

GEORGETOWN UNIVERSITY

INFORMED CONSENT TEMPLATE FOR

Social and Behavioral Research Involving Treatment Interventions

Informed consent documents explain to potential participants in research, the nature of the research project, why they are candidates for the research, what risks, benefits, and alternatives are associated with the research, and what rights they have as research subjects. Researchers have an obligation to convey to the subject all the information needed for making a truly informed and voluntary decision about participating. The consent form is one part of the dialogue that investigators have with each subject.

Consent forms at Georgetown University are written at a 6th grade reading level or lower, which means sentences and paragraphs are short, terms and concepts are simple, and technical information is explained in non-technical ways. Use of active voice facilitates clear, effective communication. Information should be accurate and precise. The consent form should be easy to look at, with a clear layout, white-space borders, and large fonts (12 pt minimum, 14 pt preferred).

In the beginning of the consent form, investigators describe what they will do and what will be asked of participants. Subjects are directly addressed as “you;” investigators are referred to as “we.” In the last section, people who want to be subjects in the study sign a paragraph that uses “I.”

The Georgetown University informed consent template for **Social and Behavioral Treatment Research** is attached. The template includes all of the required “boilerplate” language, as well as guidance on what information should be included in each section.

- All section titles are printed in **BOLD UPPERCASE** on the template and should be printed in **BOLD UPPERCASE** on the actual consent document.
- Boilerplate language is printed in lowercase on the template.
- *Guidance for filling in each section is italicized and underlined on the template and should not appear in the actual consent document.*
- Blanks (_____) indicate that the investigator should fill in the appropriate information.

- The IRB assigns a number to each project when it is submitted for review.
- The IRB number and title should appear on ALL pages of the Consent Form.
 - All pages should be numbered (Page 1 of 3, 2 of 3, etc.).

**GEORGETOWN UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH INVOLVING TREATMENT**

PROJECT TITLE

- Use the same title as you use on your IRB application. The project title should appear on ALL pages of the Informed Consent Form.

PROJECT DIRECTOR

- This may or may not be the same person as the principal investigator (PI).

PRINCIPAL INVESTIGATOR

- Name of the PI

TELEPHONE

- Give a 24-hour phone number

SPONSOR

- Name the NIH Institute, government agency, foundation, or other sponsor.

The Georgetown University Institutional Review Board (IRB) has approved this research project. For information on your rights as a research subject, call the Institutional Review Board office at 202-687-1506.

INTRODUCTION

You are invited to consider participating in a research study to investigate _____. This form will describe the purpose and nature of the research, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to participate, or not to participate, is yours. If you decide to participate, please be sure to sign and date the last page of this form.

- Begin all informed consent forms with the invitation above.
- Complete the second sentence with a straightforward description of the purpose of the study. It should be a clear and short description of the “bottom line” of the study. Hold details of the study — such as interventions, timelines, experimental groups, and so on — for the section titled “WHAT IS INVOLVED IN THE STUDY” which appears later in the document.

WHY IS THIS RESEARCH STUDY BEING DONE?

In this research study, we are investigating/testing/comparing/evaluating _____.

- Complete the sentence. Then, in one or two paragraphs, briefly give the subjects some background information about why this study is being done, including information about what is already known and what you hope to learn. Provide specific mention of any experimental interventions or procedures.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About _____ people will take part in this study. Participants in the study are referred to as “subjects.”

- Fill in the number of people who will take part in the study. If the study is being conducted at sites in addition to Georgetown, so indicate.

WHAT IS INVOLVED IN THE STUDY?

- Refer to the subjects as “you.”
- Tell subjects exactly what to expect. Explain what will happen during the study and how the study will work.
- Include the various tests, treatments, interventions, and procedures that subjects will experience.
- Specifically identify as such any that are experimental or investigational.
- Describe the schedules at which the various tests, treatments, interventions, or procedures will be presented.
- Indicate how long each intervention or procedure will take and give a timeline for the whole study. If the study is long or complicated a table or chart and a calendar can simplify this section.
- Name the various experimental and control groups in a simple way (Group A, B, and C) so that you can refer to them easily later.
- Indicate what parts of the study constitute standard care for the subject’s condition and what parts involve experimental and/or investigational treatments
- Name the people with whom the subject will interact.
- From the information you provide, subjects should be able to:
 - Understand what is going to happen to them in the study.

