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**Dana-Farber**  
Cancer Institute



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In

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[www.joincountmein.org](http://www.joincountmein.org)

# **Consent Form Addendum: Learning About Your Child's DNA with Invitae**

## **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 your child to provide an additional saliva sample to learn about their non-tumor (also called “normal” or germline DNA). 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 the end of this form. You will receive a copy of this form 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@lmsproject.org](mailto:info@lmsproject.org) or call 651-503-5556 and ask to speak with a member of the study staff about this part of the study.

Results from the sequencing of your child's non-tumor DNA will be shared with you during a telehealth appointment with a genetic counselor from Invitae/Genome Medical.

## **B. Brief Description of the Project**

The Leiomyosarcoma Project is part of “Count Me In”, a patient-driven movement that enables cancer patients to directly transform cancer research and discovery. People who have been diagnosed with leiomyosarcoma across the US and Canada have the opportunity to share information about their experience through completing surveys, sharing biological samples (saliva, blood, and/or tumor samples), and copies of their medical records with researchers. Because we are open to participants across the country regardless of where they are 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 been diagnosed with leiomyosarcoma, we are asking if you would like your child to contribute an additional saliva sample and



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learn more about your child's non-tumor ("normal" or germline) DNA. The information shared with you would be on a small number of genes associated with hereditary cancers.

If you elect to participate, we will share your name, your child's name, address, and contact information with Invitae to conduct this process. You will schedule and have a telehealth appointment with a genetic counselor from Invitae or their telehealth partner, Genome Medical to discuss the testing. An additional saliva collection kit will be sent to you to have your child provide a sample for Invitae. When the results are available, you will have a second telehealth appointment with a genetic counselor to discuss the results and any questions you may have.

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

If you choose to have your child's non-tumor DNA sequenced, this process may yield information that is of unclear significance. If you choose to learn more about your child's germline ("normal") DNA, learning about genetic risk for cancer for your child or relatives may cause worry or fear about the future. You may learn about cancer risks that are unrelated to your child's current diagnosis or are unexpected based on their personal or family history.

There is a risk that your child's information, including results of the "normal" DNA sequencing, could be seen by people who do not have permission. However, we have procedures and security measures in place designed to minimize this risk and protect the confidentiality of your information.

**E. Who do I contact if I have questions about the research study?**

If you have questions about the study, please contact the research doctor or study staff listed below by emailing [info@\[osproject.org\]\[lmsproject.org\]](mailto:info@[osproject.org][lmsproject.org]) or calling 651-403-5556:

- Nikhil Wagle, MD
- Katie Janeway, MD
- Corrie Painter, PhD

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



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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 share my and my child's information with Invitae in order to conduct panel testing of their non-tumor/"normal" DNA.

Yes

No

Thank you for your participation. We will not share any of your or your child's information with Invitae or Genome Medical.