

Institutional Review Board

Informed Consent Template

Instructions:

* This template is designed to provide assistance and guidance in the construction of research informed consent documents. While it addresses many issues, it does not address every possible situation or issue that may arise. Investigators should use this document for what it is, a template. Investigators must include all study specific information that a potential research participant should be aware of in order to make an informed, voluntary decision about taking part in the study.
* The goal of the informed consent process is to provide people with sufficient information for making informed choices. The informed consent form provides a summary of the clinical study and the individual’s rights as a research participant. This template for the informed consent form is only one part of the larger process of informed consent.
* The descriptions and information should be in lay language, defined as language understandable to the people being asked to participate (usually 6th to 8th grade). The final version should be checked for reading level.
* Individuals involved in the study should be referred to as participants or subjects, not patients.
* The use of second person (e.g., “You will receive…”) is preferred; the use of the first person (e.g., “I understand that…”) should not be used.
* Pages should be numbered and a section included for the participant to initial at the bottom of each page that does not have signatures on it (i.e. “Initial \_\_\_\_\_\_”). This way they can know that changes cannot be made to any page with out their knowledge.
* For minimal risk studies there should be language that describes:
* An explanation as to whether any compensation is available if injury occurs.
* If compensation is available if injury occurred, an explanation as to what it consists of or where further information can be obtained.
* An explanation as to whether any medical treatments are available if injury occurs.
* If medical treatments are available if injury occurs, an explanation as to what they consist of or where further information can be obtained.
* If the following criteria are applicable then they should be included in the consent:
* A statement that if the participant is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which were currently unforeseeable.
* Anticipated circumstances under which the participant’s participation might be terminated by the investigator without regard to the participant’s consent.
* The consequences of a participant’s decision to withdraw from the research.
* Procedures for the orderly termination of participation by the participant.
* A statement that significant new findings developed during the course of the research which might relate to the participant’s willingness to continue participation will be provided to the participant.
* The contents of this template were derived from the Code of Federal Regulations (Title 45, Part 46) Section 46.116 General Requirements for Informed Consent.



**Informed Consent to Participate in a Research Study**

*Study Title*

*First Name Last Name, Degree(s)*, Principal Investigator

*Introduction*

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any benefit from being part of the study. There may also be risks associated with being part of research studies. If there are any risks involved in this study then they will be described in this consent. Your participation is voluntary. Please take your time to make your decision, and ask your research doctor or research staff to explain any words or information that you do not understand.

*Why is this study being done?*

The purpose of this study is to *[Give brief explanation as to why study is being done.]*

***[Example: Phase 1 Study]***

Test the safety of *[drug/intervention]* at different dose levels. We want to find out what effects, good or bad, it has on you.

***[Example: Phase 2 Study]***

Find out what effects, good or bad, *[drug/intervention]* has on you.

***[Example: Phase 3 Study]***

Compare the effects, good or bad, of *[drug/intervention]* with *[commonly-used drug/intervention]* on you to find out which is better. In this study, you will get either the *[drug/intervention]* or the *[commonly-used drug/intervention].*  You will not get both.

*How many people will take part in this study?*

About *[state total accrual goal here]* people will take part in this study*.* A total of *[enter maximum number]* participants are the most that would be able to enter the study.

*What is involved in participating in this research study?*

*[Provide a simplified list of tests and procedures and their frequency. Include whether a participant will be at home, in the hospital, or in an outpatient setting. Identify any procedures that are experimental...(that is, what is being done as part of the research and what would be done anyway)]*

***Examples:***

Before you begin the study*…[List tests and procedures as appropriate. Use bulleted format.]*

During the study*…[List tests and procedures as appropriate. Use bulleted format.]*

*How long will you be in the study?*

You will be in the study for about *[months/weeks, until a certain event] [Where appropriate state the duration of long-term follow up.]* You can decide to stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff to discuss what follow up care and testing could be most helpful for you. The study researcher may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

*What are the risks of participating in this study?*

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the *[procedures, drugs, interventions, devices]* we are studying *include: [Describe the immediate and long-term physical, psychological, social and reproductive risks/discomforts of participating in the study. Highlight or otherwise identify those that may be irreversible, long-term or life threatening. Provide an estimate of the frequency of the risks/discomforts. If possible categorize risks/discomforts as Likely, Less Likely, Rare but serious, etc., as opposed to a long unbroken list of every side effect ever noted.]*