- Distinguish what is standard care or treatment and what is investigational.
- Understand what additional, non-investigational care or treatment they will receive as a direct result of their participation in the study (i.e., that they would not receive if they did not join the study).
- For randomized studies, include the following statement. The first blank is for the total number of groups, all of which were described earlier. The second blank indicates the chance of being in each group. Name the investigator who can break the code in emergencies.

You will be assigned to one of _____ research intervention groups. A computer will determine your group through a process that is much like picking names out of a hat. This process is called randomization. Neither the researcher nor any of the subjects will know who is in which group until the study ends. Your chance of being in any group is one in _____. In the event of an emergency, Dr. _____ can obtain information about which experimental intervention you are receiving.

HOW LONG WILL I BE IN THE STUDY?

We expect that you will be in the study for _____.

- State how long — hours, days, months, years, until a certain event or endpoint — the subjects will be part of the study. Where appropriate, state that the study will involve long-term follow-up.

The investigators or sponsors may stop the study or take you out of the study at any time they judge it is in your best interest (e.g., if you experience an injury, if you need additional or different interventions, or if you do not comply with the study plan). They may also remove you from the study for various other reasons, (e.g., _____). They can do this without your consent.

- List any additional reasons why subjects might be taken off the study.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

- Describe any serious consequences of sudden withdrawal from the study.

WHAT ARE THE RISKS OF THE STUDY?

This study involves the following risks. You should discuss these risks with the researcher, and with anyone else that you wish to.

Very likely: _____

Less likely but serious: _____

Rare: _____

Other risks of this study include _____.

There may also be other risks that we cannot predict.

- List the physical and non-physical risks of participating in the study categories above. Listing risks is preferable to describing them in a narrative fashion.
- Non-physical risks may include, for example, social, psychological, or economic harm; risk of criminal or civil liability; or damage to financial standing, employability, or reputation.
- Highlight or otherwise identify risks or side effects that may be irreversible, long-term, or life-threatening.
- List risks related to the investigational aspects of the research. If no known risks are associated with the research, state that fact.
- The following statement should be included in this section as applicable:

In the testing of new forms of treatment, there is always the possibility of some unknown and, therefore, unexpected harmful effects which can be serious or life-threatening.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

It is reasonable to expect the following benefits from this research: _____.
However, we cannot guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information we obtain in this study.

- List all the benefits that might reasonably be expected from participating in the study. If benefits may not continue after the study is over, describe that here. First describe benefits to subjects, then describe benefits to others. If there are no benefits from participating in the research, state that fact.

WHO CAN PARTICIPATE IN THE STUDY?

This study is designed for _____.
Your suitability for this study will be determined by _____.

- Explain the pre-entry criteria (tests, psychological history, others) that you will use to determine eligibility. Use active voice and give subjects a clear picture of what they will experience.

WHO CANNOT PARTICIPATE IN THE STUDY?

- Include this section below only when appropriate:

The treatments and procedures used in this study may be unsafe for an unborn baby, an infant, sperm and eggs. If you are a subject in this study and are a woman of child bearing potential, you must agree to avoid pregnancy during your participation in this study and for three months after the completion of the study (include when appropriate). If you are a subject in this study and are a man, you must agree to not conceive a child during your participation in this study and for three months after the completion of the study (include when appropriate). If you do become pregnant during the study or if you father a child during the study, you should immediately notify Dr. _____ at (202) _____. If you are already pregnant or are breast feeding, you cannot participate in this study.

WHAT OTHER OPTIONS ARE THERE?

If you do not participate in this study, the following options are available to treat your condition:
_____.

- List and briefly describe alternative interventions, including commonly used interventions available outside of research, for those who choose not to take part in the study. Include the option of not receiving treatment of any kind. If no interventions exist, you can write "No other interventions exist at this time."

Please talk to your regular care provider, and anyone else you wish to, about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Your name will not be used when data from this study are published.

