speak English, and Native Americans are excluded which may, in turn, reduce the scientific benefit of the overall study.

The IRB will not approve a study that fails to provide adequate scientific and ethical justification for excluding persons who might directly benefit from the research, nor will the IRB approve a study that fails to provide scientific and ethical justification for targeting a category of participants who are vulnerable to coercion or undue influence.

16.2 Age ranges:

Check all that apply:

☑ 0-7
☑ 8-17
☑ 18-89
☑ 90+

16.3 Will people from any of the following populations be permitted to enroll?

☑ Pregnant women AND the study involves more than minimal risk OR a physical intervention
☑ Children

Guidance on research with children.

Note: All study team members conducting research with unaccompanied children must contact Human Resources to confirm their eligibility before they will be permitted by OSU to have these minors in their care or custody. For the purposes of this application, "unaccompanied" means any research activities with children in the absence of their parent(s) or legal guardian(s).

☐ People in the European Union or the European Economic Area (EEA) (regardless of citizenship)

16.4 Will you intentionally recruit and enroll from any of the following populations?

☐ Economically or educationally disadvantaged persons
☐ Adults lacking capacity to consent
☐ American Indians or Alaska Natives
☐ Prisoners
☐ Children in foster care or wards of the state

16.5 Will any of the following OSU-affiliated groups be permitted to enroll?

Check all that apply:

☑ Students
☑ Students currently enrolled in a class or lab instructed by a study team member
☑ Employees
☑ Employees who report to or are otherwise supervised by a study team member
☐ Any of the study team members

Provide scientific justification for permitting these individuals to enroll and a plan for mitigating the potential for actual or perceived coercion:

The groups described above are permitted to participate but will not be targeted for participation. Interview teams will not know the identify of eligible participants until they knock on the door of a household selected using systematic sampling within a census block or block group.

16.6 Will people who do not speak or read English be permitted to enroll?

◉ Yes ○ No

16.7 Are people of any sex, gender/gender identity eligible to participate?

◉ Yes ○ No

16.8 Are people of any race or ethnicity eligible to participate?

◉ Yes ○ No

16.9 List any inclusion criteria not addressed above and explain why this is a scientifically appropriate population for the study:

Criteria:	Explain (if not obvious):
Randomly selected dwelling is the person's usual place of residence.	We are targeting residents of the five Oregon cities.

16.10 List any exclusion criteria not addressed above and the reason for the exclusion:

Criteria:	Explain:
Residents of nursing homes, assisted living, independent living homes	These residents are a particularly vulnerable population and the team's presence (even if permitted) is an unnecessary risk to their health.

Foster children and wards of the state	We are unable to obtain permissions from the LAR.

17.0 Identification and Recruitment of Participants

17.1 How will potential participants be identified and recruited?

A two-stage cluster sampling scheme will be used to identify four separate probability-based samples of participants in Corvallis, Oregon for data collection on four consecutive weekends and in Bend, Newport, Boardman, and Hermiston, Oregon for at least one weekend each. The scheme will be a based on the Community Assessment for Preparedness and Emergency Response (CASPER) model. Developed by the Centers for Disease Control and Prevention, the CASPER is an epidemiologic technique designed to rapidly generate population-based estimates about the health and needs of a community for public health leaders and emergency managers to take an actionable response. In the first stage, 30 clusters (census blocks) will be selected with a probability proportional to the estimated number of households (i.e. housing units) within the clusters. That is, clusters with more households will have a higher chance of being selected. Cens us blocks are combined in all communities so that all clusters have at least 50 housing units. This will create clusters that are large enough so that the participants are not identifiable. At the second stage, data collection teams will use systematic random sampling to select 16 households from each of the selected clusters. Systematic sampling requires knowledge of the total number of households in selected clusters. The sampling interval (k) is determined by dividing the total number of households in a cluster by 16 and then traveling through the cluster in a serpentine method to select every kth household to interview. Boardman has a much smaller population than the other communities. Therefore, we will select 8 households from each of the selected clusters and combine census blocks that that all clusters have at least 30 housing units. Systematic sampling begins with a random start (e.g. northwest corner of the cluster). Interview teams will maintain a tracking form to monitor the outcome of every interview attempt. Teams will revisit households not at home at the initial attempt two more times before deeming a non-respondent. Field teams will hang a notice on the doorknob indicating TRACE field staff visited their own and may return. Households will be revisited on the second day of data collection. If a Team Lead approaches a home in which there are residents who whom they have an existing relationship, the home is skipped in the sampling interval and the next house is visited. If the study team is approached by individuals not eligible for recruitment, field teams provide these individuals with an information card about TRACE.

Interview teams will approach each selected household and invite all members (adults and minors) to participate. After obtaining informed consent and assent from all interested participants, interviewers will administer a brief interview to determine age and current respiratory symptoms and then collect a nasal specimen. Thirty interview teams of 2-3 trained personnel each will collect the data – one for navigation, one for obtaining informed consent and completing the interview and one to receive the nasal specimen. Team leads are THWs or other allied or community or health worker with an equivalent skill set engaging with the public (e.g. home visitors, nurses or nursing students, medical assistants, etc.) or that work alongside the clinical team (e.g. allied health care providers). These field team leads have a close understanding of the community/participants/clients/patients they serve and have extensive training in community/participant/client/patient engagement.

Members of the interview team will receive a 5 hour just-in-time training to review objectives, roles and responsibilities of team members, how to select households, personal and biosafety safety instructions, logistics and how to properly obtain informed consent and child assent. This process start with a pilot phase to 5 census blocks and then repeated for four consecutive weekends in Corvallis. Processes will be revised if needed following lessons learned from the pilot phase.

This process described above will be repeated for at least one weekend in Bend, Oregon and Newport, Oregon.

Special procedures are also in place for participants to return the signature page of the informed consent form, given the form could be a source of infection itself and to maintain social distancing:

- The signature page is a separate page of each informed consent form.
- Participants detach the signature page, place them in individual plastic bags (one form per bag), wipe them down (as with the test kit described below), place them outside the front door to the residence, and close the door
- Field staff approach the door and retrieve the plastic bags
- Participants will be given two signature pages – one to return and one to keep

Participants are informed that in order to maintain at least six feet of distance for social distancing purposes, it may not be possible to keep the discussion confidential. Field staff encourage questions but acknowledge that neighbors and passers-by may overhear what participants say.

17.2 The recruitment materials should include the following information: a) Study title b) Name of the Principal Investigator c) A clear statement that this is research d) Contact information for study personnel.

If you will not include one or more of the above elements, provide justification for the omission:

Attach advertisement or other recruitment material (including content of electronic posts or email). Attachments are uploaded in a single section at the end of this form.

18.0 Informed Consent

18.1 Consent Process:

Required elements of consent

Will consent be sought from participants?

