# NHGRI IRB Guide to Writing Consent Forms

This table contains suggested sections, guidelines, and sample text that can be adapted and incorporated into the official, watermarked NIH Consent Form template (available at <http://www.genome.gov/27528182>). Although you may wish to “copy and paste” text directly from this table into the “official” template, please take care not to copy the guidelines and to ensure that the included text is relevant to your protocol. Italicized and bracketed text should not be copied into consent forms.

Consent form text should be written using 10 pt, Tahoma font. Exceptions may be made for research subjects with impaired vision.

Consent forms must include the required and additional elements that are covered in 45 CFR 46.116 (<http://www.hhs.gov/ohrp/policy/consentckls.html>) and, when relevant, 21 CFR 50.25 (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25>)

Indicate in the informed consent section of your protocol if you are requesting any consent element(s) to be waived or altered, or if you are asking for a waiver of documentation of informed consent. When a waiver of documentation is requested, the investigators should still create a document that describes the information that will be disclosed to prospective participants orally or in writing. This document will typically contain the same basic elements that are included in this guide.

Suggested consent form sections:

* WHY IS THIS RESEARCH STUDY BEING DONE?
* WHAT IS INVOLVED IN THE RESEARCH?
* WHAT ARE THE RISKS OF THE RESEARCH?
* ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH?
* WHAT ARE MY OTHER OPTIONS?
* WHAT IF I CHANGE MY MIND?
* WILL MY RESEARCH INFORMATION BE SHARED WITH OTHERS?
* WILL I RECEIVE PAYMENT FOR PARTICIPATING IN THIS RESEARCH?
* CONFLICTS OF INTEREST

Investigators conducting genomic research should become familiar with the requirements of the [NIH Genomic Data Sharing (GDS) policy](https://gds.nih.gov/) and should review the consent guidance available at:

<https://gds.nih.gov/pdf/NIH_guidance_elements_consent_under_gds_policy.pdf>

*NIH strongly encourages investigators seeking consent to include consent for future research use and broad sharing of genomic and phenotypic data generated from the specimens or cell lines. NIH also recognizes that in some circumstances broad sharing may not be consistent with the consent of the research participants whose data are included in the dataset.*

Investigators are also encouraged to seek additional guidance from the online NHGRI Informed Consent Resource (ICR) at: <http://www.genome.gov/InformedConsent/>. The NHGRI ICR was created to provide the research community with information and examples to assist with the development of informed consent processes and consent forms for genomics-related research projects