Every effort will be made to keep your clinical records, research records, and other personal information confidential. However, we cannot guarantee absolute confidentiality.

Individuals from the Georgetown University IRB, other Georgetown University offices, Federal regulatory agencies, and _____ may look at records related to this study, both to assure quality control and to analyze data. Your name and any material that could identify you will remain confidential except as may be required by law.

- In the blank above, list all such individuals and agencies who will have access to the data and records. Be sure to include government funding agencies where applicable.

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage: _____

- Describe confidentiality protections here. State whether you are keeping data on a computer that will identify the subjects in the study. If you are, explain how you are protecting this information. Give details: for example, is the computer in a locked room; is it part of a network; is a password required for getting onto the system; who has access to the data, etc.
- A Certificate of Confidentiality can be granted by the U.S. Department of Health and Human Services (HHS). This Certificate will protect the investigators and project staff from being forced to release any research data in which the subject is identified, even under a court order or subpoena. This protection is not absolute. For example, it does not apply to State requirements to report child abuse, etc. to the appropriate authorities.
- Use the following language only where a Certificate of Confidentiality has been obtained. Insert in the blank any other circumstance in which the investigator will voluntarily surrender information.

A Certificate of Confidentiality has been obtained from the U.S. Department of Health and Human Services for this research. The Certificate protects the investigator from being forced to release information collected in the study. However, this protection is not absolute. The investigator must comply with laws requiring reporting of child abuse, elder abuse, and domestic violence, and may voluntarily release information about you if _____.

WHAT ARE THE COSTS?

Qualified study subjects will/will not have to pay for the study intervention. You or your insurance company will have to pay for _____.

- Select will or will not. List any expected costs. Additional charges which may be incurred by the subject as a result of their participation in a study should be indicated. In cases where there will be no additional charges, this fact should also be indicated.

WILL I BE PAID FOR PARTICIPATING?

Study subjects will/will not be paid for participating in this study.

- Indicate whether subjects will be paid for participating.
- Include the following language only if subjects will be paid for their participation. Explain how and when payments will be made. The payment schedule must not be coercive (i.e., payments may not be excessive, and payments should ordinarily be prorated and paid out incrementally, rather than in a lump sum at the completion of the study).

Payments will be made as follows:

WHAT IF I GET INJURED DURING MY PARTICIPATION?

Researchers will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds have been made available by Georgetown University or its affiliates, the District of Columbia, or the Federal government to compensate you for a study-related injury or illness.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Participation in this study is entirely voluntary at all times. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with Georgetown University or any of its employees.

If you decide to leave the study, the procedure is: _____.

- Describe procedures for withdrawing and any follow-up that you will request for subjects who withdraw early. Follow-up such as questionnaires that are part of the research cannot be forced upon subjects who wish to withdraw.
- Describe potential adverse effects of early withdrawal on the subject's health or welfare.

Throughout this study, researchers will tell you about new information related to the interventions in the study, interventions that may be appropriate for you, or any other information that may affect your interest in remaining in the study.

- When the study has a Data Safety and Monitoring Board (DSMB), include the following:

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. You will be told about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

- Insert the following statement when applicable:

Materials obtained from you in this research may be used for commercial purposes. It is the policy of Georgetown University and its affiliates not to provide financial compensation to you should this occur.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

Call Dr. _____ at 202-_____ day or night if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

- Fill in the name of one or more researchers who can be reached 24-hours a day.

Call the Georgetown University IRB Office at 202-687-1506 with any questions about your rights as a research participant.

Statement of Person Obtaining Informed Consent

I have fully explained this study to the subject. I have discussed the study's purpose, its experimental and nonexperimental procedures and interventions, the possible risks and benefits, the standard and research aspects of the study, the alternatives to participation, and the voluntary nature of participation. I have invited the subject to ask questions and have answered any questions that the subject has asked.

Signature of Person Obtaining Informed Consent

Date

Consent of Subject (or Legally Authorized Representative)

I have read the information provided in this Informed Consent Document

(or it was read to me by _____).

My questions were answered to my satisfaction.

I voluntarily agree to participate in this study.

