



CaPSLL Cancer Patient Safety Learning Laboratory

What You Need to Know About the Cancer Patient Safety Learning Laboratory (CaPSLL) Study

What are we studying?

We will be studying what we call “non-routine events” to see how they are related to unfavorable outcomes for cancer patients. “Non-routine events” are any event that was unexpected, unusual, frustrating, or disappointing to you that was related to or could affect your health or healthcare.

What are some examples of non-routine events?

- A patient had symptoms (for example, blistering) that she was not expecting and ***has not been able to reach the doctor for several days*** to discuss.
- A patient had an initial unexpected reaction to secondary drugs in chemotherapy. So, clinicians changed the dosage of the chemotherapy medications. The medication that was delivered ***did not contain the new dosage*** and had to be reordered.
- A doctor ***did not order a port soon enough*** and then rescheduled the surgery appointment without notifying the patient. That patient had to reschedule again because the port had not come in yet.

Why are we studying non-routine events?

By better understanding why and how non-routine events happen, we hope to make care for cancer patients safer and better. The primary purpose of this study is to create better ways to tell when cancer patients are not doing as well as they should be doing.

Who will be in this study?

The study will include adult cancer patients being treated as outpatients (not staying in the hospital). It will also include family members and other people in the patient’s circle of care. It will also include clinicians and staff who will help document and report the patient’s care and any non-routine events.

We will also collect data directly from patients about their daily life during cancer treatment. We will use this information to build tools to help clinicians better detect and respond to non-routine events.

What will you need to do while you are in the study?

You will participate in this study for up to 6 weeks. While you are in the study, we will ask you to wear a Fitbit watch to track your activity and heart rate. We will help you set up the Fitbit. The only thing you will have to do is ***keep the Fitbit charged***. To do this, simply take off the watch and attach it to the charger for about an hour every few days. Make sure you clip the charger securely to the watch.

In addition to the Fitbit, you will need a smartphone that can connect to the Fitbit, via Bluetooth. Please remember to ***keep your smartphone’s Bluetooth on at all times***. If you don’t have a suitable smartphone but still wish to be in the study, we will loan you one while you are in the study. You will need to sign a loan agreement for this phone. You will need to ***keep the phone charged***. You can do this easily every night.

Institutional Review Board

Date of IRB Approval: 08/27/2019



We will put 3 applications (apps) onto your phone. These apps are:

- Fitbit
- MyCap
- Google Maps

The apps will be linked to an email address provided by the study team. You will not need to do anything with the Fitbit and Google Map apps. They will work automatically. You will need to interact with the MyCap app at least once a week. We will show you how to do this.

Here is a quick overview of what will be expected of you:

Daily activities:

- Keep the Fitbit and smartphone charged.
- You can use MyCap at any time to report any non-routine events that may occur.

Weekly activities:

- Fill out the weekly check-in on MyCap.
 - If you forgot to do a weekly task, you can scroll back on the MyCap app to the date of the weekly tasks to complete any tasks you may have missed.
- Check in with us by phone or in person (in-person meetings will be scheduled around your regular visits).
 - If you are not going to be at Vanderbilt University Medical Center within one week or so from the last time you saw someone from our research team, we can schedule to meet you somewhere in public or call you.

Wrap-up activities:

- Complete the final surveys.
- Return your device(s) to us.

What information will we be collecting on MyCap?

We will collect information about symptoms you are having and any issues that are affecting your health and quality of life. We will use this information to help us identify and respond more quickly to problems that patients like you are having during cancer treatment.

We will ask you to share the following with us at least once each week:

- Any non-routine events or problems you are having, how serious they are, and how they are affecting your health and quality of life.
- How you are feeling and any symptoms you are having.
- What you think about the care you are receiving and your overall feeling about your health and quality of life.

How will we collect this information?

We will show you how to use MyCap to enter the information into the app on your phone. We will also check that you have the right type of smartphone and internet connection to use MyCap.

Institutional Review Board

Date of IRB Approval: 08/27/2019



How to Use the Fitbit Watch

How do I set up the Fitbit?

Don't worry about this. The research team will set up your Fitbit and connect it to your phone for you.

What do I need to know about the Fitbit?

