

Consent Form Addendum: Stool Collection (Colorectal Cancer) - Parent or Guardian

A. Introduction

This consent addendum gives new information about the research study in which you agreed to have your child participate in and will ask you to decide whether you would like to share your child's stool sample(s) for the study. The procedures noted below are in addition to those which you were informed about in the previous consent form. If you decide to have your child participate in this part of the study, please sign and date at the end of this form. You will receive a copy to the email address that you used to register for the project so that you can refer to it while you are involved in this research study.

If you or your child have any questions, please send an email to info@joincountmein.org or call 651-403-5315 and ask to speak with a member of the study staff about this part of the study.

B. Brief Description of the Project

"Count Me In" is a patient-driven movement that enables cancer patients and their families to directly transform cancer research and discovery. Anyone who has ever been diagnosed with cancer has the opportunity to share information about their experience through completing surveys, sharing biological samples (saliva, blood and/or tissue samples, and in some cases, stool samples), and copies of their medical records with researchers. Because we are open to participants across the country regardless of where they are being treated, this study will allow many more cancer patients to contribute to research than has previously been possible.

C. What are the new procedures involved?

Because your child has previously been diagnosed with colorectal cancer, we are asking if you would be willing to provide sample(s) of your child's stool for the study. If you elect to have your child participate, we will send you a sample collection kit in the mail which includes detailed instructions for how to provide your child's stool sample. We will then ask you to send the sample back to us in a pre-stamped package that we will provide. We may ask your child to provide stool samples at multiple different time points. We will contact you before sending any of the stool collection kits. If you do not want to have your child participate in the stool collection at any time, please just inform a study team member.

In addition, we will ask you/your child to complete an online survey through your project account. You will receive more information about this survey once a kit has been sent to you. After a stool sample is received, we may analyze the genes in the cells from your child's sample(s). The results of these analyses may be used to try to develop better ways to treat and prevent cancers.

D. Are there any new risks associated with participating in this portion of the research study?

There are no additional risks associated with this portion of the study.

E. Whom do I contact if my child or I have questions about this research study?

If you or your child have questions about the study, please contact the research doctor or study staff listed below by emailing info@joincountmein.org or calling 651-403-5315:

- Diane Diehl, PhD
- Elana Anastasio

For questions about your child's rights as a patient, please contact a representative of the Office for Human Research Studies at (617) 632-3029. This can include questions about your child's participation in the study, concerns about the study, a research related injury, or if your child feels/felt under pressure to enroll in this research study or to continue to participate in this research study. Please keep a copy of this document in case you want to read it again.

F. Documentation of Consent

This is what I agree to:

- You can collect my child's stool sample(s) by sending collection kit(s) to the mailing address provided on the previous form.
- You can perform (or work with others to perform) molecular tests on stool sample(s), and store the sample(s) until this research study is complete.
- You can store the responses that I/my child provide in the associated surveys until this research study is complete.
- You can share the results of the molecular tests and survey responses with established public databases (e.g., NIH/NCI data portals, cBioPortal for Cancer Genomics, Tumor Portal, The Exome Aggregation Consortium/Genome Aggregation Database) and with other qualified researchers in a manner that does not include my child's name, or any other information that could be used to readily identify my child, to be used by other qualified researchers to perform future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and studies that may be for commercial purposes.



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- You can use the results of studying my child's samples and my child's medical information for future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and/or studies that may be for commercial purposes.

My signature below indicates:

- I have had enough time to read the consent addendum and think about continuing to have my child participate in this study;
- I have had all of my/my child's questions answered to my satisfaction;
- I am willing to have my child continue to participate in this study;
- I have been told that my child's continued participation is voluntary and I can withdraw my child at any time

Signature: _____

Date: _____



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Assent Form Addendum: Stool Collection (Colorectal Cancer)

We want to tell you more about the research study that you and your parent(s) agreed to have you be part of.

We are asking if you want to provide sample(s) of your stool (poop) for the study. If you want to participate, we will send you and your parent(s) a kit in the mail to collect your sample. We will ask your parent(s) to send the sample back to us. We might ask you to share more than one stool sample with us and will contact your parents before sending any kits to your house.

We will also ask you and your parents to answer some questions online that go along with your sample kit. All of the information will help researchers better understand cancers.

There aren't any more risks in this part of the study.

If you have any questions about this study, please have your parent contact the project team at 651-403-5315 or info@joincountmein.org

I understand the information about this part of the study. My signature below means that I want to continue to be in this research study. I can decide not to continue to take part in this research study if I do not want to and nothing will happen to me if I decide I do not want to continue to participate.

If you sign your name below, it means that you agree to take part in this research study.

Child/Adolescent Assent

Signature _____

Date _____