

# Recently Revised Sections of the Consent Templates

For complete templates, see [Medical consent templates](#).

As of **02/23/2016**:

- Updated the optional parent/child checkbox on the first page
- Added text to the MRI risks language, end of the first paragraph: to add “eyeliner and other permanent makeup.” The sentence now states: You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup.
- Removed the second paragraph of the MRI risks language. Text has now been replaced with the following: There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs.
- Added a line for the printed name of each individual who needs to sign the consent. e.g., Participant, LAR, Person Obtaining Consent, witness, etc.
- Added email address for IRB NonMedical Manager to the Independent Contacts section of NonMedical templates

\* Consent templates affected by some or all of the above changes: Consent (HIPAA embedded) – Stanford, Consent – Stanford; Minimal Risk Consent (e.g., blood draws, data collection, ... surveys, etc...) - Stanford; Minimal Risk Consent - MRI for research; HIPAA Authorization – Stanford, Sample consent- Blood draws only (HIPAA included); Sample consent - Data collection only (HIPAA included); Sample consent - Use of leftover specimens only (HIPAA included); Somatic Cell Donation for Stem Cell Research (HIPAA included); NonMedical Consent; Parent or Legally Authorized Representative Permission template; Video Use Consent

As of **01/29/2016**:

- Removed the following text from the signature section regarding parental consent:  
*(Special Instructions for obtaining parental consent: The permission of both parents is required on parental consent documents unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child. When enrolling a participant, if only one signature is obtained you must check one of the reasons listed below.)*

The permission of the second parent was not obtained because:

- This parent is deceased
- This parent is unknown
- This parent is incompetent
- This parent is not reasonably available. Explain:

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The first parent has legal responsibility for the care and custody of the child

-Affected template: Video Use Consent

As of **11/24/2015**:

- Added text to the MRI Risks section, regarding contrast media, second paragraph:

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It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs.

- Affected templates: Stanford Main Consent (with HIPAA), Stanford Main Consent (w/o HIPAA), VA Consent, Stanford Minimal Risk Consent with MRI

## As of **10/27/2015**:

- Added text to the MRI Risks section, end of the first paragraph, regarding tattoos.
- Compensation for Research-Related Injury section instructional text updated:  
Removed the language referring to Spectrum under the first paragraph.  
Changed the section header “Industry Sponsored Projects (Clinical Trials)” to “Industry Sponsored or Funded Projects”
- Affected templates: Stanford Main Consent (with HIPAA), Stanford Main Consent (w/o HIPAA), VA Consent, Stanford Minimal Risk Consent with MRI

## As of **06/18/2015**:

- Changed following text in the signature section  
FROM: “Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.”  
TO: “Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.”
- Affected templates: All

## As of **03/03/2015**:

The instructions in the Costs section have been updated for clarity

## 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) Consent (no HIPAA)  
Somatic Cell Donation for Stem Cell Research (HIPAA included)
- 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:

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- 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); Consent (no HIPAA);  
Somatic Cell Donation for Stem Cell Research (HIPAA included)

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.

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.