Signature of Subject

Date

Signature of Legally Authorized Representative
Where Appropriate

Date

Upon signing, the subject or the legally authorized representative will receive a copy of this form, and the original will become part of the subject's clinical record. If there is no relevant clinical record, the original will be held in the subject's research record.

Permission for a Child to Participate in Research

- *If the research involves children, provide the following:*

As parent or legal guardian, I authorize _____ (child's name)
to become a participant in the research study described in this form.

The study's purpose, its experimental and nonexperimental procedures and interventions, the possible risks and benefits, the standard and research aspects of the study, the alternatives to participation, and the voluntary nature of participation have been explained to me by the person obtaining consent as referenced above.

My questions have been answered to my satisfaction.

Child's Date of Birth

Parent or Legal Guardian's Signature

Date

Upon signing, the parent or legal guardian will receive a copy of this form, and the original will become part of the subject's clinical record. If there is no relevant clinical record, the original will be held in the subject's research record.

Statement of Witness

I have personally witnessed (check as applicable):

- The subject (or legally authorized representative or parent or guardian) sign this informed consent document.
- The informed consent process involving both the subject (or legally authorized representative or parent or guardian) and the person obtaining consent.

Witness Signature

Date

GEORGETOWN UNIVERSITY

INFORMED CONSENT TEMPLATE FOR

Social and Behavioral Research NOT Involving Treatment Interventions

Informed consent documents explain to potential participants in research, the nature of the research project, why they are candidates for the research, what risks, benefits, and alternatives are associated with the research, and what rights they have as research subjects. Researchers have an obligation to convey to the subject all the information needed for making a truly informed and voluntary decision about participating. The consent form is one part of the dialogue that investigators have with each subject.

Consent forms at Georgetown University are written at a 6th grade reading level or lower, which means sentences and paragraphs are short, terms and concepts are simple, and technical information is explained in non-technical ways. Use of active voice facilitates clear, effective communication. Information should be accurate and precise. The consent form should be easy to look at, with a clear layout, white-space borders, and large fonts (12 pt minimum, 14 pt preferred).

In the beginning of the consent form, investigators describe what they will do and what will be asked of participants. Subjects are directly addressed as “you;” investigators are referred to as “we.” In the last section, people who want to be subjects in the study sign a paragraph that uses “I.”

The Georgetown University informed consent template for **Social and Behavioral Research NOT Involving Treatment** is attached. The template includes all of the required “boilerplate” language, as well as guidance on what information should be included in each section.

- All section titles are printed in **BOLD UPPERCASE** on the template and should be printed in **BOLD UPPERCASE** on the actual consent document.
- Boilerplate language is printed in lowercase on the template.
- *Guidance for filling in each section is italicized and underlined on the template and should not appear in the actual consent document.*
- Blanks (_____) indicate that the investigator should fill in the appropriate information.

- The IRB assigns a number to each project when it is submitted for review.
- The IRB number and title should appear on ALL pages of the Consent Form.
 - All pages should be numbered (Page 1 of 3, 2 of 3, etc.).

**GEORGETOWN UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH**

PROJECT TITLE

- Use the same title as you use on your IRB application. The project title should appear on ALL pages of the Informed Consent Form.

PROJECT DIRECTOR

- This may or may not be the same person as the principal investigator (PI).

PRINCIPAL INVESTIGATOR

- Name of the PI

TELEPHONE

- Give a contact phone number

SPONSOR

- Name the NIH Institute, government agency, foundation, or other sponsor.

The Georgetown University Institutional Review Board (IRB) has approved this research project. For information on your rights as a research subject, call the Institutional Review Board office at 202-687-1506.

INTRODUCTION

You are invited to consider participating in a research study to investigate _____. This form will describe the purpose and nature of the research, its possible risks and benefits, and your rights as a participant in the study. The decision to participate, or not to participate, is yours. If you decide to participate, please be sure to sign and date the last page of this form.

- Begin all informed consent forms with the invitation above.
- Complete the second sentence with a straightforward description of the purpose of the study. It should be a clear and short description of the “bottom line” of the study. Hold details of the study — such procedures, timelines, and so on — for the section titled “WHAT IS INVOLVED IN THE STUDY” which appears later in the document.

