**Recently Revised Sections of the Consent Templates**

*For complete templates, see*[*School of Medicine Forms & Templates*](https://rco.sites.stanford.edu/panels/hs/forms/forms-templates/medical) *or* [*Stanford University Forms & Templates*](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/nonmedical)

**As of 11/30/2023:**

The following instruction has been added to **all VA consent templates**:

*Mention any photo/video/audio recording, if applicable, how they will be used for the research, whether they will be disclosed outside VA, and their final disposition. If disclosed to an outside entity, this must be stated in the HIPAA authorization.*

**As of 09/19/2023:**

The language pertaining to pregnancy testing of minors was modified as depicted below in the (2) Medical Regular consent form templates. The entire paragraph with instructions was added to the MRI Minimal Risk consent template.

As part of this study, pregnancy testing will be performed. If you are a parent whose minor child is participating in this study, under most circumstances, California law does not permit us to disclose the result of your child’s pregnancy test to you without a signed authorization from your child. If your child’s pregnancy test comes back positive, results will be given to your child by one of the study nurses or doctors in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. Circumstances, in which we might be compelled to reveal this information without authorization from you or your child include when your child's life or someone else's life is at risk or if abuse is suspected. If we believe it is legally necessary to tell a parent or guardian of a positive pregnancy test without your child's permission, we will meet with your child first in private to discuss our concerns before divulging any information regarding pregnancy. During research, if your child has a positive pregnancy test, we may withdraw your child from the study, but unless it is legally necessary or your child provides authorization, we will not be able to confirm that pregnancy is the reason for withdrawal. If your child becomes pregnant or if there is any chance that your child is pregnant (late menstrual period), please contact the study personnel immediately so that we may provide medical assistance and counseling.

The Assent form was modified as depicted below:

If you have had your first period: (Include this header if one assent form will be used for younger and older children)

During the research, pregnancy testing will be performed. The results of the pregnancy tests will be told to you by one of the study nurses or doctors in private. Every effort will be made to keep positive pregnancy test results a secret. Although we will not typically tell your parent(s) or guardian(s) without your permission, there may be times we might need to reveal this information. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to tell your parent(s) or guardian(s) of a positive pregnancy test. If you signed a clinical permission form that parents/guardians would have access to test results, they may also see these results.  If we believe it's necessary to tell your parent or guardian of a positive pregnancy test without your permission, we would meet with you first in private to discuss our concerns prior to giving any information to your parent(s) or guardian(s) regarding pregnancy. During the research, if you do have a positive pregnancy test, we may remove you from the study. This means that even if we do not reveal the results, your parent(s) or guardian(s), may suspect that you are pregnant despite our best efforts to keep the information secret. If you become pregnant or if there is any chance that you might be pregnant (late period, broken condom, missed oral birth control pills, etc.) please contact the study personnel immediately so that we may provide medical assistance and counseling.

**As of 09/06/2023:**

The following two changes have been made to ALL consent form templates (Medical, Non-medical, and Spanish) **as applicable**:

1. This instruction has been added to the HIPAA Authorization section entitled: “What Information will be obtained, used or disclosed?”: “ Be sure that the information in this HIPAA authorization is consistent with sections 11b and 15a in the protocol application.”

1. Updated the PREP language, which is required for research involving COVID-19, as depicted below:

*~~“Due to the coronavirus public health emergency, the~~ The federal government has issued a Declaration that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the Declaration applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” please go to* [*https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427*](https://www.hrsa.gov/cicp/about/index.html%20or%20call%201-855-266-2427)*.”*

**As of 06/26/2023:**

The following Medical consent form templates with HIPAA were modified:

* CONSENT\_Medical\_Reg\_with\_HIPAA
* CONSENT\_Medical\_Reg\_with\_HIPAA\_Spanish
* CONSENT\_Minimal\_Risk\_Medical
* CONSENT\_Minimal\_Risk\_Medical\_Spanish
* CONSENT\_MRI\_Minimal\_Risk
* CONSENT Somatic Cell for Stem Cell Research
* Research Information Sheet Medical
1. to add these words to the section **“When will my authorization expire?”**: “If you are uncertain, choose a date that provides plenty of time for your work to be completed (e.g., data analysis, monitoring, etc.). ‘
2. to achieve identical language across the 5 templates, additional, minor changes were made to this section.
3. Spanish consent forms: “his/her” has been changed to “their” in the HIPAA signature panel for LAR’s.

