Recently Revised Sections of the Consent Templates

*For complete templates, see **Medical** consent templates.*

As of **1/7/2015:**

Added instruction text "Consider using large font if you anticipate recruiting participants with visual impairments, e.g., older populations, or for eye studies"

As of **12/12/14:**

- **Genomic data sharing** – new language added, required if the protocol involves genetic data that will be deposited in NIH-supported repositories.

  Affected templates: Consent (HIPAA embedded) doc; Consent (no HIPAA) doc; Somatic Cell Donation for Stem Cell Research (HIPAA included) doc
- Instruction on short form signature clarified (re: "Summary Form") – all templates with this instruction

As of **11/17/14:**

The *Short form instructions* (below "Signature of witness") elaborate further on who *should not sign* the summary (English) consent, and the POC's responsibilities.

As of **7/25/14:**

The *Procedures* section instruction and template language for disposition of left over samples has had minor revision. It now reads:

- If samples, such as tissues or blood, will not be saved at the end of the study add the following:

  *Any samples left over when the study is completed will not be saved for future research.

Affected templates: Consent (HIPAA embedded) doc; Consent (no HIPAA) doc; Somatic Cell Donation for Stem Cell Research (HIPAA included) doc

As of **7/11/14:**

The *Confidentiality* section has been revised and shortened:

CONFIDENTIALITY

#The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

*Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

*If this study falls within the jurisdiction of the Food and Drug Administration, include following: The purpose of this research study is to obtain data or information on the safety and effectiveness of (insert name of drug, device, etc.); the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

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The *Costs* section has an additional optional statement:

Costs

Include the following if there is no treatment involved and there will be no additional costs to the participant due to their participation in the research: *There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.
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Recently Revised Sections of the Consent Templates

*For complete templates, see **Medical** consent templates.*

Include the following paragraphs if there might be additional costs to the participant due to their participation in the research:

*If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Include the following paragraph, when applicable:

#The protocol director will obtain insurance authorization for treatments associated with this study prior to your participation.