- (●) All of the participants: Consent will be sought from each participant and all of the basic elements of consent will be presented to subjects
- ( ) Some of the participants: Seeking a waiver of consent, or of one or more of the elements of consent, for some participants or study activities (for example, eligibility screening)
- ( ) None of the participants: Seeking a waiver of consent, or of one or more of the elements of consent, for all participants

Indicate where and when consent will be obtained (e.g., in a location that protects the participants' privacy, prior to involvement in any study activities):

Field interview teams will obtain informed consent at the doorstep of the potential participant's residence, maintaining social distancing of at least 6 feet. Consent will be obtained before any study activities take place.

Explain how comprehension of consent information will be assessed and what questions will be asked of the participants to determine comprehension of the study information:

Examples: What questions can I answer for you? To ensure that you understand what the study involves, would you please tell me what you think we are asking you to do? In your own words, can you tell me what the biggest risk to you might be if you enroll in this study?

Capacity to consent will be determined by asking the potential participant, "So that I am sure that you understand what the study involves, would you please tell me what you think we are asking you to do?" Potential participants unable to sufficiently respond will be excluded.

Will consent be obtained in a web-based environment?

( ) Yes (●) No

Will all participants sign consent documents?

(●) Yes ( ) No

18.4 Parental Permission:

Will parental permission be obtained before children are enrolled?

(●) Yes ( ) No

If children may be enrolled in the research, provide a plan for obtaining consent from parents or legal guardians:

For eligible participants under 18 years of age, field staff first obtain documented informed consent from two parents or legal guardian and then written assent is obtained from the minor participant (unless one parent or legal guardian is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child). It is important to note here that obtaining informed consent is a *process* and a discussion between field team and eligible participants. Field staff work with parents or legal guardians to determine the most appropriate process for minors – either obtaining written assent or approval from the parent or legal guardian. Dissent from a subject of any age is respected.

Special procedures must be followed when obtaining informed consent for minors:

- Participation of all minors requires informed consent from one parent or legal guardian for each child. Similar to usual TRACE informed consent procedures, the parent or guardian has time to read the consent form, then the interviewer reviews the form with the parent or guardian, answer questions, and the form signed.
- Rather than setting rigid age categories for different types of consent, field staff work with parents or legal guardians to determine the most appropriate process for minors -- either 1) obtaining written approval from the parent or legal guardian OR 2) obtaining written approval from the parent or legal guardian AND written assent from the minor.
- For minors age <18 years, when appropriate, the child is given time to read the assent form with a lower reading level and less complicated details. The interviewer then explains the study and answers any questions the participant may have. Then the form is signed.
- For some minors <18 years, when appropriate, field staff do not go through a formal assent document, but they attempt to verbally describe the study at an appropriate reading level and answer any questions the child may have.
- *Any dissent on the part of any minor, even if the parent or guardian agrees to participation, is respected and refusal is documented.*

Special procedures are also in place for participants to return the signature page of the informed consent form, given the form could be a source of infection itself and to maintain social distancing:

- The signature page is a separate page of each informed consent form.
- Participants detach the signature page, place them in individual plastic bags (one form per bag), wipe them down (as with the test kit described below), place them outside the front door to the residence, and close the door
- Field staff approach the door and retrieve the plastic bags
- Participants will be given two signature pages – one to return and one to keep

Participants are informed that in order to maintain at least six feet of distance for social distancing purposes, it may not be possible to keep the discussion confidential. Field staff encourage questions but acknowledge that neighbors and passers-by may overhear what participants say.

All field team members (including team leads) receive 5 hours of field training including human subjects research ethics, mandatory child abuse reporting, and how to properly obtain informed consent and child assent.

18.5 Non-English Speakers:

If participants who <u>do not speak English</u> may be enrolled, describe the investigator's language proficiency in the participants' native language (conversational, fluent, do not speak the language):

We are only able to accommodate English and Spanish languages in the study due to limited resources and feasibility. Regarding enrolling Spanish-speakers, we will attempt to hire team leads who are bicultural /bilingual Spanish speakers. As stated previously, the team leads are THWs or other allied or community or health worker. with an equivalent skill set engaging with the public (e.g. home visitors, nurses or nursing students, medical assistant, etc.) or that work along side the clinical team (e.g. allied health car providers). The team leads have background as workers with a close understanding of the community /participants/clients/patients they serve and have extensive training in community/participant/client /patient engagement. However, we may be unable to hire 30 bicultural/bilingual Spanish speaking team leads. To maximize our ability to enroll Spanish-speaking participants, once the 30 clusters (census blocks) are identified, we will assign our bicultural/bilingual Spanish speaking team leads and their interview team to census blocks with a high percentage of Spanish-speaking households, per Census data. Consent forms will be provided in Spanish. Unfortunately, languages other than English and Spanish may not be accommodated.

A professional translating service (e.g. Verblink or TransNation Translation) is used to translate all consent /assent forms, and test notification letter and all other documents we provide participants into Spanish. Once we have IRB approval for the English docs, the professional translation service will translate the documents into Spanish we will submit to the IRB for approval.

Indicate whether you will use a translator and/or an interpreter and explain their qualifications. Consider issues of confidentiality related to using a translator or interpreter and describe instructions that they will receive with respect to any sensitive information. If the translator is not a native speaker of the language, is not a professional translator, or does not have a master's degree in languages, provide back translations of the documents into English:

Per above, we assign our bicultural/bilingual Spanish speaking team leads and their interview team to census blocks with a high percentage of Spanish-speaking households, per Census data.

19.0 Assent

19.1

19.2 Assent Process

Provide information about the assent process below. If the assent process will vary across cohorts, phases, or activities, add one entry for each.

Entry 1

Participant group name:	Minors <18
Are you seeking a waiver of the requirement to obtain assent for this participant group?	○ Yes ◉ No **If Yes, check the appropriate reasons below:** ☐ The ages, maturity, or psychological state of the individuals to be enrolled make them incapable of providing assent; or ☐ The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research; or ☐ The research involves no more than minimal risk, and the research could not practicably be carried out without the waiver of assent.
If no, provide a description of the assent process for this participant group:	For minors age <18 years, when appropriate, the child is given time to read the assent form with a lower reading level and less complicated details. The interviewer then explains the study and answers any questions the participant may have. Then the form is signed.
Indicate who will discuss the study with the participant and, if not the parent or legally authorized representative, describe their training in presenting information to the target population:	The lead member of the field teams will lead the introduction and consent/assent process. Team leads are THWs or other allied or community or health worker with an equivalent skill set engaging with the public (e.g. home visitors, nurses or nursing students, medical assistants, etc.) or that work alongside the clinical team (e.g. allied health care providers). These team leads have knowledge and training in engaging communities for these or similar purposes. In addition, all field team members (including team leads) receive 5 hours of field training including human subjects research ethics, mandatory child abuse reporting, and how to properly obtain informed consent and child assent. This training is provided by senior TRACE leadership.

Will a written assent document or explanation of research be provided to participants?	(•) Yes ( ) No
If yes, will a written signature be obtained from participants prior to enrollment?	(•) Yes ( ) No
If no, will the assent process be strictly verbal (no written document)?	( ) Yes ( ) No

Relevant attachments may include:

- Written assent documents
- Verbal assent guides

Attachments are uploaded in a single section at the end of this form.