**As of 05/19/2023:**

All templates on the Forms and Templates pages [for SOM](https://researchcompliance.stanford.edu/panels/hs/forms-templates/medical) and [Social & Behavioral Research](https://researchcompliance.stanford.edu/panels/hs/forms-templates/nonmedical) pages have been updated as follows: the IRB# field was changed from 6XXXX to XXXXX.

**As of 05/08/2023:**

The following two changes were made to the consent forms listed below:

1. the IRB# field was changed from 6XXXX to XXXXX.
2. “email address” was added to the instructions for Protocol Director contact information.
* CONSENT\_Non-Medical
* CONSENT\_Video Use
* Exempt Non-Medical Information Sheet
* Research Information Sheet Non-Medical
* Parent or LAR Permission form
* ASSENT Non-Medical
* Oral Consent Script

**As of 04/25/2023:**

* Added an ‘\*’ to the HIPAA Authorization sections of the associated consent templates to indicate that HIPAA Authorization text in black must appear verbatim in the IRB-approved consent form.

* Updated the [HIPAA stand-alone Stanford template](https://stanfordmedicine.box.com/shared/static/8cxasnr3yupss0f5y24isk9s9xt04wua.doc) to be consistent with other Stanford University consent form templates.

**As of 03/30/2023:**

The following language regarding COVID-19 and in-person visits has been removed from the affected consent form templates:

For studies involving in-person research, regarding COVID-19, please include this sentence or explain your SOPs (see [human subjects homepage](https://researchcompliance.stanford.edu/panels/hs) for more information).

If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation.  Alternately, you can provide a negative COVID test within 72 hours of your visit.

**As of 02/24/2023:**

A second Assent form has been created for use with Non-Medical studies. It is identical to the current Assent form, minus the pregnancy-test results language added on 02/13/2023. The ‘Assent – under 18 Non-Medical’ is posted on the [Stanford University Forms and Templates](https://researchcompliance.stanford.edu/panels/hs/for-researchers/forms-templates/nonmedical) page, version 03/2023.

**As of 2/13/2023:**

The Assent form has been modified as follows: the paragraph below regarding pregnancy test results has been added:

If applicable, include:

If you have had your first period: (Include this header if one assent form will be used for younger and older children)

During the research, pregnancy testing will be performed. The results of the pregnancy tests will be told to you by one of the study nurses or doctors in private. Every effort will be made to keep positive pregnancy test results a secret. Although we will not typically tell your parent(s) or guardian(s) without your permission, there may be times we might need to reveal this information. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to tell your parent(s) or guardian(s) of a positive pregnancy test. If we believe it's necessary to tell your parent or guardian of a positive pregnancy test without your permission, we would meet with you first in private to discuss our concerns prior to giving any information to your parent(s) or guardian(s) regarding pregnancy. During the research, if you do have a positive pregnancy test, we may remove you from the study. This means that even if we do not reveal the results, your parent(s) or guardian(s), may suspect that you are pregnant despite our best efforts to keep the information secret. If you become pregnant or if there is any chance that you might be pregnant (late period, broken condom, missed oral birth control pills, etc.) please contact the study personnel immediately so that we may provide medical assistance and counseling.

**As of 02/02/2023:**

All CONSENT form templates except VA-forms have been modified as follows:

* Instructions have been converted from red to blue.
* Gender-inclusive language is present wherever applicable
* IRB# field added to the header or footer

All CONSENT forms with HIPAA Authorizations have been changed as follows:

* Added “mailing and/or email address” to PD’s name in revocation section
* Changed the suggested expiration date from 2045 to 2050
* Added “and affiliates” to “sponsors” in the “Who May Receive or Use the Information?” instructions

Medical Regular CONSENT forms (with and without HIPAA) have been modified as follows:

* The risks of MRI and Gadolinium contrast have been moved from the “MRI” Procedures section to the “Possible Risks, Inconveniences and Discomforts” section
* The Instructions have been expanded to be a full page of information intended to be deleted before submission to the IRB.
* A paragraph to include in studies that will involve pregnancy testing of minors that discusses how, when and under what circumstances to discuss results with the minors and with parents or guardians.
* This statement with instructions has been added:

“Data collected on you to the point of withdrawal remains part of the study database and may not be removed per the Food and Drug Administration”

* “Procedures” section: instructions were modified to request the use of lay language in this section and to clarify specimen amounts
* “Alternatives” section: minor editorial changes to instructions and suggested language

Other Consent forms and templates have been modified as above, where applicable. Other minor, editorial changes and corrections have been made to consent templates as needed for consistency and accuracy.

