Variantyx

IriSight™ Analysis
Informed Consent

Patient Name (fetus of)		Affix barcode label of fetal sample here
Patient Date of Birth		

Consent

I have discussed the IriSight™ testing options with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my fetus' DNA and perform genetic testing as described.

2. I give permission for my fetus' anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my fetus' anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. In the case of direct insurance billing: I acknowledge that the information provided by me is true and correct. I authorize my healthcare provider and/or insurer to share medical information with Variantyx related to my condition, diagnosis and treatment as relevant to my genetic testing, as well as information about my healthcare plan benefits. I authorize Variantyx to release my medical information concerning my testing to my insurer. I authorize Variantyx to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that Variantyx will notify me if my out of pocket costs are determined to exceed $100. I authorize my insurance benefits to be paid directly to Variantyx. I understand that I am responsible for sending Variantyx any and all of the money that I receive directly from my insurer in payment for this test.

5. In the case that independent pre-test and/or post-test genetic counseling is required by my insurance provider and/or physician, I agree, by signing this consent form, to have a third party facilitate the genetic counseling services. By signing this consent form, I authorize Variantyx to release my contact information and any medical information necessary to the third party service, as well as authorize communication and sharing of information between the third party and my referring physician, in order to complete pre-test and/or post-test genetic counseling.

6. I ☐ give / ☐ do not give permission for Variantyx to contact me or my healthcare provider about research studies. If no option is selected, no contact will be made.

7. For New York State residents: ☐ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Patient (fetus of)/Guardian first name	**Last name**
Patient (fetus of)/Guardian signature	**Date**

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Website: www.variantyx.com | **Document number:** VYX-999-1023

Patient Name (fetus of)		Affix barcode label of fetal sample here
Patient Date of Birth		

Biological Maternal Consent

Affix barcode label of maternal sample here

I have discussed the IriSight™ testing options with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my DNA and perform genetic testing for the purpose of improving the interpretation of genetic variants identified in the fetus' DNA.

2. I give permission for my anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. For New York State residents: ☐ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

First name	**Last name**
Signature	**Date**

Variantyx

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Informed Consent

Patient Name (fetus of)		Affix barcode label of fetal sample here
Patient Date of Birth		

Biological Paternal Consent

Affix barcode label of paternal sample here

I have discussed the IriSight™ testing options with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my DNA and perform genetic testing for the purpose of improving the interpretation of genetic variants identified in the fetus' DNA.

2. I give permission for my anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. For New York State residents: ☐ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

First name	**Last name**
Signature	**Date**

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