20.0 Eligibility Screening

20.1 Will participants be screened for eligibility?

(•) Yes ( ) No

20.2 Describe the eligibility screening process, including whether it will take place before or after written informed consent has been obtained and what will be done with the data if the individual is ineligible to proceed ("screen fails"):

An individual member of the household must meet all of the following inclusion criteria to be eligible for participation in TRACE:

- The selected dwelling unit is their usual place of residence (defined as anticipated residence at this address for more than six months during a calendar year) at the time of interview or they are staying there and have no other usual place of residence..
- Is physically present at the time of data collection

Team leads verbally inquire of all household members present at the time if the dwelling is his/her usual place of residence. If NO, then the person is not eligible to participate in the study.

Field teams confirm that adults consenting on behalf of the children are legally empowered to do so.

Attach screening guide, eligibility checklist, or similar document. Attachments are uploaded in a single section at the end of this form.

21.0 Methods and Procedures

21.1 Provide a description of the methods and procedures to be followed during this research project:

- If the study involves accessing student education records, list all data to be used (e.g. course grades, assignments, GPA, video-recordings of class activities, etc.)
- Identify any surveys or questionnaires that are being tested or validated instruments that have been modified for the purposes of this study
- Identify any novel or modified experimental activities that are being tested the purposes of this study.
- Specific information related to the use of drugs, devices, biologics, food, biospecimens, and radiation will be requested later in this document.

STUDY PROCEDURES

1. **Interview**

Once informed consent is obtained, field staff first conduct a brief interview of each consenting eligible adult household member ≥18 years of age. These interviews are completed separately and responses are recorded on hard copy. Similar to the informed consent process, field staff discuss with parents and guardians the most age-appropriate method to interview minors – directly or to parent or legal guardian proxy. Field staff also collect responses to interviews with minors on hard copy. Field staff conduct the interviews to collect the following information:

- Name
- Age
- Gender identity
- Respiratory symptoms (i.e., fever, cough, shortness of breath)
- Number of residents living in the household (need only be asked of one resident)

Field staff interview participants one at a time at the front door, maintaining a distance of at least 6 feet with the participant as well as others outside the home (e.g., other residents of an apartment complex passing by). An interview is the preferred format to a self-administered questionnaire as, consistent with current recommendations to stop the spread of COVID-19, this method limits contact between the field staff and participants. In addition, we collect information that is not considered sensitive and thus an interview is entirely appropriate. The interviews should last approximately 5 minutes per person.

2. **Nasal swab specimen collection**

a. **Kit contents**

The kit includes a Quick Start Instruction Card, a specimen collection tube (Zymo Research Inc. DNA/RNA Shield Collection Tube Cat. No: R1107), a nylon flocked swab (COPAN Diagnostics Inc.), a plastic bag to place the collected sample in, a pen (to sign informed consent) and an antiseptic wipe to clean the outside of the bag. Affixed to the outside of each sampling kit are three replicate barcode stickers.

The collection tube contains 1ml of DNA/RNA Shield reagent which inactivates pathogens at the point of collection. Data on the reagent can be found **here**. Per the documentation, DNA/RNA Shield abides by the CDC guidelines for pathogen inactivation when working with SARS-COV-2. Its inactivation potential has been validated for a wide range of pathogens, including coronaviruses.

b. **Sample collection**

After field staff conduct the interview, and just before delivering the self-testing kit to the participants, staff remove one of the three barcodes and attach it to the hard copy of the interview. Thus, the other two barcodes remain with the kit that the participant receives. Project personnel then give a kit to a participant while maintaining social distancing by performing the following steps in sequence (1) requesting all participants step back into their homes by 6 ft, (2) placing the kits for each participant in the household on the doorstep, along with a plastic collection box for the completed samples, then (3) stepping back 6 feet before inviting participant(s) to retrieve the kits.

Participants self-collect their swabs using the following steps, which are stated verbally by project personnel and included on the Quick Start Instruction Card contained with the kit: (1) Before opening kit, wash hands with soap and water for at least 20 seconds. (2) Remove the sample tube, swab, and transport bag. (3) Open the swab package, leaving the head of the swab inside the package. (4) Loosen, but do not fully remove, the cap from the sample tube. (5) To collect the swab sample, remove the swab from the package, taking care that the swab head does not touch anything prior to collecting the sample, tilt the head slightly back and gently insert the swab approximately 1 inch into each nostril. The swab should be parallel to the roof of the mouth, not pointing upwards. Participant may feel some pressure but this should not hurt. Rotate swab 5 times and remove from nostril. Without delay, remove the cap of the collection tube and place the swab in the tube so the swab head comes in contact with the liquid at the bottom. Break off the swab at the break point near the middle of the swab by bending it, or cutting with a pair of scissors. Replace the tube cap and screw into place. (6) Remove one of the remaining barcode stickers and place it on the tube. Place the tube in the transport bag, laying the bag flat to squeeze out extra air. Fold over the top of the bag and sealing with the third barcode sticker. (7) Wipe off hands, and the outside of the bag, with antiseptic wipe, and return to the door where project personnel are waiting (6 feet back from entrance).

Following collection, each participant returns the samples to the field staff who remain 6 feet from the entrance to the dwelling during sample collection, but have placed a plastic collection box on the doorstep before retreating, as described above. Sample recovery follows these steps: (1) participants place completed sample transport bags in collection box, (2) participants retreat 6 feet into house, and (3) study personnel retrieve collection box. Field staff transport the specimens back to the laboratory for testing.

3. Health Education

At the completion of the data collection, field staff leave the household with information about how the residents can best protect themselves from COVID-19. Similarly, households that refuse to participate are also be given health education material.

4. Laboratory testing

When samples are received in the laboratory, the bags are opened and barcodes mapped to lab sample numbers (plate and well IDs). Samples are subjected to RNA purification and qPCR using the ThermoFisher Scientific TaqPath COVID-19 diagnostic kit, which has received emergency use authorization from the FDA (see link below). The output of the RT-PCR is a series of cycle threshold (CT) scores for each sample, which are then interpreted via the Applied Biosystem COVID-19 Interpretive Software to validate the test, and, if validated, obtain a positive or negative result ((**https://www.thermofisher.com/us/en/home/clinical/clinical-genomics/pathogen-detection-solutions/coronavirus-2019-ncov/genetic-analysis/taqpath-rt-pcr-covid-19-kit.html**).

