Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)
OU Medical Center

Study Title: Mobile Health Study and Enhanced Symptom Monitoring to Prevent Severe Illness from COVID-19 in Cancer Patients

SPONSOR: NIH/NCI

PRINCIPAL INVESTIGATORS: Bethany Hannafon, Ph.D. and Michael S. Businelle, Ph.D.

Phone Number: (405)271-8707

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?

You are being asked to take part in this trial/study because:

- You are currently receiving cytotoxic chemotherapy or immunotherapy
- You are interested in remote symptom monitoring
- You are a patient of the Stephenson Cancer Center

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to:

- Determine the effectiveness of the Symptom Tracker (Insight™) smartphone health application in monitoring symptoms and health risk behaviors, including the self-reported symptoms of COVID19.
- Rapidly identify symptoms of COVID19 in patients with cancer and triage patients for early COVID testing.
- Determine the effect of increased vital sign monitoring and COVID19 specific symptom monitoring in COVID19 positive patients on disease severity and length of recovery from viral illness.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 24 weeks, beginning today.

You can stop participating in this study at any time, and this will not affect your eligibility to receive treatment at the Stephenson Cancer Center. If you decide to stop participating in the study, we encourage you to talk to the research team first.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?
If you decide to participate in this study, you will be asked to download the smartphone application onto your personal smartphone. If you do not own a smartphone, or your smartphone is not compatible with the application, a loaned smartphone will be provided to you by the study. You will receive education on how to use the application and asked to complete an enrollment questionnaire on your smartphone. Once completed, you will begin to receive one brief daily survey about COVID19 symptoms and other relevant questions. You will be asked to report your temperature daily. If you do not own a thermometer, one will be provided to you by the study. If you are experiencing symptoms or have a known exposure to COVID19, a clinical research staff member will contact you and provide instructions on how to obtain testing. If your COVID19 testing is positive, then the study will provide a heart rate and blood oxygen monitor and you will be asked to input your temperature, heart rate and oxygen levels into the app each morning. You will also be counseled on the best medications for your symptoms and those symptoms for which you need to be seen by medical personnel.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?
If you agree to take part in this study, there may or may not be direct medical benefit to you. The researchers cannot guarantee that you will benefit from participation in this research. The Symptom Tracker (Insight™) smartphone application may result in earlier detection of the COVID19 virus and increase the chances of delivering medical care early in the course of the illness, which may improve how you recover from COVID19. Additionally, the knowledge we gain from this study may be used to facilitate the development of more effective smartphone based symptom screening assessments and intervention tools for patients receiving treatments for cancer. We hope that the information learned from this study will benefit other people undergoing chemotherapy and immunotherapy in the future.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
Some of the questions may make you feel uncomfortable. If this happens, you may take a break or stop participating in the study at any time. Any time information is collected; there is a potential risk for loss of confidentiality.

For a complete description of known risks, refer to the Detailed Information section of the consent form.

WHAT OTHER OPTIONS ARE THERE?
You do not have to participate in this research to self-screen for symptoms of COVID19. You have these options:

- You may monitor your symptoms and report directly to a medical provider of your choosing.

- You may choose not to monitor or report symptoms associated with the COVID19viral illness.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
There is no cost to you if you participate in this study. Neither you, nor your insurance provider, will be charged for anything related to the Symptom Tracker (Insight™) smartphone application used in this research study. You or your insurance provider will be charged for any prescription medications deemed necessary for treatment of chemotherapy or immunotherapy toxicities or COVID19 treatments recommended to you for management of your symptoms. You will be charged, in the standard manner, for any procedures performed for your standard medical care.

You will not be paid for participation in this study. Specifically, you will not be compensated for accessing on-demand app features or completion of study questionnaires

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 500 people will take part in this study. All individuals will participate at this location.

WHAT IS THE STATUS OF THE DRUGS (DEVICES OR PROCEDURES) INVOLVED IN THIS STUDY?
There are no investigational drugs, medical devices or procedures involved in this study.