WHY IS THIS RESEARCH STUDY BEING DONE?

In this research study, we are investigating/testing/comparing/evaluating _____.

- Complete the sentence. Then, in no more than one or two paragraphs, briefly give the subjects some background information about why this study is being done. Where appropriate, include information about what is already known and what you hope to learn.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About _____ people will take part in this study. Participants in the study are referred to as “subjects.”

- Fill in the number of people who will take part in the study. If the study is being conducted at sites in addition to Georgetown, so indicate.

WHAT IS INVOLVED IN THE STUDY?

- Refer to the subjects as “you.”
- Tell subjects what to expect. Explain what will happen during the study and how the study will work. From the information you provide, subjects should be able to understand what is going to happen to them in the study.
- Where appropriate, describe the various tests and conditions that subjects will experience.
- Where appropriate, indicate how long each test or condition will take and give a timeline for the whole study. If the study is long or complicated a table or chart and a calendar can simplify this section.
- Where appropriate, name the people with whom the subject will interact.
- Where appropriate, include the following statement. The first blank is for the total number of groups, all of which were described earlier. The second blank indicates the chance of being in each group.

You will be assigned to one of _____ research groups. A computer will determine your group through a process that is much like picking names out of a hat. This process is called randomization. Your chance of being in any group is one in _____.

HOW LONG WILL I BE IN THE STUDY?

We expect that you will be in the study for _____.

- State how long — minutes, hours, days, months, years, until a certain event or endpoint — the subjects will be part of the study. Where appropriate, state that the study will involve long-term follow-up.

The investigators or sponsors may stop the study or take you out of the study at any time they judge it is in your best interest (e.g., if you experience an injury or if you do not comply with the study plan) or for a variety of other reasons. They can do this without your consent.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

- Describe any serious consequences of sudden withdrawal from the study.

WHAT ARE THE RISKS OF THE STUDY?

This study involves the following risks. You should discuss these risks with the researcher, and with anyone else that you wish to.

Very likely: _____

Less likely but serious: _____

Rare: _____

Other risks of this study include _____.

There may also be other risks that we cannot predict.

- List the physical and non-physical risks of participating in the study categories above. Listing risks is preferable to describing them in a narrative fashion.
- Non-physical risks may include, for example, social, psychological, or economic harm; risk of criminal or civil liability; or damage to financial standing, employability, or reputation.
- Highlight or otherwise identify risks or side effects that may be irreversible, long-term, or life-threatening.
- If no known risks are associated with the research, state that fact.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

It is reasonable to expect the following benefits from this research: _____.
However, we cannot guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information we obtain in this study.

- List all the benefits that might reasonably be expected from participating in the study. If benefits may not continue after the study is over, describe that here. First describe benefits to subjects, then describe benefits to others. If there are no benefits from participating in the research, state that fact.

This research study does not provide treatment for any disorder or condition. Should subjects request such treatment, they will be referred to treatment alternatives outside this study.

WHO CAN PARTICIPATE IN THE STUDY?

This study is designed for _____.

- Where appropriate, explain the pre-entry criteria (e.g., tests, psychological history) that you will use to determine eligibility. Use active voice and give subjects a clear picture of what they will experience.

WHAT ABOUT CONFIDENTIALITY?

Your name will not be used when data from this study are published.

Every effort will be made to keep your research records and other personal information confidential. However, we cannot guarantee absolute confidentiality.

Individuals from the Georgetown University IRB, other Georgetown University offices, Federal regulatory agencies, and _____ may look at records related to this study, both to assure quality control and to analyze data. Your name and any material that could identify you will remain confidential except as may be required by law.

- In the blank above, list all such individuals and agencies who will have access to the data and records. Be sure to include government funding agencies where applicable.

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage: _____

- Describe confidentiality protections here. State whether you are keeping data on a computer that will identify the subjects in the study. If you are, explain how you are protecting this information. Give details: for example, is the computer in a locked room; is it part of a network; is a password required for getting onto the system; who has access to the data, etc.
- A Certificate of Confidentiality can be granted by the U.S. Department of Health and Human Services (HHS). This Certificate will protect the investigators and project staff from being forced to release any research data in which the subject is identified, even under a court order or subpoena. This protection is not absolute. For example, it does not apply to State requirements to report child abuse, etc. to the appropriate authorities. If study has a Certificate of Confidentiality, include the following statements.