Viral sequence of positive samples is done using RNA sequence assembly based on Illumina HiSeq RNA sequencing, at the Center for Genome Research and Biocomputing at OSU. We plan to compare the nucleic acid sequences of the captured SARS-COV-2 RNA molecules via available and widely-used bioinformatics procedures (e.g. Nextstrain.org) to discover mutations that distinguish different strains of SARS-COV- 2 in the community. Based on the patterns of mutation, we build a viral pedigree (a phylogenetic or variant analysis. The pedigree enable us to infer which strains may have entered the community separately because they exhibit many mutational differences. We infer that strains with identical or closely similar sequences originate from clusters of people who have been infected with the same strain, possibly by transmitting it to one another. Where small numbers of mutations occur in similar strains, we may be able to infer the temporal sequence in which the mutations occurred and thereby to infer the sequence of transmission events of the virus. By correlating viral sequence information with geographical and familial relationships of the individuals who provided the samples, we are able to refine the inferred pathways of spread.

It is important to note here that Oregon statute requires an ordering physician for all diagnostic tests. TRACE works with the Health Officer (also called Medical Officer in some counties) of the county in which we are sampling to serve as the ordering physician in order for Willamette Valley Toxicology to test the samples.

5. Test Result Notification and Referral

TRACE informs all participants of their test result within 7-10 days via secure email as well as US mail to the address collected at the time of the interview. The consent and assent forms state that the test found SARS-CoV-2 or the test did not find SARS-CoV-2 in their sample. For a positive test result, TRACE advises participants to self-isolate, follow CDC guidelines on what to do if they test positive and contact their medical provider for follow-up. TRACE works with large providers in the area and makes them aware that patients may be contacting them for follow-up. We also inform participants with a positive test result that a positive test result does not mean that they have COVID-19 but they could develop COVID-19 or spread the disease to others. The notifications will also include educational material for how participants can best protect themselves and their family, how to deal with possibly being stigmatized, mental health impacts, financial health impacts, etc. Notifications of a negative test result will similarly state that the negative test result could be based on a poor-quality sample and that participants should still follow social distancing guidelines from federal, state, and local public health authorities. Participants are also notified of an 'indeterminate' result and describes the reasons for this result. TRACE seeks to minimize the number of 'indeterminate' test results by retesting these samples.

See the Appendix for the test result notification letters and emails. We will also include a CDC COVID-19 Test Kit Fact Sheet with the notification that all labs include in their notifications (included in Appendix).

6. Mandatory Reporting

Under Oregon law, we are required to report to the appropriate authorities any information concerning **child abuse or neglect**. We may also report threats of harm to self or to others.

7. Operations

a. Field Staff

Field staff includes 30 teams of 2-3 members and each team consists of a team lead and 1-2 Oregon State University (OSU) students. The team leads are THWs or other allied or community or health worker with an equivalent skill set engaging with the public (e.g. home visitors, nurses or nursing students, medical assistants, etc.) or that work alongside the clinical team (e.g. allied health care providers). THWs is an umbrella term for frontline public health workers who are trusted members of the community and have extensive training in community engagement. There are five specialty types of THWs:

- Community Health Workers (CHW)
- Birth Doulas
- Personal Health Navigators (PHN)
- Peer Support Specialists (PSS)
- Peer Wellness Specialists (PWS)

Senior TRACE personnel have existing relationships with local health departments and agencies who employ individuals eligible to serve as team leads. Team Leads are responsible for obtaining informed consent, child assent, conducting the brief interview (below) and overseeing collection of the nasal swab specimen (below). OSU student members of the field teams lead the navigation through the selected census blocks and assist with transporting materials. The OSU student members of the field teams are identified, trained, and certified as collaborators rather listed as study personnel. As of June 1, Team Leads are hired as OSU temporary employees.

b. Staff Training

All field staff complete a training developed consistent with the **Johns Hopkins Bloomberg School of Public Health Human Subjects Research Ethics Field Training Guide**. This training guide covers ethical interaction with human participants and data integrity. In addition, all field staff receive approximately 5 hours of just-in-time training *before each weekend of data collection*. This is necessary to account for any changes in protocol and for new field staff. The training is led by Dr. Jeff Bethel, Co-Director and Co-PI of TRACE. Aslan Noakes, TRACE Field Operations Manager will lead the training due to any unforeseen absence by Jeff Bethel. Aslan Noakes has complete knowledge of all aspects of data collection and is qualified to lead the training.

This comprehensive, interactive training addresses the following topics:

This specific training was suggested by the OSU IRB staff and seconded by the Board.

- Overview of COVID-19
- Overview and purpose of the study
- Household selection process
- Approaching households
- Obtaining informed consent and minor assent
- Conducting the interview
- Collecting, handling, and transporting the nasal swab specimen
- Tracking form
- Materials for households
- Safety
- Communication
- Logistics

Outside of Corvallis, the field team training also incorporates input and perspectives from the local OSU Extension Office and law enforcement. For example, the local Extension Office may inform us that the issue of mask wearing is highly politicized in the community. We will then include in our training tools and responses that our field teams can use when asked by a community member why they are wearing masks. We will also consult with local law enforcement to learn if there are areas of the community in which our field teams should be particularly mindful. This local knowledge is vital to not only the success of the project but also the safety of the field teams. Working with local local enforcement also provides us an opportunity to make them aware of TRACE field teams' presence in the community. Consulting with local stakeholders also reveals whether cellphone service is erratic and backup plans are needed. In Boardman and Hermiston, we have determined that cell phone service is strong throughout the city limits, the assessment are for both communities.

All field staff also complete the OSU Mandatory Reporting of Child Abuse online training prior to data collection.

c. Pilot testing

The first weekend of data collection serves as a pilot period. Field staff approach five randomly selected census blocks (1 team per census block) and work through the protocol described above. This pilot period allows senior TRACE personnel to modify any existing procedures if deemed infeasible in the field.

d. Field staff testing

Special procedures are also in place for to ensure study personnel do not pose a risk of infection to study participants or the community. All field staff are tested for SARS-CoV-2 Tuesday or Wednesday before each weekend of data collection with a result available on Friday. Nasal specimens are collected from field staff by trained medical personnel at OSU Student Health Services. We also query field staff to determine if they have experienced any symptoms related to COVID-19 such as fever, cough, and shortness of breath or close contact with a known case. All field staff testing positive or reporting any of these symptoms are excluded from working in the field for the remainder of the project in a given community. Field staff are informed of their test result by TRACE senior personnel and provided similar guidance and resources that study participants receive with their test result. Field staff are also encouraged to adhere to social distancing measures throughout their participation in the project to decrease their risk of infection.

Weekly testing in combination with the use of personal protective equipment (i.e. masks and gloves) among field staff is sufficient to greatly minimize the risk of infecting study participants as well as fellow members of the field teams. While the infectious period may begin one to two days before symptoms appear, people are likely most infectious during the symptomatic period, even if symptoms are mild and very non-specific. Also, asymptomatic and pre-symptomatic transmission of SARS-CoV-2 has been documented; however, risk of transmission is thought to be greatest when patients are symptomatic since viral shedding is greatest at the time of symptom onset and declines over the course of several days to weeks.

