RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: The Key to Oregon Study-COVID-19 Symptom Tracking

PRINCIPAL INVESTIGATOR: Jackilen Shannon, PhD
CONTACT INFORMATION: keyparticipant@ohsu.edu

You are being asked to join a research study. This consent form gives you important information to help you decide if you want to join the study or not.

PURPOSE:
We want to learn more about the COVID-19 virus and how it spreads across Oregon. We are measuring symptoms and the number of people who are infected with this virus. We will share this information with state and local decision makers about whether such things like stay-at-home orders and wearing masks are working to control spread of the infection. We also want to learn about people’s behaviors during this outbreak and how the crisis is affecting their lives.

STUDY ACTIONS:
If you choose to join, you will be asked to:
- Consent to the study in the website
- Answer daily questions about your symptoms that will take between 1-10 minutes a day
- Take your temperature with your own thermometer or a no cost, study-provided, internet-connected thermometer
- Answer questions (survey) once a week.
- Choose if you want to allow us to contact you for future research
- Choose if you want to add your study information into a repository (a large database that has many people’s information in it)

If you meet a certain level of symptoms or you are chosen randomly, we may send a COVID-19 testing kit to you. We may offer to send testing kits to all adults in your household. The testing kit(s) will need to be returned for testing.

The study will last about one year but you can choose to leave the study at any time.

RISKS:
You may experience the following risks:
- Mental distress or possible financial hardship if you are found to be positive for COVID-19.
- Feeling uncomfortable about questions, but you may choose not to answer any question.
- Possibility of a breach of confidentiality, but this is a small risk, as we follow all of OHSU’s privacy rules.
**BENEFITS:**
If you choose to join this study, you may benefit from being tested for COVID-19 and possibly getting earlier treatment for the infection. You may also help cut the risk of spreading the infection to others.

**ALTERNATIVES:**
You may choose not to join this study.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY
Research Consent and Authorization Form

TITLE: The Key to Oregon Study - COVID-19 Symptom Tracking

PRINCIPAL INVESTIGATOR: Jackilen Shannon, Ph.D.

CO-INVESTIGATOR: Paul Spellman, Ph.D.

CONTACT INFORMATION: Email: KeyParticipant@ohsu.edu

WHO IS PAYING AND PROVIDING SUPPORT FOR THE STUDY?
Oregon Health & Science University (OHSU) Foundation and the State of Oregon

WHY IS THIS STUDY BEING DONE?
We want to learn more about the COVID-19 virus and how it spreads across Oregon. We are measuring people’s symptoms and the number of people who are infected with this disease. We want to learn about the best actions people and communities have been taking, and should take, to contain the spread of the infection, and when it may be safe to return to regular daily routines, too. We will share these findings with state and local decision makers. We would like you and 100,000 other households to join this study.

This study asks you to take your temperature and answer symptom questions daily, and answer questions weekly about how the COVID-19 crisis is affecting your daily life. The study will last about one year but you may choose to leave the study at any time.

There are two parts of the study that are optional:
1. Giving us permission to contact you about future research studies, and
2. Giving us permission to add your information and specimens to a data bank, also called a repository.
   Information and data stored in a repository is stored forever and may be used and shared for future research.

WHAT ACTIONS DO I TAKE WHEN JOINING THIS STUDY?
You will use the letter we mailed to you to find the study website, read, understand, ask questions about the consent (this form), and make decisions about joining the study and giving permission about the two optional parts of the study. After you make your decisions, you may choose to consent and join the study.

There will be no cost to you or your insurance company to join this study.

Requesting the Kinsa thermometer
When you enroll, you may request that a free Kinsa thermometer be mailed to you. The Kinsa thermometer will come with directions about how to use it and how to download the Kinsa smartphone application (app) to answer your daily symptom questions. The Kinsa thermometer connects to the internet through a Bluetooth connection. The Kinsa app will ask if you want your temperature and symptom information sent directly to OHSU.

