**IRBIS 5.09.16 Update:**

Revisions to Consent Form Template Language/Tags

**GWAS/Genetic Data Sharing**

The GWAS consent template language was revised be more general so it included not only studies submitting genetic data into GWAS but other genetic research databases as well. This new language will cover the consent information the IRB looks for when providing institutional certification to share genetic data.

The language is shown below:

> Will my genetic information be shared?
> Your blood and tissue samples contain genes that are made of DNA unique to you. To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by this institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with information from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future as technology advances. Researchers will always have a duty to protect your privacy and to keep your information confidential.

We also created a specific version for the parental permission form that addresses the parents rather than the child subject.

**Parent Permission vs. Subject Consent**

Previously, the Stored Specimens Consent Forms only spoke to the subject so did not address situations where the parent was reading the form to decide on their child's participation. To address this, the following language was added to the beginning of both Stored Specimens Consent Forms:

- If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child.

**GINA Language**

There were multiple versions of the GINA language that populated in different forms and application tags/macros. All GINA language templates were standardized. The language is shown below:

- [Delete if no genetic testing will take place under the known aims of the main study. If the possibility of genetic testing is limited to future, unspecified research on stored specimens, the language can be covered in the stored specimens consent document.]

  Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

An additional version of the GINA language made for the parental permission form that addresses the parents rather than the child subject.

The GINA language was not previously part of the Stored Specimens WITHOUT identifiers template. Even though no identifiers are being kept, given advancing genetic technology in relation to identifiability, we decided to add the GINA language to the Stored Specimens WITHOUT identifiers template.

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**Medical Records**

The template language for medical records was updated to now address placing both a consent form and/or information created during the study (e.g. research MRI) into medical records. The language is shown below:

> [Only include if applicable. Please remove if no research information nor the consent form will be entered into subjects' medical records. Please note if you are creating a medical record for the subject as part of the research study, this language should remain.]
>
> By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

An additional version of the medical records language made for the parental permission form that addresses the parents rather than the child subject.

The language populated with a "Yes" response in application question A.4.A.1. (Is this an interventional study?). Since non-interventional studies can create data for the medical record, moving forward a "Yes" response to A.4.1. (Will you be using any methods or procedures commonly used in biomedical or clinical research?) will populate the template language.

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**Imaging and Incidental Findings**

Additional versions of the imaging/incidental findings language made for the parental permission form that addresses the parents rather than the child subject.

The imaging/incidental findings language will now populate in the section “What if we learn about new findings or information during the study?” where it fits better.

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**Template Language/Tag Ordering**

The template language/tags for ABUSE and COMMUNICABLE, were move to directly after information about the Certificate of Confidentiality information in section “How will information about you be protected?”