impact genetics

Step 1a: *Informed Consent to Perform Genetic Testing for Uveal Melanoma [NY]*

I, _____, consent to participate in a DNA-based test to identify genetic changes correlating with prognosis for survival in patients with uveal melanoma. I understand this test requires tumor and blood *(or other normal)* samples from the patient for use in prognostic testing.

By signing below, I acknowledge that:

1. My participation in this DNA testing is voluntary.
2. Any surgical risks associated with the tumor collection method have been explained to me by the team obtaining the sample.
3. It is possible that the quantity or quality of tumor submitted for testing may be inadequate for testing.
4. I understand that no DNA tests on uveal melanoma are entirely accurate. Patients with a good prognosis can develop metastatic disease *(albeit rarely)* and vice versa.
5. All test results are ***confidential***. Except as described in point 9 below, no information will be printed or released that discloses the patient's identity without my additional written permission. Only the referring specialist designated on the Uveal Melanoma Requisition Form will receive a written report of test results.
6. Impact Genetics is not a DNA banking facility and patient DNA samples may not be available for future testing.
7. There is a chance that the test may reveal unexpected abnormalities that may be of value in my medical care. Impact Genetics will inform the referring specialist designated on the Uveal Melanoma Requisition Form of such a result.
8. The referring specialist reviewed this consent form with me, and explained the implications of the test results to me. Any questions that I asked have been answered to my satisfaction. I know that I may continue to ask questions about the collection, use and disclosure of my personal genetic information.
9. If necessary to obtain reimbursement of test fees, Impact Genetics, its agents and legal representatives, may disclose information that identifies me.
10. I received a copy of this consent form and the referring specialist whom I designate on the Uveal Melanoma Requisition Form received a copy of this consent form.

Consent for Future Research:

After all analysis required to reach a genetic diagnosis is complete, Impact Genetics has my consent to use any surplus DNA in an ***anonymous*** fashion for research. Future research is only possible if 'Consent for Banking Sample' is also marked ***'Yes'***.

☐ YES ☐ NO

Consent for Banking of Sample:

Impact Genetics is not a DNA banking facility and patient DNA samples may not always be available for future testing. However, Impact Genetics has my consent to bank any surplus DNA samples indefinitely, for future clinical testing as requested by me. If "no" is checked or if neither box below is checked, the sample will be destroyed within 60 days after test completion.

☐ YES ☐ NO.

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Signature of Patient or Consenting Parent: _____ Date _____

Statement of Referring Physician:
I reviewed this form with my Patient. I offered to answer any questions.

Signature of Referring Physician: _____ Date _____

CAP 7175554 CLIA 99D990947 IGADM-1100 Rev 04Sep2018

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Information About the Uveal Melanoma Prognostic Genetic Test

What is Uveal Melanoma?

Uveal melanoma *(UM)* is a melanoma *(type of cancer)* of the eye, involving the iris, ciliary body or choroid *(collectively referred to as the uvea)*. These malignant *(cancerous)* tumors arise from the pigmented cells *(melanocytes)* within the uvea.

Purpose and Principle of the Test

Approximately 50% of patients diagnosed with UM will develop metastases within 10 years of treatment of the primary intraocular tumor. Multiple factors contribute to the survival prognosis of a patient with uveal melanoma including genetics of the tumor, histologic grade, size and clinical stage of the tumor *[Damato, B. et al. Progress in Retinal and Eye Research, 2011]*.

One of the most important indicators of poor prognosis in UM is loss of chromosome 3 *(monosomy 3)*. Metastatic disease develops almost exclusively in patients with this genetic abnormality. Other genetic factors contributing to the survival prognosis include copy number variation of chromosomes 1, 6 and 8 *[Damato, B. and Coupland, S.E. Arch Ophthalmol. 2009]*. The prevalence of monosomy 3 in small tumors *(basal diameter <10 mm)* is as high as 35% *[Damato, B. and Coupland, S.E. Arch Ophthalmol. 2009]*. For this reason, it is important to analyze the genetics of the tumor in addition to other factors such as size.

Cancer is often unpredictable and many patients find it difficult to come to terms with a diagnosis of cancer. Sharing this information with family members and friends can be very challenging. Some patients feel, however, that knowing their chance of survival is valuable. This knowledge empowers life planning and may initiate the development of support strategies. Many individuals diagnosed with this condition state that they have hope they will be considered to be at low risk for the cancer to spread; however, knowing either way can allow them to understand more clearly their risk for the future. If cancer spreads to the liver, there is limited treatment available to cure it at this time.

Some specialists will change treatment and/or surveillance for metastases depending upon the genetic make-up of cancer cells *(determined through genetic prognostic testing)*.

Test Method: Impact Genetic's Mutation Identification Strategy

Fresh tumor sample is obtained from the affected eye either by a biopsy at the time of radiation plaque therapy or taken directly from the removed *(enucleated)* eye by a pathologist. Frozen tumor samples or banked tumor DNA can also be submitted for analysis. In addition, a blood or buccal sample is required and used for comparison analysis. **Impact Genetics** isolates DNA from the specimens provided *(unless provided DNA directly)* and performs molecular tests to identify the chromosomal alterations in the tumor DNA. The results from testing can be used to predict if these tumor cells have a high or low risk to metastasize and can be used in the design of appropriate surveillance and treatment plans and for life planning.

Impact Genetics is certified under the US Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing. **Impact Genetics**'s tests were developed, and their performance characteristics determined, by **Impact Genetics**. They have not been cleared or approved by the US Food and Drug Administration, which has determined that such approval is not necessary.