

Consent and Authorization Form

COMIRB
APPROVED
For Use
30-Oct-2025

Principal Investigator: Dr. Catherine Lozupone

COMIRB No: 21-2851

Version Date: October 30, 2025

Study Title: *Dietary Intervention to reduce Clostridioides difficile recurrence in oncology patients*

You are being asked to be in a research study. In this form “you” means either you or your child. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

Why is this study being done?

This study will learn more about how diet effects infection with *Clostridioides difficile* in people undergoing cancer treatment. People undergoing cancer treatment are at high risk for infection with *C. difficile*, which can cause diarrhea. This infection can come back about 25% of the time even after treatment with antibiotics. This study will look to see if eating a higher fiber, lower fat diet can prevent *C. difficile* infection from coming back after treatment. It will also compare rates of *C. difficile* recurrence in individuals getting oral nutrition versus nutrition through intravenous or gastric/nasogastric tube feeds.

You are being asked to be in this research study because you or your child is undergoing treatment for cancer and has an infection with *C. difficile*.

Other people in this study

Up to 112 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to take a survey on your normal diet. If you are primarily getting nutrition intravenously or through a gastric or nasogastric tube, you will be assigned to a non-intervention group. If you are primarily getting nutrition by mouth, you will then be randomly assigned to either: 1) a special diet or 2) your regular diet. If you are assigned the special diet, you will be asked to meet with a trained dietician to design a list of high-fiber foods, such as fruits and vegetables that you like, from which you will be asked to eat a certain number of items per day for 6 weeks. You will also receive a list of items high in saturated fat such as meats and cheeses, which we will ask to avoid for 6 weeks.

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Based on your food preferences, we will provide groceries that support your special diet once per week via an online home delivery service (e.g. Amazon Pantry). We will ask you to report back to us weekly on how much of the provided food you ate. Once every two weeks, we will call you to complete a 24-hour food recalls (i.e. when you list everything that you ate in the past 24 hours), for a total of three during the six-week diet.

We will ask you to provide one stool sample per week during the 6 weeks of the study (6 samples total). We will ask you to report on the consistency of your stool (on a scale ranging from runny diarrhea to hard pellets). The diet may be stopped if it appears to be causing you abdominal discomfort. Other factors that may affect what bacteria are in your intestines, such as antibiotics and chemotherapy or other drugs, will also be recorded both during and before the 6-week study.

If you are randomly assigned to your normal diet, you will be asked to provide one stool sample per week, to complete three 24 hour food recalls, and will be asked to report on stool consistency and any antibiotics or chemotherapy drugs taken, but we will not change your regular diet.

In addition, information regarding your disease and treatment will be recorded.

We will use tests in our lab to figure out what bacteria are living in your stool sample and what chemicals they are making. We may also use your stool sample in a mouse study to better understand how these bacteria affect the health of the intestines. Your samples may have diagnostic or commercial value. Dr. Lozupone, her associates or her successors will keep the clinical samples and/or information derived from them to the end of the study.

What are the possible discomforts or risks?

Although the diet is intended to have a health benefit, there is potential for discomfort and risks. Diets high in fiber can sometimes promote gas production by microbes that can lead to bloating or increased flatulence. Limiting preferred foods can lead to weight loss. We will work closely with you to find a diet that is enjoyable and safe. We will monitor these risks throughout the study and potentially recommend termination of your involvement if these side effects are too high. You are free to end your involvement in the study at any time.

Another potential risk of study participation is loss of confidentiality. Your samples will be given a unique study number and all work involving these samples will only refer to this study number. There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

No long-term medical care or financial compensation for research related injuries will be provided by the National Institutes of Health or the Federal Government.

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What are the possible benefits of the study?

This study is designed for the researcher to learn more about whether consumption of a diet that is higher in fiber and lower in saturated fat may decrease the risk having a recurrence of *C. difficile* infection during cancer treatment. The study diet may decrease the risk of infection coming back.

Who is paying for this study?

This study is being supported by the National Institutes of Health (NIH).

Will I be paid for being in the study?

You will be paid \$300.00 (\$50 per week) for your participation in this 6-week study. If you leave the study early, or if we have to take you out of the study, you will be paid a pro-rated amount for the number of weeks that you participated. If you are randomly assigned to the special diet, you will also receive groceries delivered to your home. You will be paid using Amazon gift cards that will be e-mailed to you weekly.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

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The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Catherine Lozupone. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Catherine Lozupone at (303) 724-7942. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call 720-777-2129 with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- University of Colorado Denver
- Children's Hospital Colorado (Children's Colorado)

Children's Colorado shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that other healthcare professionals could view your information.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

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The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel

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your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Catherine A. Lozupone Ph.D.
12700 E. 19th Avenue, Room 3113
Anschutz Medical Campus, Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities for information required by local or state law.

The Certificate of Confidentiality cannot be used for information in your medical records.

A Certificate of Confidentiality does not prevent disclosure of your information to the NIH, Food and Drug Administration (FDA), or federal funding agency.

You should understand that a Certificate of Confidentiality 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 consent to receive research information, then the investigator may not use the

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Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

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Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Tissue samples and the data with the samples.

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Optional Consent for Data and Specimen Banking for Future Research

Dr. Catherine Lozupone would like to keep some of the data and stool that is taken during the study but is not used for other tests. If you agree, the data and stool will be kept and may be used in future research to learn more about the role of the gut microbiome in health of children undergoing cancer treatment. The research that is done with your data and stool is not designed to specifically help you. It might help people who have *Clostridioides difficile* and other diseases in the future. Reports

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about research done with your data and stool will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and stool will not affect your care.

The choice to let Dr. Catherine Lozupone keep the data and stool for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and stool can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want Dr. Catherine Lozupone to use your data and stool any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Catherine Lozupone decides to destroy them.

When your data and stool are given to other researchers in the future, Dr. Catherine Lozupone will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes data and stool are used for genetic research (about diseases that are passed on in families). Even if your data and stool are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and stool will only be used for research and will not be sold. The research done with your data and stool may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and stool include learning more about how to prevent *Clostridioides difficile* infection and other diseases. The greatest risk to you is the release of your private information or discomforts associated with a change in your typical diet. Dr. Catherine Lozupone will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Catherine Lozupone.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and stool, you may still take part in the study.

I give my permission for my data and stool to be stored in a central sample bank in Dr. Lozupone's laboratory for future use by the study investigators:

1. I give my permissions for my data and stool samples to be kept by Dr. Lozupone for use in future research to learn more about how to prevent, detect, or treat

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Clostridioides difficile infection or to otherwise improve health in children as they undergo cancer treatment.

☐ Yes ☐ No _____ Initials

2. I give my permissions for my data and stool samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

☐ Yes ☐ No _____ Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

☐ Yes ☐ No _____ Initials

HIPAA Authorization for Optional Additional Study Procedures –

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

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Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____ Date: _____

Print Name: _____

_____ d o Date _____
Child (13-17 year olds)

Consent form explained by: _____ Date _____

Print Name _____

Investigator: _____ Date: _____
Investigator must sign within 30 days

Witness Signature: _____ Date _____

Witness Print Name: _____

Witness of Signature ☐

Witness of consent process ☐

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