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| **Section** | **Instructions/Guidelines** | **Sample Text** |
| WHY IS THIS RESEARCH BEING DONE? | *Explain why/how the participant was selected for the research, the purpose of the research, and approximately how many people will be enrolled in the protocol.* | You are being asked to participate in this research because [*describe reason for eligibility, e.g., you have a particular disease, because a particular disease runs in your family, healthy or unaffected individuals are needed, etc*.].The purpose of this study is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **WHAT IS ­­­INVOLVED IN THE RESEARCH?** | *Briefly explain the study design. Describe the examinations and tests in which the subject will participate. Explain how treatment groups will be assigned, how long each procedure will take, how long participation in the entire study will take, where the study’s procedures will take place, etc.*  *Describe the procedures that are part of study. Distinguish between the procedures that are for research purposes only and those that are also clinically indicated (“needed for medical care”) but will also produce data for the research. Procedures should be described chronologically in the order they will be conducted in the study (e.g., during initial visit, follow-up visit, on the first day of your stay at the Clinical Center, etc.) Tables of bulleted lists may be used to communicate the requirements of the study*  *In addition to describing what kinds of samples will be collected and how (e.g., blood draws, biopsies, buccal swabs), indicate what clinical and genomic data will be generated from these samples.*  *Define and explain medical terms in ordinary language (e.g., describe the amount of blood to be drawn by using household measures such as teaspoons and tablespoons).* | We will collect [*amount*] of blood with a needle and will do genetic research about [*disease*.]  Most of the tests, exams, and procedures that we will do in this study are part of the usual care for your condition. For example, each time you come to the NIH, we will take your medical history and perform a physical examination.  Using DNA from your blood or tissue sample, researchers will study your entire genetic sequence, known as your genome. The genome sequence will be read, and this information will be stored.  Your genomic data and health information will be studied along with information from other participants in this research, and it will be stored for future studies by this and other research teams.  *If applicable:* We will try to grow some of your cells and modify them in the laboratory to make them into “induced pluripotent stem (iPS) cells.” These are special cells that can form any type of cell in the body and may be grown in the laboratory in a flask or dish forever. |
| *If the study involves a survey, describe the type of information to be collected; specify if the questions are personal or sensitive in nature (e.g., dealing with psychological or emotional experiences, sexual habits, marital and/or family situations, alcohol or illegal drug use, etc.). Provide an estimate of how long it will take to complete the survey* | We will ask you to fill out a questionnaire about your family’s health. |
| *Indicate what (and under what circumstances, if applicable) clinical and genetic results will be provided to research participants, and whether secondary findings will be actively sought.* | Genetics is a fast moving field and new findings for a wide range of diseases are announced every day. By sequencing your entire genome or exome, we may also discover possible misspellings in genes not currently recognized as being associated with [specific disease under investigation].  These are called incidental findings.  Since we are looking exclusively for genome regions associated with [specific disease under investigation], we will not intentionally look for these incidental findings and will generally not inform you about your genetic information.  In rare cases where we happen to find specific gene variants that we think are urgently important to your health, we will tell you about them after confirming the finding in a clinical laboratory. This type of result will be very uncommon, and most people in this study will not have a result like this.  We will, however, periodically recheck your genome or exome sequence as new information related to your specific disease becomes available and may report back to you any of our findings. |
| **WHAT ARE THE RISKS OF THE RESEARCH?** | *List each intervention as a subheading and then describe any reasonably foreseeable risks, discomforts, and inconveniences, and tell how these will be managed.*  *Include relevant psychological, social, legal, and economic risks, e.g., family and/or community risks~~,~~ or the challenge of handling uninterpretable/ambiguous genetic test results concerning disease risk.*  *Indicate if unforeseen risks are possible (e.g., “Other unforeseen or unknown problems may occur. You will be monitored closely for any problems.”).* | Possible risks and discomforts you could experience during this research include:  Blood collection:  There may be some physical discomfort when we collect your blood with a needle.  There is a small chance that you will develop a bruise, feel lightheaded, faint, or develop an infection at the needle site.  Skin biopsy:  If your tissue is collected through a skin biopsy, you will experience some discomfort at the biopsy site, which is usually mild and goes away in a few minutes. It can be treated with minor pain relievers. Normally, the risks include a reaction to the local anesthetic (very rare), bleeding (occasional), infection (rare), and scarring at the biopsy site (always)  Psychosocial risks:  Some people are concerned that research about genetic causes of illness may give information that is not only about themselves, but also about their relatives and other groups of people who are like them. [*Describe relevant implications for the particular population.*]  It is possible that in the course of this study, we will learn that assumed family relationships are incorrect (such as learning that a child was adopted or has a different parent). It is our practice not to discuss such information with you unless it has direct medical implications for you or your family.  There may be a risk that genetic information obtained as a result of participation in research could be misused for discriminatory purposes. However, state and federal laws provide some protections against genetic discrimination. If you have any questions, please ask your Principal Investigator. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your information. Measures to protect your information are described below. These problems may also occur if you disclose information yourself or agree to have your research records released.  *Risks related to research uses of radiation: Suggested text for radiation risks will be provided by the Radiation Safety Committee (RSC). The following URL should be added to the required RSC language, which links to a pamphlet entitled: “An Introduction to Radiation for NIH Research Subjects:*   * <http://www.genome.gov/Pages/Research/Intramural/IRB/ResearchPatientBrochure.pdf> |
| **ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH?** | *State potential direct benefits that may be associated with an intervention being studied for the participant (if applicable) and/or collateral benefit to participants (medical or genetic counseling care).*  *Do not overstate benefits; be realistic.*  *If a subject will not benefit from participation, clearly state so. (e.g., “You should not expect your condition to improve as a result of participating in this research.”) If the subject may benefit from the initial research but not secondary/future uses of their samples and data, this should be stated as well.*  *State possible general benefit for science or for other subjects with similar diseases or for the population at large, if applicable.*  *Ensure that the description of benefits is consistent with the benefits described in the protocol.*  *Do not list financial compensation as a benefit in this section.* | There is no direct benefit to you from participating in this research. However, we hope to learn more about [disease name] or [your or your family member’s illness]. |
| **WHAT ARE MY OTHER OPTIONS?** | *Explain realistic alternatives to participation. Specifically, state the treatment that would be recommended, offered, or available to subjects if they decline to participate.* | Instead of being in this research study, you have these options:  (*or*)  You do not have to participate in this study if you do not want to. |