8. Data Management and Security

Data management and security for the collected data are addressed in complete detail within the Data Management and Security Plan (see appendix A). In brief summary:

- Clear data management and security roles and responsibilities of all TRACE personnel and collaborators, including training of all personnel in data management and security procedures
- Documented secure data flow procedures from field data collection using paper forms; transport of paper forms for data entry; data entry and database management using state of the art Research Electronic Data Capture (REDCap) software, and data integration with biospecimen results.
- Use of bar coding and subject identification numbers to minimize use of personal identifiers when handling specimens and questionnaire data
- To protect the privacy and confidentiality of participants, personal identifiers are separated in a coded database (bar codes and subject identification numbers) with access limited to the PI and Database Coordinator
- Data architecture that meets or exceeds OSU standards for level 3 information security for confidential data (personally identifiable and health information) and managed by the University Information Technology and with oversight from the Chief Information Security Officer
- Data sharing limited to results reporting of only aggregate data of prevalence rates and de-identified coronavirus sequence data
- For participants who opt to receive test results via secure email, we added an email verification step to ensure results are going to the participant

21.2 If any of the activities would be conducted regardless of the research, briefly describe those activities here:

NA

21.3 Will participants be audio or video recorded?

○ Yes ◉ No

21.4 Does the study involve conducting research activities online?

○ Yes ◉ No

21.5 Is the study designed to be implemented in phases, where fully describing one phase is dependent upon the outcome of another?

○ Yes ◉ No

21.6 Describe each study team members' role on the project and their qualifications to safely and appropriately to conduct these activities (e. g., related academic degree(s), previous professional experience in a relevant area, applicable certification, specialized skills):

Dr. Benjamin Dalziel, PhD (PI): Assistant Professor of Integrative Biology, leverages high-volume observational data to analyze epidemic dynamics. His BSL-2 lab is fully equipped to perform the required high-throughput RNA purification and RT-PCR assays, and it contains extensive space for sample storage. Dr. Dalziel collaborates with co-PI Tyler, who directs the Center for Genome Research and Biocomputing, where we will sequence the viral genomes. Dr. Dalziel has collaborated with the International Federation of Red Cross and Red Crescent Societies to develop mobile-phone-based systems for emergency response and community-based disease surveillance by volunteers. Emergency response teams have applied these tools in rural Haiti to monitor cholera and in West Africa to coordinate the information management systems of two Ebola treatment centers during the 2014-2015 Ebola epidemic in West Africa. The tools enabled response teams to track the timing, location, and Ebola infection status of thousands of safe burials of non-hospitalized Ebola victims.

Dr. Jeffrey Bethel, PhD (Co-PI): serves as Associate Professor and Director of the Epidemiology Program in the College of Public Health & Human Sciences at OSU. Dr. Bethel is well-positioned to conduct this work, given his background and expertise in infectious disease epidemiology and disaster-related research, both as a public health practitioner and as an academic researcher. Dr. Bethel was an epidemiologist at the Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), where he conducted infectious disease surveillance along the US-Mexico border and was intimately involved in pandemic influenza planning. As an academic, he has conducted research on enteric diseases, influenza, and tick-borne diseases. He is former Co-Director of the CDC-funded Oregon Integrated Food Safety Center of Excellence, which helps state and local health departments build their capacity to track and investigate enteric diseases. Dr. Bethel also has extensive experience with rapid data collection, which lies at the heart of the proposed project. Specifically, Dr. Bethel has led several Community Assessment for Preparedness and Emergency Response (CASPER) projects to assess household-level preparedness of communities during the inter-disaster phase. Dr. Bethel has extensive experience applying CASPER methods to identify a population-based sample, develop data collection tools, train interviewers, and collect and analyze data.

Aslan Noakes, RN, MPH (Field Operations Manager): oversees the logistics and staffing of the field teams and assists with their training, with emphasis on PPE & infection prevention protocol. She has been a nurse for 10 years, with experience in college ambulatory care and occupational medicine. She also runs a hypertension management program in Haiti and a for-profit social enterprise, Empower Haiti Together.

Field Team: Team leads and others who will collect data in the field will be identified as the project proceeds. They will be trained in accordance with training setion of this protocol. Their training will be documented and recorded at the time for continuing review.

Matthew Peterson (Database Coordinator): Senior Faculty Research Assistant at the Center for Genome Research and Biocomputing (CGRB), is tasked with developing health and data informatics solutions for the Center. He holds a Masters in Applied Information Management from the University of Oregon and has over 20 years' experience in data management, data security, and information technology. Matthew has extensive experience as a system administrator, database administrator, and programmer, both in industry and academia. He is the Database Coordinator for TRACE-COVID-19, where his responsibilities include designing, implementing, managing, and securing data acquisition and notification platforms.

Dr. Brett Tyler (Co-PI): a Professor and Director of the Center for Genome Research and Biocomputing. He is a co-PI of the TRACE project. He has over 30 years' experience in data management. He is responsible for overseeing the TRACE data management team.

Justin Preece: Senior Faculty Research Assistant in the Department of Botany and Plant Pathology. He has over 20 years' experience in data management and information technology in the private and public sectors. He is the Data Entry Computer Lab Manager for TRACE, where his responsibilities include training the data entry staff, and maintaining quality control and data privacy measures.

22.0 Compensation

22.1 Describe any compensation or incentives for participants:

Participants will not receive payment for participation. However, we will provide participants in Corvallis with a digital thermometer as a token of our appreciation. Costs have become prohibitive for procuring the digital thermometers for communities beyond Corvallis in addition to some concern over their use.

23.0 Costs

23.1 Describe any costs to participants that are associated with the study (e.g., parking, travel, etc.):

None. The entirety of the participants' participation takes place at their front door and should last less than 30 minutes.

24.0 Biological Samples

24.1 Indicate what biological samples will be received or collected:

Participants will submit a nasal swab specimen to test for SARS-CoV-2. Participants are given a self-testing kit to obtain their own sample.

Note: Rachel Aber and Elizabeth Knorr (see 24.9 below) will not be handling personally identifiable information or samples.

24.2 Will any of the samples be obtained prospectively from living individuals?

(•) Yes ( ) No

24.3 Where possible, risks should be minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes:

Check all that apply:

- [x] Samples are being collected separately from any clinically indicated procedure or another approved study
- [ ] Study involves taking additional samples during clinically indicated procedure or another approved study
- [ ] Study involves using samples leftover from a clinically indicated procedure or another approved study

24.4 If blood samples will be collected, provide the maximum volume to be collected in an 8-week period and the frequency of collection:

NA

24.5 Will any clinical lab testing be conducted?

(•) Yes ( ) No

Describe the purpose of the tests:

The main purpose of the study is to determine the prevalence of SARS-CoV-2 infection in communities. Therefore, nasal swab specimens will be tested for the presence of SARS-CoV-2, the main outcome of this study.

Will results will be disclosed to participants and/or their treating physician?

(•) Yes ( ) No

Will the human biological material be tested/collected in a CLIA-certified lab?

(•) Yes ( ) No

Attach the CLIA certificate. Attachments are uploaded in a single section at the end of this form.