You do not have to download the Kinsa app to join this study. You do not have to agree to have your Kinsa data sent directly to OHSU to join this study. If you do not download the Kinsa app, or if you do not choose to allow to have your Kinsa temperature and symptom information sent directly to OHSU, you can still answer the daily questions and enter your temperature on the OHSU website.
If you download the Kinsa app, Kinsa will know that you have joined the study and will collect your temperature and symptom information. Any temperature and symptom information you provide will be handled and used by Kinsa as described in the Kinsa app agreement.

**What to Expect (Overview of Study Activities):**
We will send daily emails to remind you to track symptoms you might be feeling. We will ask you questions about your symptoms and about how the COVID-19 crisis is affecting your daily life.

<table>
<thead>
<tr>
<th>Study Activity</th>
<th>Consent Process</th>
<th>Study Entry</th>
<th>Daily until end of study (planned for 1 year)</th>
<th>Weekly until end of study (planned for 1 year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent (15 minutes)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily Symptom Tracking questions (1 minute)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take Your Temperature (1 minute)</td>
<td>X</td>
<td>X</td>
<td></td>
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</tr>
<tr>
<td>Questions about how the COVID-19 crisis is affecting your life (surveys) (5-10 minutes)</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Total time</td>
<td>27 minutes</td>
<td>1-10 minutes a day</td>
<td>10 minutes every week</td>
<td></td>
</tr>
</tbody>
</table>

**Daily Symptom Tracking:**
The symptom tracking survey will ask you:
- general questions about how you are feeling each day,
- to take your temperature, using your own thermometer or the Kinsa thermometer.

**COVID-19 Testing:**
When your symptoms meet a specific level or you are chosen randomly, we may offer to send a COVID-19 testing kit to you. We may also offer to send official testing kits for all people over the age of 18 in your household. We may ask you to travel to a collection site to test you in person OR we may send a testing kit that you have to return to a collection site OR a testing kit that we send with a pre-paid return package.

If you have symptoms that you think might be COVID-19, please talk to your healthcare provider.

We will create a medical record for you at OHSU so that your testing results are entered into an official medical record. This means your test result will be visible to healthcare providers who have access to your medical record. We must use some of your personal information, such as your name, date of birth, birthplace and mother’s maiden name to create your medical record. If we send testing kits to other adults in your household, we will have to create a medical record for these adults but they will only receive the testing kit and will not be part of the study unless they choose to join themselves.

By law, OHSU will share both positive and negative test results with the Oregon Health Authority (OHA). This is for public health tracking (also known as surveillance).

**Additional Questions:**
Once a week, we will ask you questions through the website about your behaviors, such as physical and social distancing, during the COVID-19 crisis. We will also ask you other questions about how the COVID-19 crisis is impacting your daily life at home or work. These questions will take you up to 10 minutes to finish.

**Optional Contact for Future Research and Repository Permission:**
If you choose to give us permission to contact you for future research studies, and/or keep your information for future research in the study’s repository, we will label your information as described in the **WHO WILL SEE**
MY PERSONAL INFORMATION? Section (below).

If you do not choose to allow us to contact you about future research studies or keep your information for future research in the study’s repository, we will delete all your data after the end of this study.

WILL I GET MY RESULTS FROM THIS STUDY?
If you are found to have positive test results, a clinical study staff member will talk to you directly. Your information will also be sent to OHA. Study staff will talk to you about tracking your symptoms. You may also be contacted 7-14 days after you receive your results to check on how you are doing.

If you are found to have negative screening test results, the study staff will reach out to you over the phone OR by secure electronic communication OR by mail.

IF I CHOOSE TO JOIN THIS STUDY, WHAT RISKS AM I EXPOSED TO?
There are minimal risks to you to join this survey and sample collection study. You may experience the following risks:

Psychological Risk: if you are found to be positive for COVID-19, you may experience mental distress. The behavior survey questions may make you uncomfortable. You do not have to answer any question you do not want to.

Financial Risk: if you are found to be positive for COVID-19, you may experience financial hardship in treating the infection or from being told by health officials to isolate yourself. This study does not pay for or give any medical care.

Breach of Confidentiality: Since we use email to send you daily reminders, updates about the study and communication, there is a small risk that your information could be seen without your permission. There is no way to make sure your email is private if you share a computer or email account with another person. We cannot make sure that your email is opened and read by you, the addressee.