The most important thing you need to know is how to charge the Fitbit. This goes for your smartphone as well.

How do I charge the Fitbit?

Step 1: Get your Fitbit and Charger. Remember to plug the charger into a power source.

Step 2: Line up the gold pins under the Fitbit (A) and inside the charger clip (B) as shown below. The hole in the Fitbit charger (C) must be on the same side as the button on the Fitbit, as the button fits into the hole.



Step 3: Clip the charger onto the Fitbit snugly (D) until it clicks. You will know the Fitbit is charging when the Fitbit vibrates and shows the battery charging (E).



To keep the Fitbit watch charged, we would like you to charge it every second or third day for about one (1) hour. A good time to do this is in the evening while you are relaxing or getting ready for bed. But any time when you are not very active will do. **Be sure to put the watch back on after it has charged.** If you forget to charge the Fitbit, no worries, just charge it the next day. If you forget for several days, you may get a low battery alarm. A full charge usually takes about two (2) hours.

What data will the Fitbit be collecting?

The Fitbit will collect data on:

- How your heart rate changes when you are active and what it is when you are resting.
- The number of minutes you are active, the number of steps you take, and how far you go.
- How much sleep you get. **Be sure to wear your Fitbit to bed.** An important part of the study will be the data we collect while you're sleeping.
- How many calories you burn.

Why are we collecting these data?

We hope to find patterns in individual patients and populations of patients that will help us predict who might have problems with their cancer treatment.

What else should I know?

- To see the data collected by your Fitbit, open the Fitbit app on your phone and the data will automatically download and display on the phone.
- Turning your wrist to look at your Fitbit can cause it to "wake up." If this annoys you at night, cover the watch with the wrist band we have given you. But don't take the watch off to sleep!
- The watch is **not waterproof**. You cannot wear it while you swim or bathe, and you should never hold it under water. It will resist water, though, so it is **OK to shower** with it.
- Keep the band and your wrist clean. Take off the Fitbit periodically to let your skin breathe.
- If you are doing an activity that makes you sweat, use the wrist band we provided to keep the sweat away from where the watch touches your skin.
- If the Fitbit application on your phone logs you out, contact us and we'll help you log back in.

Institutional Review Board

Date of IRB Approval: 08/27/2019

Troubleshooting & Common Concerns

Your smartphone and/or Fitbit has stopped working.

If your Fitbit stops working, call CaPSLL so we can help you troubleshoot any issues that may have occurred. If you were given a smartphone by CaPSLL and it stops working, call CaPSLL so we can try to help fix any issues. If you are using your own smartphone, please inform us if it quits working. However, CaPSLL will not be able to help you fix a personal smartphone.

You have lost your Fitbit and/or smartphone. What should you do now?

Please call or email the CaPSLL team as soon as possible. We will work with you to determine the best thing to do, given the situation.

Will your doctors see the information you report in MyCap and/or the Fitbit data?

No, your doctors have no way of seeing or getting any information gathered for this study by our research team. Any information that you share with the CaPSLL team **will NOT** become part of your medical record.

You think that your symptoms are getting worse. Should you report that, even if you have already done your weekly tasks?

If your symptoms are getting worse, please call your provider or clinical staff, or 911 **IF** it is an emergency. The CaPSLL study team and its members **are NOT qualified** to give you and/or your caregivers any medical advice. If you have questions about your health or healthcare, please call your physician or the Office of Patient Relations at 615-322-6154.

Your Project Team



Sadler
Research
Assistant I



Bishop
Research
Intern



Joyce
Data Analysis
Manager



Carrie
Informatics
Nurse
Specialist



Dan
Research
Professor



Jason
Research
Associate
Professor



Matt
CRISS Director

CaPSLL Research Study Contact Information:

Email: capsll@vumc.org

Phone: (615) 294-9372

Web: <https://criss.app.vumc.org/capsll.html>



VANDERBILT  UNIVERSITY
MEDICAL CENTER

1211 - 21st Avenue South, Medical Arts Building, Suite 732, Vanderbilt University Medical Center, Nashville, TN 37211

Copyright Vanderbilt University Medical Center

Institutional Review Board

Date of IRB Approval: 08/27/2019