| **WHAT IF I CHANGE MY MIND?** | *Explain that the subject may withdraw from the study at any time, and specify what will happen to their samples and data upon withdrawal.*  *Describe circumstances where data/biological materials may not be removed or destroyed, such as iPS cells, data deposited into dbGaP and other repositories.* | You may stop participating in this research study at any time. If you choose, you may request to have your [*data/biological materials/interview transcript*] destroyed.  It may not be possible to withdraw samples or delete data once they have been deposited in research databases and shared with other researchers.  We will not destroy the iPS cells once they are created. These cell lines may be shared with other investigators, and re-contacting all recipients of the cell lines made from your samples may not be possible. |
| **WILL MY RESEARCH INFORMATION BE SHARED WITH OTHERS?** | *Specify who (e.g., members of the research team and specified others) will have access to the data/biological materials. (Note: Some additional information about confidentiality is included within the standardized language on the last page of this template as required by the NIH Clinical Center. It is not necessary to repeat any of this language in the body of the consent form.)*  *Include a brief description of how personal information, research data, and biological materials will be coded, stored, etc. to prevent access by unauthorized personnel.*  *If applicable, state if and when (1) links to the codes for personal identifiers, and/or (2) actual data/biological materials will be destroyed.*  *If a pedigree of the participant’s family might be published, indicate what measures will be used to protect the identity of the family.*  *For studies that are generating genomic research data and are subject to the NIH Genomic Data Sharing Policy, this section should include information about the study’s plan to deposit data into repositories.*   * *Whether data/biological materials will be shared with other researchers.* * *What restrictions, if any, will be placed on the use of these data/biological materials (e.g., whether use is restricted only the disease of interest, or broader research use will be allowed.) Note that if the consent form describes limits on future uses of samples and data, these limits (also known as “data use limitations” or DULs) should be described and justified in the research protocol as well.* | Data from this research study will be identified with a code number instead of your name. The key for this code will be stored in a secure, password-protected database  *If applicable:* We may publish a chart that shows your family tree and who is affected with the condition, but we will not use your family’s name. If you have a unique family, others may still be able to figure out who is affected with the condition that runs in your family.  *If applicable:* If we determine that it would be helpful to enroll other family members in this study, we will contact them only with your assistance and permission.  When we share samples, genomic data, and health information that we collect from you with other researchers, we will not provide information that can identify you, such as your name, address, or phone number. There will be a code to link your samples and data with your name and other personal information. This code will be kept at the NIH and stored in a password-protected secured database.  *Example of language for broad sharing and future use:*  Your samples, genomic data, and health information will be stored and shared with other researchers. The samples and information will be available for any biomedical or health-related research question.  *Example of data use limitation (DUL) language:*  Your coded medical information and information from detailed analyses of your coded samples will be put in a controlled-access database. Controlled-access data can only be obtained if a user has been authorized by the appropriate Data Access Committee. The information in this Controlled-access database will be available only to researchers requesting access to conduct research on [specific disease]. |
| **WILL I RECEIVE PAYMENT FOR PARTICIPATING IN THIS RESEARCH?** | *Describe any payments that will be made to research participants.*  *Specify what is being paid for, and when and in what manner the research participant will be paid. Clearly state the total amount that the participant will be paid.*  *Include information regarding how amounts are pro-rated if a participant does not complete the study.*  *If anticipated payment will be $600 or greater to an individual in a year, include a statement that the total annual dollar amount will be reported to the IRS.*  *Include a statement about potential commercial uses of biological materials collected.* | You [*will/will not*] receive payment for taking part in this research study*.* [*If participants will be paid, describe amount of payments and when payments will occur. Be specific.* e.g., This study requires 4 clinic visits, each lasting 2 hours. You will be paid $30 per visit. The total payment for completing the study will be $120.]  It is possible that research using your [*data*/*biological materials*] may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any money that may result from such commercial tests or treatments.  *For research with iPS cell lines:* Cell lines will not be sold to other researchers. Although it is possible that the cell lines generated from the tissue samples will have commercial potential, you will not receive financial benefits resulting from future commercial developments and/or patents issued based on research with cell lines generated from your tissues. The iPS cells will not be used for cloning or to grow artificial organs or organisms. They will not be used in reproductive research. |
| **CONFLICTS OF INTEREST** | *Mandatory text for covered protocols:* | The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process: <http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf>. You may ask your research team for additional information or a copy of the Guide. |
|  | *Additional text regarding conflicts of interest should be included as appropriate, per the “Guidelines for Completing the Clearance of NIH Personal Investigator Financial Holdings.”* | *Examples from NIH HRPP SOP 21:*  *If there are non-NIH investigators and no identified conflicts with NIH investigators:*  No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. However, there are some non-NIH collaborators on this study who may receive payments or benefits, limited by the rules of their workplace.  *Use this statement if developing a new drug or device:*  The National Institutes of Health and the research team for this research study have developed (a drug, imaging agent, device) being used in this study. This means it is possible that the results of this research study could lead to payments to NIH. By law, the government is required to share such payments with the employee inventors You will not receive any money from the development of \_\_\_\_\_\_\_\_\_ *(drug/imaging agent/device).*  *Use this if the protocol is part of a CRADA:*  The NIH and the research team for this study are using (a drug, imaging agent, device) developed by (company name) through a joint study with your researchers and the company. The company also provides financial support for this study.  *Use this if the protocol involves a Clinical Trial Agreement:*  *(Company name) is providing (the drug/device) for this study to NIH without charge. No NIH employee involved in this study receives any payment or other benefits from (Company).*  *Use this if an investigator has a waiver:*  No conflicts of interest exist among NIH investigators based on federal regulations. One or more NIH employees have a personal financial holding in the manufacturer of the product(s) used in the study, but the conflict has been resolved by NIH ethics staff and Institute Leadership. |
| ***Include the following additional elements as appropriate*** | * *Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent* * *Any additional costs to the subject that may result from participation in the research* * *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject* * *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject* |  |
| ***For applicable FDA-regulated clinical trials*** | The consent document for applicable FDA-regulated clinical trials must include the following statement, per HRPP SOP 15 and 21 CFR 50.25(c) | A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. |