By agreeing to join this study, you accept the risks associated with using email for these generic communications, including any breach of confidentiality not caused by OHSU, and any problems with the internet or your internet service provider, computer/device’s hardware or software, or any other service that you use to access email.

Important Note: We will not send personal information (for instance, your testing results) about you to your email unless we send it encrypted.

WHO WILL SEE MY PERSONAL INFORMATION?
Health information is private and is protected under federal law and Oregon law. We will take steps to keep your personal information confidential. We will collect data through a HIPAA compliant website, store it in a HIPAA compliant database and restrict access to the study team. However, we cannot guarantee total privacy.

By agreeing to be in this study, you are giving permission (also called authorization) for us to use your health information to conduct and oversee this research study. You are also giving permission for us to share it with others outside of OHSU who are involved in conducting or overseeing the research, including:

- The Office for Human Research Protections, a federal agency that oversees research involving humans.

If you agree to the optional repository, we may also share your specimens and information with other researchers to use for future research studies. If you agree to be contacted for future research studies, we will share future research opportunities with you to see if you are interested in joining those other studies.

We will not release information about you to others not listed above, unless required by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.
To help us protect your privacy, we have a Certificate of Confidentiality that protects your information from people who try to get your information using a court order. However, the Certificate of Confidentiality cannot prevent us from reporting child or elder abuse or neglect, harm to yourself or others, or communicable disease that we are required by law to report. The Certificate of Confidentiality also does not keep you from giving the information to others if you want to.

OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments, so we will release your COVID-19 test results to OHA.

When we send information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

We may continue to use and disclose your information as described above indefinitely (forever).

**WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?**

Samples and information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

There will be no cost to you or your insurance company to join this study.

**WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?**

If you believe you have been injured or harmed as a result of joining this study, contact the study team at keyparticipant@ohsu.edu

OHSU and the funder do not offer any financial compensation or payment for the cost of any injury or harm. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

**WHERE CAN I GET MORE INFORMATION?**

If you have any questions, concerns, or complaints regarding this study now or in the future, contact the study staff at keyparticipant@ohsu.edu

This research has been approved and is overseen by an Institutional Review Board (“IRB”), a committee that protects the rights and welfare of research subjects. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

**DO I HAVE TO TAKE PART IN THIS STUDY?**

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. You do not have to join this study if you want to receive normal medical care, including COVID-19
testing. You can contact your own doctor or healthcare provider or local health department for information about testing without being in this study.

**IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**
If you do join the study and later change your mind, you have the right to stop being in the study at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the study team if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

The Key to Oregon Study Staff (Knight Cancer Institute Clinical Research)
2720 S Moody Ave (KCRB)
Mail Code: KR-CEDR
Portland, OR 97201

or send an email to keyparticipant@ohsu.edu

If you choose to leave the study, we will act on your request as soon as the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you choose you no longer want to stay in this study, your COVID-19 test results will stay in the OHSU medical record, but we will delete all data and information from the study records.

You may be removed from the study if the study staff learn you are not over 18 years old, as this is a requirement for joining the study.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

You will be able to save a PDF and/or print a copy of your consent with this information after you submit your responses.

**AGREE TO JOIN PROJECT:**
Choosing 'I Agree' below indicates that you have read this entire form and you agree to be in this study.

☐ I agree: I have read this consent and agree to join this study.

☐ I DO NOT agree to join this study.

**OPTIONAL PARTS:**
The optional parts of this study are explained in detail throughout this consent form and listed here as a summary. Please indicate by checking the box next to each of the optional parts that you either give permission or do not give permission for that option. You can still join the main part of the study even if you choose not to give us permission for the optional parts.

☐ I give my consent for my sample and information to be stored in a repository and used for future research studies.

☐ I DO NOT give my consent for my sample and information to be stored in a repository and used for future research studies.
☐ I give my consent to be contacted to see if I want to participate in future research studies.

☐ I DO NOT give my consent to be contacted to see if I want to participate in future research studies.