**As of 11/11/22:**

 -- Research Information Sheet with HIPAA

 -- Minimal Risk Medical Consent form

 -- MRI Minimal Risk Consent form

The language below has been revised or inserted into these forms:

**SPONSOR:** #(Name of institution/company) is providing financial support and/or material for this study. This section may be deleted if the study is un-funded or internally funded (i.e. receiving support and/or funding only through Stanford).

**As of 10/13/2022:**

* Research Information Sheet with HIPAA (now rev11 v 10/2022)

Added to the Contact Information section this sentence: ““You should also contact him/her at any time if you feel you have been hurt by being a part of this study.”

**As of 5/2/2022:**

In the “Payment” sections of 6 Stanford ICF templates\*\* the following template instruction was changed:

If participants will be paid $100 $200 or more, add the following:

****Payments may only be made to U.S. citizens, legal non-citizens, and those who are in a status that allows them to receive a taxable payment from a U.S. payer. You may need to provide your social security number to receive payment

**\*\***Templates changed with 04/2022 version date:

* CONSENT\_Medical\_Reg\_with HIPAA
* CONSENT\_Medical\_Reg\_No\_HIPAA
* CONSENT\_Minimal\_Risk\_Medical
* CONSENT\_MRI\_Minimal\_Risk
* CONSENT Non-Medical
* Research Information Sheet (for waivers of documentation)

**As of 1/5/2022:**

A new Research Information Sheet template for Exempt studies has been added to the Non-Medical/Social Behavioral page.

The Non-Medical consent form and Research Information Sheet were updated as follows:

* This statement has been added: “Study data will be stored securely, in compliance with Stanford University standards, minimizing the risk of confidentiality breach.”
* The wording of the first “future use” statement has been revised to read: “In accordance with scientific norms, the data from this study may be used or shared with other researchers for future research (after removing personally identifying information) without additional consent from you.”
* The template instructions were also clarified.

**As of 11/11/2021:**

The changes made to the consent templates effective 10/7/21 have been made to

 -- CONSENT Somatic Cell for Stem Cell Research

The Telephone Screening Scripts 1a and 1b have had the following language added:

*\*If you are contacting potential participants, please cite the reason for contacting the potential participant. For example, in a previous research study you consented to be contacted for future research studies or your treating physician referred you to our research study.*

**As of 10/7/2021:**

The following consent forms, as applicable, were modified as described in numbers 1-3 below. **Also note**, the[GDPR](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#gdpr1) consent form [language](https://stanfordmedicine.box.com/shared/static/1igt6tuic4mqdtgshz5umj9qd8jnv2ok.docx) was revised throughout.

* CONSENT\_Medical\_Reg\_with HIPAA
* CONSENT\_Medical\_Reg\_No\_HIPAA
* CONSENT\_Minimal\_Risk\_Medical
* CONSENT\_MRI\_Minimal\_Risk
* CONSENT\_Non-Medical

**1)** In the “**Financial considerations**” sections, payment language was revised and separate instructions were added for reimbursement language.

 **2)** Changes to **“Procedures”** section:

1. Moved and clarified language pertaining to:
* future use of data and specimens
* whole genome sequencing
* return of clinically relevant results
1. Added language about in-person research and COVID-19, per Stanford Research Recovery Handbook
2. Revised the following sections:
* MRI
* Gene Transfer
* Genetic Data Sharing
* Communicable diseases

**3 )** Within the Research-Related Injury sections Options 1 & 2, the Stanford-required sentence: “You do not waive any of your liability rights….” was moved to appear just before the federal-COVID-19 required language.

**As of 4/19/21:**

 **1)** The payment language was revised as follows in the consent form templates listed below:

“Payments made only be made to U.S. citizens, ~~legal~~ resident aliens, and those who ~~have a work eligible visa~~ are in a status that allows them to receive a taxable payment from a U.S. payer. You may also need to provide your social security number to receive payment.”

* CONSENT\_Medical\_Reg\_with HIPAA
* CONSENT\_Medical\_Reg\_No\_HIPAA
* CONSENT\_Minimal\_Risk\_Medical
* CONSENT\_MRI\_Minimal\_Risk
* CONSENT\_Somatic\_Cell\_for\_Stem\_Cell\_research
* Research Information Sheet
* Parent\_or\_LAR\_Permission form

 **2)** The contact email address for Non-Medical IRB staff has been corrected to irbnonmed@stanford.edu in the following templates:

* CONSENT\_Non-Medical
* Research Information Sheet
* Parent\_or\_LAR\_Permission form

 **3)** The address for the Stanford IRB has been corrected to 1705 El Camino Real in the following VA consent templates:

* CONSENT\_VA\_Minimal\_risk\_No\_HIPAA
* CONSENT\_VA\_Reg\_with\_HIPAA
* CONSENT\_VA\_Regular\_No\_HIPAA

**As of 12/7/20:**

The following paragraph has been added to the research-related injury sections of the consent form templates listed below for use in studies involving COVID-19 research:

“Due to the coronavirus public health emergency, the federal government has issued a Declaration that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the Declaration applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” please go to [https://www.hrsa.gov/cicp/about/index.html](%20https%3A/www.hrsa.gov/cicp/about/index.html%20) or call 1-855-266-2427.”

