I, __________________________ voluntarily request the Casey Eye Molecular Diagnostics Laboratory to perform DNA-based testing for (condition) ___________________________ in myself and/or my child.

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The following points have been explained to me:

1. DNA testing is performed on biological samples, which will be collected using standard techniques. I understand that there may be risks associated with obtaining my sample. Additional samples may be needed if the specimen is damaged in shipment or inaccurately submitted.

2. DNA testing may detect an abnormality, called a mutation, in a gene and this may indicate that I, or the individual being tested, may have, or may develop the specific disease/condition being tested for. In other cases, DNA testing is unable to identify an abnormality although an abnormality may still exist. This event may be due to current lack of knowledge of the complete gene structure or an inability of the current technology to certain types of changes (ie. mutation in a gene). Additionally, there is the possibility that a gene alteration of unknown significance may be identified.

3. The accuracy of genetic testing is limited by the test methods used, the clinical diagnosis, the nature of the specific condition for which testing is requested and the reported family relationships. An inaccurate clinical diagnosis in the patient or family members can lead to an incorrect interpretation of the test result.
   - Genetic tests are relatively new and are continuously being expanded and improved. The tests are not considered research, but are considered to be the best and newest laboratory service available at the time of testing. This testing is complex and utilizes specialized materials so that there is always a very small possibility that the test will not work properly or that an error will occur. A low error rate, estimated to be approximately 1 in 1000 sample is thought to exist in even the best labs.
   - Genetic testing in family members may disclose true biological relationships are inconsistent with what has been shared with the lab. For example, non-paternity may be detected, which means that the stated father of an individual is not the true biological father.
   - DNA testing performed is specific for the condition and in no way guarantees my health or the health of my living or unborn children. The accuracy of test interpretation is dependent on the clinical diagnosis provided to the lab, and CEI Molecular Diagnostics Laboratory cannot be responsible for inaccurate clinical diagnoses made elsewhere.

4. Due to the complexity of the DNA-based testing, and the potential implications of the test results, results will be reported directly to the physician or genetic counselor who ordered the testing so that appropriate genetic counseling services can be provided. **Results are confidential and will only be released to other medical professional or parties with my written consent in accordance with Oregon Genetic Privacy Statutes.**
5. The CEI Molecular Genetics Laboratory is not a DNA banking facility and cannot guarantee the future availability of patient DNA. Requests for additional studies may be made by the referring provider and additional fees may apply.

6. Once testing is complete, patient identifiers may be removed and remaining DNA samples may be used for laboratory purposes, including anonymous research. These samples will not be available for future clinical studies. Results from such testing cannot be attributed to specific patients and the results will not be reportable.

I can request that remaining DNA not be used for research purposes by initialing here: ______

7. Although there are federal, and in some instances additional state laws, protecting individuals from discrimination based genetic disease status, there is potential for insurance, employment and social discrimination should your genetic information become known to others.

The risks, benefits and limitations of DNA testing have been explained to me. I have read and will receive a copy of this consent form.

/    /    :    □ am □ pm
Patient Signature       Date        Time

/    /    :    □ am □ pm
Parent/ Guardian Signature       Date        Time

Physician/Genetic Counselor/Ordering Provider Statement:
I have provided a detailed explanation of the risks, benefits and limitations of genetic testing to the patient/parent/guardian. I have reviewed this consent form in its entirety and I have answered patient/guardian questions.

/    /    :    □ am □ pm
Clinician Name (printed)       Clinician Signature    Date        Time