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| **Medical Research Sample** **Consent Form**The following template contains the *required elements* *of informed consent*. **Researchers should use these headings and suggested text (in bold) when writing a consent form**. |

 **[**insert title of study**] Consent Form**

**1. Introduction**

**You are invited to be in a research study of [**insert general statement about study**]. You were selected as a possible participant because [**explain how subject was identified**]. We ask that you read this document and ask any questions you may have before agreeing to be in the study.**

**This study is being conducted by [**indicate University affiliation**].**

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| *tips** Invite subject to participate.
* For a relative or parent do not have the document invite "you" It should say "your relative" or "your child".
* Include typeface that is **12-point type** or larger. If the population has trouble handling small print, then make accommodations.
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**2. Background**

**The purpose of this study is[**explain research questions and purpose in lay language**]**.

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| *tips** Define or explain research terms.
* Use declarative sentences suited for an **eighth-grade** reading level.
* Keep the description as brief as possible.
* Give some indication of previous work done in the area.
* Include key elements of the research process.
* Include the duration of the study.
* Explain if the drug or device being tested is experimental. (Required if applicable).
* Give enough information to make an informed decision, but not so much (or so technical) that the subject becomes confused.
* Describe all quantities with lay term equivalents, e.g., teaspoons.
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**3. Procedures**

**If you agree to be in this study, we will ask you to do the following things:[**explain tasks and procedures from the subject's point of view (what will he/she be expected to do?)**]**.

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| *tips** Estimate the total amount of time for the person involved in the study.
* Explain the frequency of procedures.
* Explain how the person is assigned to groups.
* Disclose any additional costs or charges for the research procedures with estimated amounts.
* Describe "randomization" in lay terms.
* State the probabilities of assignment to each group.
* For survey/questionnaire studies, state that not all questions need to be answered in order to participate.
* Explain if the procedures are experimental. (Required if applicable.)
* Identify additional procedures due to "research" participation separate from "treatment" procedures.
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**4. Risks and Benefits**

**This study has the following risks:[**explain risks, hazards, or discomforts, including the likelihood of the risk. Be honest and accurate**]**.

**The benefits of participation are:[**describe any benefits to the subject or others that may reasonably be expected from the research**]**.

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| *tips** If there are significant physical or psychological risks (such as stress or invasion of privacy) to participation, tell the subject under what conditions the researcher will terminate the study.
* Identify the risks of being in the placebo group.
* If there is no benefit to the subject, say so.
* If there is the possibility of injury as a result of the research, include information as to the medical treatment and compensation.
* If there is an inducement or a reward for participation, specify terms of disbursement on the document.
* FDA regulations require that payment to subjects be prorated over time, so that in the event a subject withdraws from a study, prior to termination of the research, he/she receives some compensation for participation.
* Describe the payment method for subjects, if any.
* **Do not** make payment an inducement, only a compensation for expenses and inconvenience.
* If the subject is a student who receives class points or some other token, include that information under benefits.
* If a person is to receive some money or other token to participate, explain when it will be paid and any conditions of full or partial payment.
* If there is a monetary incentive being provided to a person who refers the subject, make sure it is disclosed in the consent document.
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**5. Alternatives to participating in this study**

**[**State the alternative treatments for the subject and the risks and benefits of alternatives**]**.

**6. Compensation**

If the research involves a physically invasive procedure (e.g. spinal manipulation, exercise, acupuncture, etc.), where there is even a **slight risk** of injury, include the appropriate compensation statement in the consent document.

Case 1: *For funded projects where a contract exists agreeing to pay for research-related injuries:*

**In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research-related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.**

Case 2: *For projects where there is no already identified source of payment:*

**In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research-related injury, let the study physicians know right away.**

Case 3: *There is no physical component to this research, so there is minimal risk of physical* *injury:*

A statement concerning compensation for medical treatment is not required.

**7. Confidentiality**

**The records of this study will be kept private except as required by law. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Your record for the study may, however, be reviewed by the sponsor [**include study sponsor, if applicable**]. To that extent, confidentiality isn't absolute.**

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| *tips** If data will be made available to anyone other than the participant, the investigator, or the investigator's staff, then describe the purpose of the disclosure and the nature of the information to be furnished.
* Specify the duration of time the data will be retained before erasure or destruction.
* Disclose use of such data for other purposes, including educational purposes, and obtain permission in a special portion of the consent document.
* If tape recordings or videotapes are made, explain who will have access, if they will be used for educational purposes, and when they will be erased.
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**8. Voluntary Nature of the Study**

**Your decision whether or not to participate will not affect your current or future relations with the University [**or with other cooperating institutions, insert names**]. If you decide to participate, you are free to withdraw at any time without affecting those relationships.**

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| *tips** Be sure wording reflects the voluntary nature of participation.
* Consent is ongoing, so include a sentence about withdrawal.
* Explain if monetary benefits will be adjusted due to early withdrawal.
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**9. New Information**

**If during the course of this research study, there are significant new findings discovered which might influence your willingness to continue, the researchers will inform you of those developments.**

**10. Contacts and Questions**

**The researcher(s) conducting this study is(are) [**insert names**]. You may ask any questions you have now. If you have questions later, you may contact the researchers at [**include phone number with area code**].**

**If you have questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you may contact Dr. Linda Bowers,**

**Human Subjects Committee chairperson, Northwestern Health Sciences University, 2501 W. 84th Street, Bloomington, MN 55431; telephone (952) 888-4777 x 431.**

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| *tips** If the researcher is a student, include the names and phone numbers of the principal investigator and, where applicable, the faculty supervisor for questions.
* Include as a contact someone not involved in the study.
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**11. Statement of Consent**

**You will be given a copy of this form to keep for your records.**

**I have read the above information. I have asked questions and have received answers. I consent to participate in the study.**

**Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Parent or Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_**

**Signature of Investigator or Person Obtaining Consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_**

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|  *tips** Add a signature space to document assent of children to participate in the study. Parental signatures are still required.
* If the potential subject is not competent, use an assent document with caregiver consent. Do not use a witness.
* If you use a witness line, it should clearly describe what the signer is witnessing, e.g., witness to signature.
* Use the signature of the investigator to establish who discussed the study with the subject.
* Include IRB expiration date on the consent form.
* Give participant a copy of the signed consent form.
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