* CONSENT\_Medical\_Reg\_with HIPAA
* CONSENT\_Medical\_Reg\_No\_HIPAA
* CONSENT\_Minimal\_Risk\_Medical
* CONSENT\_MRI\_Minimal\_Risk
* CONSENT\_Somatic\_Cell\_for\_Stem\_Cell\_research
* CONSENT\_Non-Medical
* Research Information Sheet
* Parent\_or\_LAR\_Permission form
* Oral Consent Script

**As of 7/1/20:**

The statement: May we contact you for future research studies? Yes\_\_ No\_\_ has been added to the

 following consent form templates:

* CONSENT\_Minimal\_Risk\_Medical
* CONSENT\_MRI\_Minimal\_Risk
* CONSENT\_Non-Medical

**As of 12/2/19:**

All Consent form templates that include the Stanford IRB address have been updated with the new

 Stanford IRB address: *1705 El Camino Real, Palo Alto, CA 94306.*

**As of 10/24/19:**

VA Consent forms. Minor administrative changes were made to all VA consent forms.

* CONSENT\_VA\_Minimal\_risk\_No\_HIPAA (v. 10/22/19);
* CONSENT\_VA\_Minimal\_risk\_with\_HIPAA (v. 10/22/19);
* CONSENT\_VA\_Reg\_with\_HIPAA (v. 10/22/19);
* CONSENT\_VA\_Regular\_No\_HIPAA (v. 10/22/19)

Minor changes include:

* Added this statement (or removed “$100 or more” from the statement): \*If paying participants, add the following: You may need to provide your social security number to receive payment.
* Removed VA contact information from the Research-related Injury sections
* In the HIPAA Authorizations, added a prompt to specify the identifier(s)/code used to link health information to individuals

**As of 7/31/19:**

CONSENT\_Minimal\_Risk\_Medical

* Added language to the Procedures section about video/audio recordings:

If the research will include audio- or videorecordings, the following language should be added:

You give consent for your [video/audio] recordings to be used for (describe proposed use of the recordings and what will happen to the recordings, e.g., shown at scientific meetings; and describe the final disposition of the tapes).(Please note, this option is also applicable if the recordings are used for purposes that are not part of this research project, e.g. future analysis, professional presentations, etc)

Please initial your choice: \_\_\_Yes \_\_\_No

**As of 6/24/2019:**

Short form consent templates (40 languages translated):

* Added a statement that key information has been provided
* Added a statement about future use of information or biological specimens (new basic element)
* Added a statement for each of the 3 new additional elements
	+ Use of specimens for profit
	+ Return of research results
	+ Whole genome sequencing
* Added a statement referencing study being listed in a clinical trial registry
* Removed statement about *ClinicalTrials.gov*

As of **6/3/2019**:

 CONSENT Medical Regular No HIPAA (v. 5/25/19); CONSENT Medical Regular with HIPAA (v. 5/25/19);

 CONSENT Minimal Risk Medical (v. 5/25/19); CONSENT MRI Minimal Risk (v. 6/3/19).

* Added a statement to the “Procedures” section regarding whole genome sequencing (new additional consent element)
* Revised and renamed the “Tissue Sampling” sections of the consent; “Tissue Sampling for Research” is now “Future Use of Private Information and/or Specimens” and “Tissue Sampling for Genetic Testing” is now “Genetic Testing and Future Research”.
* Other minor changes in the above 2 sections to be specific to use of information and specimens for future research.
* Moved language regarding future use of de-identified information and specimens from the “Confidentiality” section to the newly-renamed “Future Use of Private Information and/or Specimens” section
* Removed from the “Future Use of Private Information and/or Specimens” section the Optional information about return of results and the Yes/No questions about saving samples for future research
* Minor changes to the MRI Risk language section that discuss tattoos; added risk of tinnitus.