There may also be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

*Are there benefits to taking part in this study?*

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: *[Describe the benefits an individual participant could reasonable expect from participating in the study.* ***Note: compensation/extra credit does not count as a direct benefit of participating in the study****]*

*What other options do I have?*

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

*[List commonly available alternatives.]*

*What about confidentiality?*

We will do our best to make sure that your personal information is kept confidential. However, we cannot guarantee absolute confidentiality. Federal law states that we must keep your study records private. Nevertheless, certain people other than your researchers may also need to see your study records. By law, anyone who looks at your records must keep them completely confidential. If we publish the information we learn from this study, you will not be identified by name or in any other way.

Those who may need to see your records are:

* Certain university and government people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. These include the Hanover College Institutional Review Board (IRB) as well as individuals from the Federal Office for Human Research Protections, *[list government agencies such as the U.S. Food and Drug Administration (FDA) (if applicable), the Department of Health and Human Services (DHHS), etc.]*. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
* *[List this phrase if applicable]* People at the company who paid for this study *[the name of the sponsoring agency]* may look at the study records and pertinent portions of your medical records to make sure the study is done in the right way.

*[If research is FDA-regulated, the following template language is required]* Because this research is regulated by the Food and Drug Administration (FDA), the FDA may choose to inspect and copy medical or research records that identifies individual research participants. Clinical trial information will be entered into the clinical trial registry databank maintained by the National Institutes of

Health/National Library of Medicine (NIH/NLM).

*[If data are being collected via online survey platform (e.g. Qualtrics), include the following statement:]* Surveys will be completed through the Qualtrics online survey platform, which has security safeguards in place to ensure that your responses are protected (<https://www.qualtrics.com/security-statement/>).

*What are the costs of participating in this study?*

*[Use one of the following paragraphs as appropriate:]*

**[*Example: No costs]***

There are no costs to you for taking part in this study. All the study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

**[*Example: Billed to insurance]***

Taking part in this study may lead to added costs to your or your insurance company. We will give you an estimate of what the added cost may be based on your particular situation and insurance coverage.

*Will you be paid for participating?*

***[Example: Compensation for participation is available (list conditions, such as dollar amount per visit or payment upon study completion.)]***

You will be paid *$$* if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid *$$* for each complete study visit.

***[Example: No payment for participation is available]***

You will receive no payment or other compensation for taking part in this study.

*Who is funding this study?*

*[If you do not have external grant/corporate funding, omit this section.]*

***[Example: Industry-sponsored clinical drug trial; no vested interest by researchers]***

This study is being sponsored by *[Name of sponsor].* The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

*What Are Your Rights As A Research Study Participant?*

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. *[Include any details if there are additional steps for discontinuing]*

***[Example: Study in which materials need to be returned]***

Taking part in this study is voluntary, and you may withdraw from the study or skip any questions without penalty. If you decide that you do not want to complete part of the study or do not want to continue at all, please simply let the researcher know, and you will be sent a postage-paid box to return any study equipment you have been given.

***[Example: Study in which abrupt discontinuation can be dangerous]***

Taking part in this study is voluntary, and you may withdraw from the study or skip any questions without penalty. However, because of the potential for withdrawal effects, it is strongly recommended that you do not stop taking the study medication all at once. Please let the study researchers know that you do not want to continue, and they will advise you on how to safely stop the medication.

*Who do you call if you have any questions or problems?*

For questions about the study or in the event of a research-related injury, contact the study investigator, *Name* at *Telephone number (also include after hours number)* or *email address.*  You should also call the investigator if you have a concern or complaint about the research.

For questions about your rights as a research participant, contact the Hanover College Institutional Review Board (IRB) chair at IRB@hanover.edu. You may also contact the IRB chair if:

* You have concerns or complaints about the research.
* The research staff cannot be reached.
* You want to talk to someone other than the research staff.

***SIGNATURES***

You agree to take part in this study and confirm that you are 18 years of age or older. You have had a chance to ask questions about being in this study and have had those questions answered. By signing this consent form you are not giving up any legal rights to which you are entitled.

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 Participant Name (Printed)

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 Participant Signature Date

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 Person Obtaining Consent Date