24.6 Will the study involve genetic testing?

( ) Yes (•) No

24.7 Will samples be stored for future studies?

(•) Yes ( ) No

Indicate how long samples will be retained, how they will be stored, and what they will be used for:

Given what we know about SARS-CoV-2 is changing quickly, samples will stored indefinitely in a freezer on the OSU campus. Samples may be tested at a later date since more will be undoubtedly be learned about the virus in the future and we will want to confirm with our samples.

The information in the consent form should convey the disease, condition, or specific field of study for future projects. Explain whether and how participant permission will be sought for future studies of existing samples:

The consent form includes a section regarding "Future Studies" in which we seek participants' permission at the time of data collection/consent for future analysis of their samples for the virus as well as additional sequencing. We inform participants that their name and other identifying information will not be included in future analyses.

Indicate whether participants will be contacted by researchers in the future for the purpose of updating information:

We disclose in the consent form that we may contact participants in the future for a related study.

Indicate whether and how participants can opt out of any sharing or future use of their sample:

Withdrawal of samples provided by participants will be very difficult since the samples are quickly taken to OSU lab for preparation and then to WVT for testing (see sec 8.4 and 27). Any future use of the samples and data beyond the TRACE team and public health officials (SARS-CoV-2 test results are mandatory reported now) will occur after the data and samples have been de-identified (per the consent form).

24.8 Provide location(s) of material handling, manipulation, and storage at OSU (i.e., building and room):

Cordley Hall 5016

24.9 Provide the names of all personnel who will be working with biological materials:

Benjamin Dalziel, Rachel Aber, Elizabeth Knorr

25.0 Privacy and Confidentiality

25.1 Instructions:

Many of the terms used in this section are defined in the **glossary** under the heading "Privacy, Confidentiality, and Identifiers".

25.2 Privacy, in the context of a research protocol, means respecting an individual's right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing, and circumstances of obtaining personal information from or about them. Explain how privacy will be respected when identifying and recruiting potential participants:

Participant confidentiality will be protected throughout the study. Regarding identifying and recruiting potential participants, per the sampling scheme previously described, field staff will *not* have any personal identifiable information (including name and address) before approaching a prospective household in the field (second stage of the sampling scheme).

There is a separate OSU study looking at SARS-CoV-2 in wastewater. We will share the locations of the randomly selected clusters (i.e. census blocks) in Bend, Newport, Boardman, and Hermiston with these researchers so that they can test wastewater in these areas of Bend and Newport for SARS-CoV-2. We will also share the identifies of randomly chosen clusters (i.e. census blocks) in Bend, Newport, Boardman and Hermiston in which the virus was detected in at least one TRACE participant. No personal identifying information will be shared, only location of census blocks and whether or not any sample tested positive in a given census block (yes/no). Note that the IRB has previously made a determination that the wastewater study does not involve human subjects.

25.3 Check all that apply:

- [x] Direct and/or indirect identifiers will be requested or recorded
- [ ] Data will be collected anonymously or provided to researchers without identifiers
- [ ] Researchers will know the identity of participants but will not record identifying information
- [ ] Other

25.5 List the direct identifiers (e.g., names, social security numbers, addresses, telephone numbers, student ID, medical record number, mTurk ID, photographs, video recording):

Name
Address
Email address
Telephone number

25.6 Indicate whether identifiers or codes will be retained that could link the identity of the participant to the sample:

TRACE uses bar coding and subject identification numbers to minimize use of personal identifiers when handling specimens and questionnaire data. To protect the privacy and confidentiality of participants, personal identifiers are separated in a coded database (bar codes and subject identification numbers) with access limited to the PI and Database Coordinator via a secure laptop stored in a secure room on OSU campus (see Data Management and Security Plan)..

25.7 List the indirect identifiers (e.g., combination of demographic and other variables such as gender, race, ethnicity, age, zip code, company affiliation, class standing, department, audio recording):

Gender
Date of birth
Race
Zip code

25.8 Describe the steps that will be taken to minimize the chances of a breach of confidentiality during and after data collection (e.g., coding system, pseudonyms, etc.):

Data management and security for the collected data is addressed in complete detail within the Data Management and Security Plan (see attached). In brief summary:

- Clear data management and security roles and responsibilities of all TRACE personnel and collaborators, including training of all personnel in data management and security procedures
- Documented secure data flow procedures from field data collection using paper forms; transport of paper forms for data entry; data entry and database management using state of the art Research Electronic Data Capture (REDCap) software, and data integration with biospecimen results.
- Use of bar coding and subject identification numbers to minimize use of personal identifiers when handling specimens and questionnaire data
- To protect the privacy and confidentiality of subjects, personal identifiers are separated in a coded database (bar codes and subject identification numbers) with access limited to the PI, Data Management Team Lead, Data Entry Computer Lab Manager, and Database Coordinator (all listed as study team members)

- Data architecture that meets or exceeds OSU standards for level 3 information security for confidential data (personally identifiable and health information) and managed by the University Information Technology and with oversight from the Chief Information Security Officer
- Data sharing limited to results reporting of only aggregate data of prevalence rates and de-identified coronavirus sequence data

25.9 Will a copy of the consent form, test results, or other research study information be placed in the participants' record (e.g., medical, personnel, or education record)?

○ Yes ◉ No

26.0 Record Retention

26.1 Will the Principal Investigator store research records in a secure and audit accessible manner for a minimum of three years post-study termination?

◉ Yes ○ No

26.2 Will the student researcher also store research records after the study has closed?

○ Yes
○ No
◉ N/A

26.3 If the study is FDA-regulated, confirm the PI will also comply with the following relevant records retention requirements:

In accordance with **21 CFR 312 (drugs),** an investigator or sponsor shall retain the records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified:

○ Yes
◉ N/A

Comments:

In accordance with **21 CFR 812 (devices)**, an investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol:

○ Yes
○ No
◉ N/A

Comments:

26.4 Will a link between study code numbers and direct identifiers be retained after data collection is complete?

◉ Yes ○ No

Explain why this is necessary and state how long the link will be retained:

Yes, a link between study code numbers and direct identifiers will be retained after data collection is complete. We may need to know the identify of persons who test positive for SARS-CoV-2 so that we can contact them again for future studies, including testing their blood for antibodies to SARS-CoV-2. We may also want to retest some participants for SARS-CoV-2. The link will be retained indefinitely.

26.6 Will data be stored for future studies?

(●) Yes ( ) No

Indicate how long data will be retained, how it will be stored, and what it will be used for:

Data are stored indefinitely on secure servers and will be used for future analysis.

The information in the consent form should convey the area of study for future projects. Explain whether and how participant permission will be sought for future studies of existing data:

The consent form includes a section regarding "Future Studies" in which we seek participants' permission at the time of data collection/consent for future analysis of the virus and the epidemic. We inform participants that their name and other identifying information will not be included in future analyses.

Indicate whether participants will be contacted by researchers in the future for the purpose of updating information:

Participants consent to future contact as part of the initial consent process.

