# Supplemental Information: Constructing a Consent Form

Federal regulations and TUN guidelines require that the following information be provided to prospective participants when obtaining consent [Federal Policy 45 CFR 46.116(a)]. **If this is a study that falls within FDA rules, additional or different requirements may apply** (21 CFR 50.25).

**See the ‘Checklists of requirements for informed consent’ document to locate the specific components required for your study**, locatednext to this document on the TUN IRB web page. In addition, the consent form must **begin** **with a concise and focused presentation of key information** that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. It must be organized in a way that facilitates comprehension.

* **Components of ‘Key Information’**
	+ The study involves research, and participation is voluntary
	+ Explanation of the purpose, duration of participation, and description of the procedures that will involve the subject
	+ Description of any reasonably foreseeable risks or discomforts to the subject
	+ A description of any benefits to the subject or to others which may reasonably be expected from the research
	+ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

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This example is adapted from protocols which have been reviewed by the committee, and it is meant to provide specific information about the kind of content and language that should appear in a consent form. Thus, it is not a template, and researchers will need to consider all the guidelines to match the investigator’s particular research situation. Italicized headings at the beginning of a paragraph are merely reminders of the major topic in that paragraph; such headings do not necessarily need to be included in the consent form. Please keep in mind that the consent form must provide the information a subject would need to weigh the risks and benefits of participating in the research, and that the benefits to the individual participant may be different from the overall benefits of conducting the research study.

If a waiver of written consent or an alternate method of documenting consent is requested in a protocol, the investigator must still clearly indicate how the research will be explained to each subject, how the consent of the participants will be obtained, and who will validate the act of consent. In some instances the committee can waive the requirement of a signed written consent form, but only rarely can it waive the process of obtaining informed consent, and only if the participants are not placed at any risk by doing so.

# Sample 1: Example of a Consent Form

Consent to Participate in Research

**KEY INFORMATION**

|  |
| --- |
| ***What are you asking me to do?*** |
|  | We are asking you to volunteer for a research study. If you agree to participate, you will immediately be given a sterile cotton swab. You will swab the inside of your cheek to collect cells, and the cells will then be handed to a research assistant. You will then be free to go. The entire process will take less than five minutes. The research assistant will take your cells to a laboratory to extract your DNA and analyze the genetic markers.  |
| ***Why?*** We want to know more about the accuracy of human identity testing using DNA. |
|  |  |
| ***What are the risks to me?*** |
|  | There are no known health risks or foreseeable discomforts associated with your participation in this study. We have measures in place to keep your information confidential and not expose your genetic information: (1) your name or other personal information will never be linked with your DNA sample, (2) your cells will be destroyed after the test has been run, and (3) your participation in this study will be kept confidential.  |
| ***How does this benefit me or others?*** |
|  | We will not return results to individual participants, so you may not personally benefit from participating in this research. However, DNA studies like this have led to clearer evidence of guilt or innocence in criminal cases, more accurate resolution of paternity conflicts, and increased ability to identify victims of war and natural or man-made disasters. |

*(Study title, name of researchers)* This study is being conducted by Dr. in the Department of XXXXXXX at Touro University Nevada.

 *(confidentiality)* Your cheek sample will be labeled in a way that it cannot be traced back to you by the technicians handling your sample. Your participation in this study will also be kept confidential. However, the results of the study as a whole may be shared with the scientific community and become a matter of public record. Once your profile for the DNA markers we are studying has been obtained, your cheek sample will be destroyed. Furthermore, no other genetic testing will be done on your sample. Any sample remaining in the laboratory two years after you provided it will also be destroyed, regardless of whether the sample has been successfully tested.

The information we obtain about your DNA markers, which will not be linked to you in any way, will be kept for future research without your additional consent. The information will not be used for commercial profit. Destruction of the cheek sample will prevent any further DNA testing on your cells beyond the detail needed for this study.

*(compensation)* You will receive $2 for providing your DNA sample.

*(contact information)* If you have any questions about this research, you may contact Dr.

 at (702) 777-xxxx or by e-mail at xxxxxxxx@touro.edu. This study has been approved by the Touro University Nevada IRB (TUN.IRB@tun.touro.edu).

You may decline to be a participant in this study without any consequences. Your signature below indicates that you have read this information and agree to participate in the research.

☐ I have received a paper copy of this document.

Signature of Participant\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_