As of **4/23/2019**:

Translated short forms (various languages):

* Added footnote referencing 8/18 version 10 of the English short form (for NCI CIRB)
* Removed the paragraph that included the non-medical IRB phone number (since non-med does not use short forms)

As of **3/05/2019**:

Short form consent template (English version):

* Added a statement that key information has been provided
* Added a statement about future use of information or biological specimens (new basic element)
* Added a statement for each of the 3 new additional elements
	+ Use of specimens for profit
	+ Return of research results
	+ Whole genome sequencing
* Added a statement referencing study being listed in a clinical trial registry
* Removed statement about *ClinicalTrials.gov*

As of **1/18/2019**:

Renamed templates:

|  |  |
| --- | --- |
| **New Document Name** | **Old Document Name** |
| ASSENT\_Children\_Under\_18 | SU\_assent |
| ASSENT\_Adults\_Unable\_to\_Provide\_Consent | SU\_assent\_non-consenting\_adult |
| CONSENT\_Medical\_Reg\_No\_HIPAA | SUSampCons |
| CONSENT\_Medical\_Reg\_with\_HIPAA | SUSampCons\_CA\_privacy |
| CONSENT\_Minimal\_Risk\_Medical | Med\_survey\_consent |
| CONSENT\_MRI\_Minimal\_Risk | Med\_MRI\_consent |
| CONSENT\_NCI-CIRB\_with\_HIPAA | SU\_Template\_for\_CIRB\_studies |
| CONSENT\_Non-Medical | SampCons\_TEM02C07 |
| CONSENT\_Somatic\_Cell\_for\_Stem\_cell\_research | SUSampCons\_somatic\_cell |
| CONSENT\_VA\_Miminal\_risk\_No\_HIPAA | Med\_survey\_consent\_VA |
| CONSENT\_VA\_Regular\_No\_HIPAA | VASampCons |
| CONSENT\_Video\_Use | Video\_consent\_TEM-C9 |

* Added new VA templates with embedded HIPAA
	+ CONSENT\_VA\_Reg\_with\_HIPAA
	+ CONSENT\_VA\_Minimal\_risk\_with\_HIPAA
* Added Key Information/Concise Summary to:
	+ CONSENT\_Medical\_Reg\_No\_HIPAA (dated 1/21/19)
	+ CONSENT\_Medical\_Reg\_with\_HIPAA (dated 1/21/19)
	+ CONSENT\_VA\_Regular\_No\_HIPAA (dated 1/18/19)

As of **12/17/2018**:

*Med\_survey\_consent, Med\_survey\_consent\_VA, MRI-TEM-C4, VASampCons, SUSampCons* and *SUSampCons\_CA\_privacy:*

* Added the new element of consent (Future Use) paragraphs under Confidentiality as:

\*If this study collects identifiable private information or identifiable specimens include one of the two following statements:

Identifiers might be removed from identifiable private information or identifiable specimens and, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

OR

Your specimens or private information will not be used for future research even if all identifying information is removed.

* Changed the following words to **specimen** for consistency:
	+ Tissues
	+ Samples
* Changed the following words for consistency:
	+ Data to **information**
	+ Medical information to **information**

*SUSampCons* and *SUSampCons\_CA\_privacy:*

* Removed CTRU language

As of **09/14/2018**:

* Added IRB2 email address under Contact Information:

If you are not satisfied with how this study is being conducted … , or email at IRB2-Manager@lists.stanford.edu.

As of **04/12/2018**:

*Removed requirement that witness be fluent in both languages from signature block for Short Form Consent Process:*

*(e.g., staff, translator/interpreter, family member)*

As of **03/22/2018**:

*Revise Payment/Reimbursement section:*

* If participants will be paid $100 or more, add the following:

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

As of **03/14/2018**:

*In Payment/Reimbursement section:*

* If participants will be paid, add the following:

Payments greater than $100 may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

*Med\_survey\_consent\_VA:*

* Corrected typo in “**What are my alternatives to being in this study?”:**

*If the study is not a treatment study, you can state there are no alternatives to the study or you can request an alteration of consent from the IRB to leave this required consent form element out.*

As of **03/12/2018**:

* Added dbGap info under Gene Transfer Studies:

If the protocol involves genetic data that will be deposited in NIH-supported repositories the following three paragraphs must be included:

Genetic Data

Information from analyses of your coded samples and your coded medical information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, 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.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

As of **11/02/2017**:

* Added [NIH Certificate of Confidentiality language](https://humansubjects.nih.gov/coc/suggested-consent-language)

As of **08/10/2017**:

* Confidentiality section
* Removal of Tissue Banking section
* Signature section (witness language)

\* 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,

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 consentBlood 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] 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:

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:

* 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.