Indicate whether and how participants can opt out of any sharing or future use of their data:

Participants cannot opt out of future use of their data.

27.0 Sharing Data and Biological Samples

27.1 Will data and/or samples be shared with individuals or entities external to OSU (e.g., made public, shared with sponsor, sent to collaborators, given to people at the site of research, etc.)?

(●) Yes ( ) No

Why and with whom?

As previously described, samples and participant information will be shared with WVT Lab. The samples are shared with WVT so they can test the samples for the presence of SARS-CoV-2. All participant information (including identifiers) and samples are shared with WVT because this information is required with WVT's mandated reporting to public health officials.

Will shared data and/or samples be individually identifiable?

(●) Yes ( ) No

Will data security plan at the external site match or exceed the OSU data security plan?

(●) Yes ( ) No

Describe how security will be maintained in transit:

Per Section 8.4 of the IRB Application and the Data Management and Security Plan (attached), data and samples are taken from OSU to WVT for reporting purposes and testing, respectively.

Barcoded interview data are stored on an OSU-approved, level 3 data storage mechanism and physically taken to WVT. WVT needs the participants' personal information from the interviews to complete their mandatory reporting of test results to the local health department. After OSU/OVDL complete preparation of the samples including splitting them for sequencing, project staff package nasal swab samples in accordance with BSL2 procotols and transport them to the WVT for testing. After WVT completes testing the samples, results are stored on an OSU-approved, level 3 data storage mechanism and project staff will again physically retrieve it and return to the the OSU Dalziel Lab.

A similar process will occur for data collection in Bend and Newport with the only difference being that the locations are nearly 3 hours and 1 hour apart, respectively. Samples and interviews will be transported on Saturday and Sunday of data collection, respectively. Samples will not be stored in Bend or Newport overnight. A similar process will also occur in Boardman and Hermiston. However, since Boardman and Hermiston are 4-5 hours from OSU, we will store samples and completed interviews in a secure location

within the local Extension Office, which falls within the purview of the College of Public Health and Human Sciences.

27.3 Will the intent to share data be disclosed to research participants as part of the consent process?

(•) Yes ( ) No

28.0 Publication

28.1 Could any of the participants be identifiable in publication or presentation (e.g., results will be reported using direct quotes, group or tribe name, company name and position title)?

( ) Yes (•) No

28.2 Is the study student-driven (for the purpose of a thesis, dissertation, or other)?

( ) Yes (•) No

28.3 Will manuscripts, presentation materials, theses, or dissertations be stored in Scholars Archive?

( ) Yes (•) No

28.4 Will individually identifiable data or specimens be stored in an archive or repository?

( ) Yes (•) No

29.0 Data Security

29.1 What is the data security level for this study?

Level 3

Use this matrix to determine the data security level and related requirements for this study.		Breach of confidentiality p	
		No Risk	Minimal Risk
Are data and/or subjects:	De-Identified or anonymous?	**Level 1**	**Level 1**
	Identifiable or coded?	**Level 1**	**Level 2**

29.4 Data Security Level 3:

Will the following security requirements be met?

- Information will be shared and stored in a manner that provides access only to authorized individuals.
- Data will not be disclosed to additional parties without prior IRB approval specifically authorizing the disclosure.
- If information is stored on a computer, the system will have fully patched operating systems and applications, and current virus definitions.
- When feasible, information will be stored in a local system of record (e.g., local server, approved cloud).

- All mobile computer systems or portable storage media will be encrypted with at least the 256-bit encryption comr encoding devices sold in the United States.
- If the data are coded, and there is a linked list of codes and identifiers, this list will be stored separately from all c
- Identifiable information will not be stored on student researchers' computers after the study has ended, unless jus and approved by the IRB.
- Computers must have host-based firewalls enabled in addition to being behind a networked firewall context.
- A plan for routine back-ups of all data must be in place, with the appropriate security mechanisms for that data, in security addressed.
- **The researchers will review the data security plan with the Information Security Office before initiatin**

(•) Yes ( ) No

Outline any additional safeguards that will be taken:

See the attached Data Management and Security Plan for full details.

30.0 Potential Reporting Obligations

30.1 Study includes collection of information regarding child abuse or neglect OR it is reasonable to expect that child abuse or neglect could be observed or revealed to the researchers?

(•) Yes ( ) No

30.2 Study includes collection of information regarding sexual harassment or sexual violence OR it is reasonable to expect that such information could be revealed to the researchers?

( ) Yes (•) No

30.3 Study includes collection of information regarding harm to self or others OR it is reasonable to expect that such information could be observed or revealed to the researchers?

(•) Yes ( ) No

30.4 Describe the reporting plan:

Under Oregon law, we are required to report to the appropriate authorities any information concerning child abuse or neglect. We may also report threats of harm to self or to others. OSU has a reporting protocol in place (**https://youth.oregonstate.edu/abuse**), to which we will adhere.

30.5 Describe the relevant training that study team members have, or will receive, to minimize risks to participants and comply with the reporting requirements:

Study team members have or will complete the OSU Mandatory Reporting of Child Abuse online training. PIs have already completed this training and all field staff will complete this training before data collection.

31.0 Certificate of Confidentiality

31.1 A Certificate of Confidentiality has been automatically deemed issued because this study is NIH-funded and includes individually identifiable data?

( ) Yes
(•) No
( ) N/A

31.2 A Certificate of Confidentiality from the NIH has been obtained or will be sought for this study because it includes the collection of individually identifiable, "sensitive" data?

- ○ Yes
- ◉ No
- ○ N/A

32.0 Risks

32.1 If children will be enrolled, which of the following four federal categories applies:

Check one:

- ○ Research does not involve greater than minimal risk to children.
- ○ Research involves more than minimal risk to children but the study holds prospect of direct benefit to the participants.
- ○ Research involves more than minimal risk to children and there is no prospect of direct benefit to participants, but the study likely to yield generalizable knowledge about the participants' disorder or condition.
- ◉ Research is not otherwise approvable under the federal regulations but the study presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the participants.

32.2 Describe all reasonably foreseeable risks to study participants:

The interview questions included in the study do not pose risks to participants or their health. The collection of the nasal swab specimen (self-test) may cause slight discomfort. Again, note that we are collecting a nasal swab, not a nasopharyngeal swab which is much more invasive. There is also a small risk that participants' personal health information and result of the COVID-19 test may be accidentally released. This accidental release may have economic and occupational impact on the participant. In addition, accidental release could result in the participant being stigmatized by others for a positive COVID-19 test result.

There is also a risk of accidental infection of participants by field staff.

Replicating TRACE in additional communities beyond Corvallis does not increase risk to study participants.

32.3 Describe all steps taken to minimize risks:

Steps to minimize breach of confidentiality are summarized in part 24.8 and described in great detail in the Data Management and Security Plan (attached).

Instructions for participants to safely and properly collect a nasal swab specimen are included in the self-test kit we provide to participants. They are clear, step by step instructions in plain language with visuals.

