*THIS DOCUMENT MUST BE WRITTEN IN A LANGUAGE UNDERSTANDABLE TO THE PARTICIPANT*

| http://staffnet/Staff/Reference/MarketingandBrandingResources/CHALogoForEveryday.png | **SHORT FORM****(2018 Revised Common Rule Requirements)** |
| --- | --- |
| **Study Title:**       |
| **Name of Principal Investigator:**       |
| **Name and telephone number of study contact to call with questions:**       |
| **CHA IRB Number:** CHA-IRB-      |

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

After presenting the summary, the investigator must tell you about

1. the purposes, procedures, and duration of the research;
2. any procedures which are experimental;
3. any reasonably foreseeable risks, discomforts, and benefits of the research;
4. any potentially beneficial alternative procedures or treatments;
5. and how confidentiality will be maintained, and how your health information will be protected including whether your personal information and/or biospecimens collected during this study will be stored and used for future research.

Where applicable, the investigator must also tell you about

1. any available compensation or medical treatment if injury occurs;
2. the possibility of unforeseeable risks;
3. circumstances when the investigator may halt your participation;
4. any added costs to you;
5. what happens if you decide to stop participating;
6. when you will be told about new findings which may affect your willingness to participate;
7. how many people will be in the study;
8. use of your biologic specimens for commercial profit, and whether you may share in this profit;
9. whether you will be told about your research results; and,
10. whether the research will include whole genome sequencing.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

**Getting Help (Contacts)**

Call the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study.

If you have questions about your rights as a study participant please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair Telephone: 617-806-8702

Patient Relations Manager Telephone: 617-665-1398

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

**Documentation of Assent**

The person doing this research study has explained what will happen to me if I participate in this research study. My signature below means that I want to be in this research study. I can decide not to participate in this research study if I do not want to and nothing will happen to me if I decide I do not want to participate.

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Signature of Participant (under 18 years of age) Date

**Documentation of Consent**

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

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Signature of Participant Date

OR Legally Authorized Representative

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OR Legally Authorized Representative to the Participant

I have informed the study participant, of:

• The procedures, purpose, and risks related to participation in the above-described study;

• How his/her health information may be used, shared, and reported, and;

• His/her privacy rights.

The study participant has been provided with a signed copy of this form, and a copy of the IRB-approved Informed Consent Form.

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Signature of Researcher Obtaining Consent Date

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Printed Name of Researcher Obtaining Consent

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Signature of Witness Date