WHAT IS INVOLVED IN THE STUDY?
If you take part in this study, you will have the following tests and procedures:

- If you meet the qualifications for this study, you will be asked to complete a questionnaire today. We will measure your height and weight. The enrollment questionnaire will ask about your cancer diagnosis, current treatment, overall health, education, income, gender, tobacco use, alcohol use and other health behaviors, neighborhood, mood, stress, coping, and social support.
- You will download the Symptom Tracker (Insight™) smartphone application onto your personal smartphone, or a smartphone will be loaned to you. If you own a smartphone that is compatible with the smartphone app, you can use your personal smartphone to complete surveys. You will use the smartphone to complete one daily survey for the next 24 weeks. The smartphone will ring and vibrate about 30 minutes after you wake up, to alert you that it is time to complete a brief survey about current symptoms. You will respond to surveys by using the smartphone touch screen. You will also be able to click a button in the app during the day to enter any changes in your symptoms (fever, cough, shortness of breath) or report personal contact with someone who has tested positive for COVID19 at any time.

- Smartphone surveys will each take approximately 30-120 seconds to compete. You will not receive payment for completing phone surveys. If you borrow a study phone, we will send you a postage paid envelope to return it to us at the end of the study.
- If you report symptoms of COVID19, especially after a known exposure to someone infected with the virus, clinical research staff will contact you by phone and provide instructions for where to obtain COVID19 testing and how to manage your symptoms until you receive your test results. At this time, COVID19 test results are available the same day as the testing occurs, usually within 12 hours of the test being obtained.

- If you test positive for COVID19, you will be provided with a pulse oximeter, which is a device that you place on your finger to measure your heart rate and the level of oxygen in your blood. This device will be mailed overnight to the address that you provide when you are notified of your test results by our nursing staff. You will also be provided with instructions on how to use the device. You will be asked to report (into the app) the measurements of your heart rate and blood oxygen levels every morning until you receive medical instructions that you have recovered from the virus or have you been told by a health care provider that you no longer need to self-quarantine. You will also be able to enter additional measurements that you take at any time if your symptoms change.
- If you are diagnosed with COVID19, the brief daily smartphone survey will begin to assess changes in your viral symptoms and your vital signs. You will continue to respond to surveys by using the smartphone touch screen. You will also be able to click a button in the app during the day to report worsening symptoms that would prompt the need for clinical evaluation or urgent medical intervention. Once you have been instructed by a healthcare provider that you no longer have COVID19, the survey will return to the standard symptom screening survey.
- Approximately 24 weeks (six months) from today, you will complete a longer survey on the phone. This survey will ask you questions that are similar to the ones you will answer today. In addition, you will receive a call from the study team so you can express your opinions about the use of the Symptom Tracker (Insight^{TM}) smartphone application. Once you complete the final study survey and phone call, you can remove the application from your smartphone. If you are using a borrowed study phone, we will send you a postage paid envelope to return it to us at this time.
- After you complete the final survey, a staff member will contact you for a final study interview. This 10-15 minute phone call interview will be recorded and will be used to ask your opinion about the study smartphone app and survey questions. Any additional information that is needed to answer questions about your overall health, cancer status or treatment for COVID19 will be obtained from your medical records. This data will be collected, given a code to protect your identity and entered into a secure data base at the University of Oklahoma Health Sciences Center.

Table 1. Summary of Study Visits and Surveys.

Timeline	Description of Study Visits

SCREENING and BASELINE VISIT	☐ Complete eligibility screening measures. ☐ If eligible, complete self-report questionnaires. ☐ Smartphone app instructions will be provided. ☐ If you do not own a compatible smartphone, one will be loaned to you.
SMARTPHONE SURVEYS	☐ The smartphone app will prompt: • One survey each day. • Results from your daily screen will prompt a nursing phone call if screening indicates elevated risk for COVID19.
	• If screening indicates elevated risk for COVID19, we will advise you on where COVID19 testing can be completed. • If you test positive for COVID19, you will be mailed a device to measure your heart rate and blood oxygen levels. You will receive instructions on how to use this device. • In addition, if you test positive for COVID19, some of the survey questions will change, but it will still be administered one time per day. • Once you receive medical instructions that you have recovered from the virus or have you been told by a health care provider that you no longer need to self-quarantine, the survey will be changed back to the standard symptom survey.
WEEK 24 FOLLOW-UP ASSESSMENT	☐ ☐ The smartphone app will prompt a longer final survey. ☐ Study staff will call to ask you some final study questions. ☐ This assessment will take 10-20 minutes to complete. ☐ Those who borrow a study phone will use the pre-paid packaging we send to you to return it (including charger) to us via mail.

