

## **Consent Form Addendum: Stool Collection (Colorectal Cancer)**

### **A. Introduction**

This consent addendum gives new information about the research study in which you agreed to participate and will ask you to decide whether you would like to share 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 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 have any questions, please send an email to [info@joincountmein.org](mailto: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 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 you have previously been diagnosed with colorectal cancer, we are asking if you would be willing to provide sample(s) of stool for the study. If you elect to participate, we will send you a sample collection kit in the mail which includes detailed instructions for how to provide your 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 you 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 participate in the stool collection at any time, please just inform a study team member.

In addition, we will ask you 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 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 I have questions about this research study?**

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

- Diane Diehl, PhD
- Elana Anastasio

For questions about your 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 participation in the study, concerns about the study, a research related injury, or if you feel/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 stool sample(s) from me 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 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 name, or any other information that could be used to readily identify me, 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.
- You can use the results of studying my samples and my 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.



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**My signature below indicates:**

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

Signature: \_\_\_\_\_

Date: \_\_\_\_\_