- Use the following language only where a Certificate of Confidentiality has been obtained. Insert in the blank any other circumstance in which the investigator will voluntarily surrender information.

A Certificate of Confidentiality has been obtained from the U.S. Department of Health and Human Services for this research. The Certificate protects the investigator from being forced to release information collected in the study. However, this protection is not absolute. The investigator must comply with laws requiring reporting of child abuse, elder abuse, and domestic violence, and may voluntarily release information about you if _____.

WILL I BE PAID FOR PARTICIPATING?

Study subjects will/will not be paid for participating in this study.

- Indicate whether subjects will be paid for participating.
- Include the following language only if subjects will be paid for their participation. Explain how and when payments will be made. The payment schedule must not be coercive (i.e., payments may not be excessive, and payments should ordinarily be prorated and paid out incrementally, rather than in a lump sum at the completion of the study).

Payments will be made as follows:

WHAT IF I GET INJURED DURING MY PARTICIPATION?

Researchers will make every effort to prevent study-related injuries. If you are injured or become ill while you are in the study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds have been made available by Georgetown University or its affiliates, the District of Columbia, or the Federal government to compensate you for a study-related injury or illness.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Participation in this study is entirely voluntary at all times. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with Georgetown University or any of its employees.

If you decide to leave the study, the procedure is: _____.

- Describe procedures for withdrawing and any follow-up that you will request for subjects who withdraw early. Follow-up such as questionnaires that are part of the research cannot be forced upon subjects who wish to withdraw.

- Where appropriate, describe potential adverse effects of early withdrawal on the subject's health or welfare.

Throughout this study, researchers will tell you about new information related to the interventions in the study, interventions that may be appropriate for you, or any other information that may affect your interest in remaining in the study.

- When the study has a Data Safety and Monitoring Board (DSMB), include the following:

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. You will be told about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

- Insert the following statement when applicable:

Materials obtained from you in this research may be used for commercial purposes. It is the policy of Georgetown University and its affiliates not to provide financial compensation to you should this occur.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

Call Dr. _____ at 202-_____ during regular business hours if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

- Fill in the name of one or more researchers who can be reached during business hours.
- Add the following sentence only where appropriate:

If you think you are in immediate danger, go to the nearest emergency room.

Call the Georgetown University IRB Office at 202-687-1506 during regular business hours if you have any questions about your rights as a research participant.

Statement of Person Obtaining Informed Consent

I have fully explained this study to the subject. I have discussed the study's purpose, its procedures, its possible risks and benefits, and the voluntary nature of participation. I have invited the subject to ask questions and have answered any questions that the subject has asked.

Signature of Person Obtaining Informed Consent

Date

Consent of Subject (or Legally Authorized Representative)

I have read the information provided in this Informed Consent Document
(or it was read to me by _____).

My questions were answered to my satisfaction.

I voluntarily agree to participate in this study.

Signature of Subject

Date

Signature of Legally Authorized Representative
Where Appropriate

Date

Upon signing, the subject or the legally authorized representative will receive a copy of this form, and the original will become part of the subject's research record.

Permission for a Child to Participate in Research

- If the research involves children, provide the following:

As parent or legal guardian, I authorize _____ (child's name)
to become a participant in the research study described in this form.

The study's purpose, its procedures, the possible risks and benefits, and the voluntary nature of participation have been explained to me by the person obtaining consent as referenced above.

My questions have been answered to my satisfaction.

Child's Date of Birth

Parent or Legal Guardian's Signature

Date

Upon signing, the parent or legal guardian will receive a copy of this form, and the original will become part of the subject's research record.

Statement of Witness

I have personally witnessed (check as applicable):

- The subject (or legally authorized representative or parent or guardian) sign this informed consent document.
- The informed consent process involving both the subject (or legally authorized representative or parent or guardian) and the person obtaining consent.

Witness Signature

Date