Study Groups

All study participants will download the Symptom Tracker (Insight™) smartphone application onto their personal phone or a study provided phone. The Symptom Tracker (Insight™) smartphone application will use your answers to daily questionnaires to screen you for symptoms of COVID19 and initiate testing and therapy for viral illness as soon as symptoms develop. All participants will receive information on how to use the Symptom Tracker (Insight™) smartphone application at the baseline visit.

If you screen positive for increased risk for COVID19, you will be called and provided with a testing date and time. If you test positive for COVID19, then the clinic nurse will contact you. Your address will be confirmed and a pulse oximeter will be mailed overnight to the address provided. A pulse oximeter is a device that measures your heart rate and blood

oxygen levels. You will receive information on how to use the pulse oximeter and you will be asked to enter the values for your temperature, heart rate and blood oxygen level into the app each morning until a medical provider informs you that you have recovered from the virus or have you been told by a health care provider that you no longer need to selfquarantine. You will also receive instructions on which medications and over the counter remedies you can use to help control viral symptoms. Information about symptoms that indicate the need for an in-person evaluation or emergency services will also be discussed with you at this time. You will continue to use the app to monitor your symptoms, but some questions on the daily survey will change, including when to access emergency services (meaning to call 911).

WHAT ARE THE RISKS OF THE STUDY?
Every effort will be made to keep your information confidential; however, this cannot be guaranteed. All members of the research team are required to undergo training about how to keep information confidential. Your data will be labeled with an ID number that can be matched to your personal information (such as your name) that will be kept in a separate, locked filing cabinet.

Participants will use a study smartphone or their personal smartphone to complete assessments through an encrypted mobile application and all data will be automatically saved and sent to the secure study server. For those who receive study smartphones, the research staff will use a unique Google Play Store login to download the study app onto the phone. Passwords will only be known to research staff. At the conclusion of your time in the study, you will return the borrowed phone and all data collection through the Insight application will end. Study data will then be removed from the study phone. If you use your personal mobile device, you will use your personal Google Play Store account to download the Insight app. At the conclusion of your time in the study, the study data will be removed from your phone and all data collection through the Insight application will end. We will also give you instructions on how to delete the app from your personal device once you complete the study.

<u>Risks for females:</u>
If you are a female, there are no additional risks to you or your unborn child, including birth defects that result directly from participation in this study. If you become pregnant or suspect that you are pregnant, you should immediately inform the study personnel and your treating oncologist. If you become pregnant or suspect that you are pregnant while in this study, contact your doctor.

WHAT ABOUT CONFIDENTIALITY?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. Organizations include the US Food & Drug Administration and other regulatory agencies, the National Cancer Institute and its representatives. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. However, this website will not include information that can identify you. At most, the website will include a summary of the study and results. You can search this website at any time.

To help protect your privacy, a Certificate of Confidentiality will be obtained from the federal government. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluating federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. However, this website will not include information that can identify you. At most, the website will include a summary of the study and results. You can search this website at any time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. However, at certain times during the treatment, it may be harmful for you to withdraw, so please be sure to discuss leaving the study with the

principal investigator or your regular doctor. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

DO I HAVE ANY OTHER RIGHTS OVER MY DATA?
Depending on where the sponsor for your study is located and other factors, you may have additional rights over your personal data collected in this study. For example, the European Union General Data Protection Regulation (GDPR) and some state privacy laws might apply. If the GDPR applies, generally you may have the following rights:

1. The right to request the information collected to be corrected.
2. The right to withdraw your consent for the use of your personal information at any time.
3. The right, in some circumstances, to receive your personal information in a structured, commonly used and machine-readable format and the right to provide your information to a third party.
4. The right to strict confidentiality of your personal data when it is used/shared.
5. The right to limit the use/sharing of your personal information in certain circumstances.
6. The right under some circumstances to request the erasure of your personal data.
7. The right to file a complaint with a privacy protection regulator if you believe any of the rights above have been violated.

You can receive more information regarding these rights in the Privacy Notice for Research Participants, located on the OUHSC Office of Human Research Participant Protection (HRPP) website at https://compliance.ouhsc.edu/HRPP/Participant/Privacy-Notice.

If you have any questions and requests, please contact the HRPP Office at 405-271-2045.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have questions, concerns, or complaints about the study or have a research-related injury, contact the research office of Bethany Hannafon, Ph.D. at 405-271-8707 during the regular business hours of 8AM and 5PM, Monday-Friday. After 5 pm on weekdays and over the weekends, you may reach the investigators at 405-271-5656.

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

For questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

SIGNATURE:
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	Printed Name	Date

_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date