**Sample NIH GWAS Statements**

NIH Genome-Wide Association Studies (GWAS) have strict requirements for the information contained in consent forms in order to accept data for inclusion in genomic data sharing (GDS) data repositories. These sample statements below comply with NIH GWAS policy requirements. This is suggested wording only. Not all paragraphs will apply to the research. The sample language should be added to the correct sections of the consent form.

**Risks Associated with Loss of Privacy in Genomic Research:**

* While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
* Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information could potentially be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease. There also may be other privacy risks that we have not foreseen.
* Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.
* Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as [insert specific details]. These facts are important because they will help us learn if the factors that cause [insert specific condition] to occur or get worse are the same or different based on these facts. Thus, it is possible that study findings could one day help people of the same race, ethnic background, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.
* In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Coding of Genetic Specimens and Medical Information:**

* Your [identify specimen(s) here] and medical information will be labeled with a code. Only the researchers conducting this study will have the information that matches the code to traditional identifying information, such as your name, address, phone number, or social security number. The information that matches the code to your identifying information will be kept in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of this identifying information about you.

**Storage and Release of Genetic Samples and Medical Information:**

* Your coded [identify specimen(s) here] will be sent to a National Human Genome Research Institute (NHGRI) sequencing laboratory for detailed analysis. Remaining portions of your samples will be stored for an unlimited period of time for future use in research related to diseases or, perhaps, in other research projects. Information from analyses of your coded samples and your coded medical information will be put into databases along with information from the other research participants. These databases will be accessible by the Internet.
* Anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet. Your coded medical information and information from more detailed analyses of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from a National Institutes of Health Data Access Committee. Note that traditional identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into either the public or controlled-access databases for this project.

**Re-contacting Participants for Future Research:**

* In the future, we may want to obtain additional samples or follow-up information about your health or medical care. Should this be needed, an authorized person from the CHLA research team will contact you to ask whether you would be interested in participating in this additional research.

**Withdrawing of Genetic Specimens and Data by the Research Participant:**

* If you want to withdraw from this project you can contact [Insert Name & Contact Information] at [Insert Name of Institution] and he/she will destroy any remaining specimens of yours that have been obtained for the study. In addition, it may be possible for [him/her] to destroy the link between you and your genetic and medical information. However, the samples and data generated from your specimens that have already been distributed to other research centers or placed in the research databases cannot be withdrawn.
* As a part of the study, your child's samples, genomic data, and health information will be stored and used for future research. When your child reaches age 18, we will try to contact him or her to ask whether he or she wants to continue to participate in research. If we cannot find your child, we will remove identifying information, and continue to include his or her samples, genomic data and health information in research.
* We may learn information relevant to your child's or your family's health. [Tailor based on the plans for returning results, for example:] If this happens, we will tell you only information directly related to diseases and disorders that affect children. Your child can request additional information when he or she is 18.