To prevent accidental infection of participants by field staff, strict social distancing protocols are implemented. These state that field staff must remain at least 6 feet away from participants or closer when the door to the dwelling is closed (e.g. to retrieve consent form or nasal swab specimen from front step). We are also testing all field staff for COVID-19 weekly prior to data collection so that infected personnel are not interacting with the community.

32.4 Because the study is greater than minimal risk, attach a Data and Safety Monitoring Plan in the section at the end of this form, or provide the following information:

Definition of an adverse event for this study:

Adverse event for this protocol includes tailure of infection control measures.

Definition of a serious adverse event for this study:

Serious adverse event for this protocol includes tailure of infection control measure

Provide a plan for managing adverse events:

We would become aware of an adverse event if a complaint was received from the participant. If this occurs, we will notify the IRB immediately and tell the participant to inform their healthcare provider for follow-up.

Summarize any reporting requirements and timelines:

We will notify IRB immediatley of any adverse event.

Indicate if there are any individual or overall study stopping rules:

There are no individual stopping rules. Overall study stopping rule includes becoming aware of failure of infection control measures.

Provide the plan for reporting adverse events or unanticipated problems (e.g., breach of confidentiality, incarcerated participant, or an unresolved complaint):

We will immediately notify the IRB of any adverse evens or unanticipated problems.

If the potential harm related to physical, psychological, or financial risks is greater than minimal, describe the plan for paying for related costs to participants:

OSU does not have a program in place to pay for research-related harms.

33.0 Benefits

33.1 Describe potential benefits to the individual participants, to society, and to science:

Participants do not directly benefit from being in the study. However, the study will have great benefit to society and science. Our data will help local, state, and federal health officials to combat COVID-19 more effectively, predict the spread of the disease more accurately, inform containment and mitigation strategies for specific communities, allocate resources to locations that need them most, and evaluate the effectiveness of enacted strategies. Accurate data regarding the prevalence of SARS-CoV-2 will help us as a nation to assure that we react appropriately (neither overreact nor under-react), minimize the human and economic costs, and return our culture and our economy to normal as soon as possible. Without community-level testing, we will continue to fight an invisible forest fire.

34.0 Training and Oversight

34.1 Is the PI the only member of the study team?

○ Yes ◉ No

34.2 Describe the plan for confirming or providing training related specifically to the study activities and for supervising all study team members:

Training

Senior personnel directly involved with participants or who have access to personally identifiable data will complete (or have completed) relevant CITI training.

Field staff receive approximately 5 hours of just-in-time training *before each weekend of data collection*. The training is led by Dr. Jeff Bethel, Co-Director and Co-PI of TRACE. Aslan Noakes, TRACE Field Operations Manager will lead the training due to any unforeseen absence by Jeff Bethel. Aslan Noakes has complete knowledge of all aspects of data collection and is qualified to lead the training. This is necessary to account for any changes in protocol and for new field staff. This comprehensive, interactive training addresses the following topics:

- Overview of COVID-19
- Overview and purpose of the study
- Household selection process
- Approaching households
- Obtaining informed consent
- Conducting the interview
- Collecting, handling, and transporting the nasal swab specimen
- Tracking form
- Materials for households

- Safety
- Communication
- Logistics

Outside of Corvallis, the field team training also incorporates input and perspectives from the local OSU Extension Office and law enforcement. For example, the local Extension Office may inform us that the issue of mask wearing is highly politicized in the community. We would then include in our training tools and responses that our field teams can use when asked by a community member why they are wearing masks. We will also consult with local law enforcement to learn if there are areas of the community in which our field teams should be particularly mindful. This local knowledge is vital to not only the success of the project but also the safety of the field teams. Working with local local enforcement also provides us an opportunity to make them aware of TRACE field teams' presence in the community. Consulting with local stakeholders also reveals whether cellphone service is erratic and backup plans are needed. This would be incorporated into the training. In Boardman and Hermiston, we have determined that cell phone service is strong throughout the city limits, the assessment are for both communities.

Data collected from field team leads and student researchers about procedures and their test results will not be included in the analysis.

Supervision
Project personnel will accompany the 5 field teams during the first weekend of pilot testing to ensure that all study protocols are followed. We will also review completed interview forms, tracking forms, consent documentation, and all other documents to ensure forms are completed correctly. We will also hold a debrief with field teams from the pilot phase to learn how the process went in the field. and if changes are needed. The information gained from the first weekend of pilot testing may result in changing the training for the subsequent weekend of full data collection (i.e. 30 teams).

The protocol for supervising field teams will change once we are past the pilot phase. We do not have the personnel to accompany each of the 30 teams in the field throughout the weekend of data collection. Rather, project personnel will accompany each of the 30 teams for a few houses in their assigned clusters to ensure that protocols are followed. We will also contact field teams to complete a short online survey to obtain their feedback regarding the data collection process in the field. We will repeat this every weekend of data collection.

34.3 Describe the plan for training related specifically to obtaining informed consent and maintaining confidentiality:

All field staff complete a training developed consistent with the Johns Hopkins Bloomberg School of Public Health Human Subject Research Ethics Training (**https://www.jhsph.edu/offices-and-services/institutional-review-board/training/jhsph-human-subjects-research-ethics-field-training-guide.html**). This training guide covers ethical interaction with human participants and data integrity. This training will be repeated before every weekend of data collection.

From the JHSPH website:
"This guide is intended to be used as a tool for training individuals who will be "engaged" in some aspect of a human subject research interaction or intervention. It is directed, in particular, to principal investigators who are responsible for training of study team members who will (1) obtain informed consent from research participants, or (2) collect data from human subjects through individual or focus group interviews, testing, physical measurements, or other procedures involving direct contact, hereafter called a "data collector." the contact and language level of the guide is specifically worded to help the investigator convey basic research principles and behavior that accords with those principles to data collectors."

In addition to the training on human subjects research ethics, the 5 hour training of all field team members (including team leads) includes mandatory child abuse reporting and how to properly obtain informed consent and child assent. This training is provided by senior TRACE leadership.

34.4 Explain how oversight of study team members will be handled during PI absences (sabbaticals, non-contract months, etc.):

PI Dalziel and Co-PI Bethel have no plans for sabbatical and are funded throughout the study period. At least one of them will be available for oversight of study team members at all times.

35.0 Application Questions Complete

35.1 Having completed the application questions, please return to section 1.0 to confirm that you have selected the appropriate review level, then return to this section to complete the application.

35.2 Click the box below to close all help text notes (required):

If the application is complete and ready to be submitted, please click "Close Help Text, Examples, Links". If you are revising the application in response to submission corrections or review response, you can click "Re-open Help Notes" to make all help notes visible again.

- (•) Close Help Text, Examples, Links
- ( ) Re-open Help Text, Examples, Links

35.3 Please click Save & Continue to proceed to the Initial Review Submission Packet.

The Initial Review Submission Packet is a short form filled out after this application has been completed. This is where you will attach documents.