**RESEARCH SUBJECT CONSENT FORM**

**Title:** Title

**Protocol No.:** Sponsor’s protocol number

**Sponsor:** Name

**Investigator:** Name

Address

City, State, Zip Code

Country

**Daytime Phone Number:** Phone Number

**24-hour Phone Number:** Phone Number (A 24-hour phone number is required for studies that are more than minimal risk)

|  |
| --- |
| Instructions for Research Consent Summary  We encourage all research studies whose consent document is longer than 4 pages to include an initial concise summary. (If your research is federally funded, is submitted after 1/20/2019, and the consent document is longer than 4 pages, an initial summary is required. The initial summary cannot exceed three pages or one third of the length of the remaining consent document (exclusive of face page and signature blocks), whichever is shorter.  The templated statements in the “RESEARCH CONSENT SUMMARY” below provide a guide to the content of the summary. The content should be adjusted to be appropriate for the specifics of the study. Under each heading, limit the description to the key information that is relevant to why one might or might not want to take part in the research. Defer the greater detail to the body of the consent form following the initial summary  For example, with a cancer trial the initial summary should identify the most important risks, like the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them. The initial summary should emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form. |

# RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

# What should I know about this research?

* Someone will explain this research to you.
* Taking part in this research is voluntary. Whether you take part is up to you.
* If you don’t take part, it won’t be held against you.
* You can take part now and later drop out, and it won’t be held against you
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

# How long will I be in this research?

We expect that your taking part in this research will last \_\_\_\_\_ hours, days, weeks, months, years, or until a certain event.

# Why is this research being done?

The purpose of this research is to \_\_\_\_\_. Explain in no more than a few sentences the main purposes of the research.

# What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include \_\_\_\_\_. Briefly outline in simple terms the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study.

# Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include \_\_\_\_\_. In simple language, explain the risks and discomforts that are most likely to affect someone’s decision about whether to take part in the research study. Identify the most important risks, like the information that a doctor might deliver in the clinical context. Emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form.

# Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include \_\_\_\_\_. In simple language, explain the reasonably expected benefits to subjects that are most likely to affect someone’s decision about whether to take part in the research study. If there are no benefits, state: It is not expected that you will personally benefit from this research.

Possible benefits to others include \_\_\_\_\_. In simple language, explain the reasonably expected benefits to others that are most likely to affect someone’s decision about whether to take part in the research study.

# What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include \_\_\_\_\_. List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted.

# What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is Describe any additional information that may be important in this specific study, such as large out of pocket expenses, subject responsibilities that many people might consider burdensome (e.g., abstinence from sexual relations, cigarettes, or alcohol, inability to drive a car while taking study medication, need for overnight stays or admittance to a secure facility), unusual issues related to privacy or confidentiality (e.g., situations where the subject’s research participation is likely to be reported in the media), or serious implications for future treatment (e.g., taking the study drug may limit future treatments options.) If there is no other information in this category, this section can be omitted.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise, delete.] If you are released from jail before you finish this research, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in this research after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

**DETAILED RESEARCH CONSENT**

Organize the information in sufficient detail relating to the research in a way that facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. Do not merely provide lists of isolated facts.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

When the research involves consent by a legally authorized representative or parent, and this consent is specific to the child (i.e., the parent/guardian is not participating any research activities, including surveys or they are signing a separate consent describing their responsibilities/participation), include the next paragraph:

In this consent form “you” generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, “you” in the rest of this form generally means the research subject.

# What should I know about this research?

* Someone will explain this research to you.
* This form sums up that explanation.
* Taking part in this research is voluntary. Whether you take part is up to you.
* You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
* You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

# Why is this research being done?

The purpose of this research is to explain in simple terms the main purposes of the research. You can use simple illustrations, diagrams or figures if they are helpful in the explanation.

About \_\_\_\_ subjects will take part in this research.

# How long will I be in this research?

We expect that your taking part in this research will last \_\_\_\_\_ hours, days, weeks, months, years, or until a certain event.

# What happens to me if I agree to take part in this research?

Tell the subject what to expect using simple terms. Include all procedures done because the subject is taking part in this research, including procedures to monitor subjects for safety.

Do NOT describe procedures that will be performed regardless of whether the subject takes part in this research.

When appropriate for your research, include the following items:

Describe where this research will be done

Provide a time-line description of the tests and procedures that will be done, including screening procedures. You can use tables or charts if they are helpful to explain the schedule.

Describe each group or arm

If the research involves random assignment describe this and the probability of assignment to each group, For example:

You will be put into a study group by chance (like a coin toss/ like drawing straws). You have a(n) \_\_\_\_\_ out of \_\_\_\_ chance (XX%) of being placed in each group. You cannot choose your study group.

If the research involves blinding, include language describing a single (subject only) or double (subject and research team) blind study design, as appropriate. For example:

During the research, you (or you and the study doctor) will not know which group you are in. (Your study doctor can find out in case of an emergency).

* Identify all hospitalizations, outpatient visits, and telephone or written follow-up
* Indicate the length and duration of visits and procedures
* Identify all unapproved drugs, devices, tests, and procedures as experimental.
* For studies conducted under an IND, IDE, or abbreviated IDE, state:

[name of the product or device] is investigational, which means that it is not approved by the Food and Drug Administration (FDA).

* Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental
* If blood will be drawn, indicate how often and the amount in English units
* Identify all questionnaires or diaries by name and explain what they involve and how long and how often they will need to be completed
* For research on investigational drugs or devices, list any options for the subject to get the drug/device after the research, and who will pay for this.
* Describe any planned future research (extension study, follow-up study, analysis of specimens). Describe them and whether subjects will be asked to sign a separate consent form.
* Indicate whether the study treatment will be available at the end of the study.

If applicable, explain whether the subject will be told clinically relevant research results, and if so, under what conditions.

Include if the research may involve whole genome sequencing:

The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

# What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: Describe the responsibilities of the subject.

Describe any warning or precautions that the subject needs to know

Describe any warnings regarding pregnancy or fathering a child

Describe any requirements to for the subject or the subject’s partner to abstain from sexual relations or use contraception

Describe any requirements to avoid certain activities or refrain from taking certain drugs

Describe any requirements to keep research articles out of the reach of children or others

Describe any requirements to promptly report certain side effects to the investigator

Describe requirements to follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.

Describe any requirements to avoid or minimize contact with others

Describe any situations where the subjects should immediately contact the investigator or immediately seek medical attention

# Could being in this research hurt me?

In simple language and in a simple bullet format (whenever possible), explain the known possible risks and discomforts.

List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last. Also, list any rare, but serious risks.

If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks.

Describe the duration of the risks and discomforts. Note whether the risks and discomforts will go away when the study drug, device, or procedure is stopped.

Describe the side effects of any comparator drugs.

Describe any risks of washout, withholding treatment, or randomization.

Consider:

Physical risks (for example, medical side effect)

Psychological risks (for example, embarrassment, fear or guilt)

Privacy risks (for example, disclosure of private information)

Confidentiality risk (if identifiable information is being retained, then there is a risk of loss of confidentiality)

Legal risks (for example, legal prosecution or being reported for child abuse)

Social risks (for example, social ostracizing or discrimination)

Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)

It is unnecessary to list details of previous clinical trials.

Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product:

In addition to these risks, taking part in this research may harm you in unknown ways.

Include for research that involves pregnant women or women of child-bearing potential and known risks to an embryo or fetus:

Taking part in this research may hurt a pregnancy or fetus in the following ways:

Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known:

Taking part in this research may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

# Will it cost me money to take part in this research?

Include for research that may result in additional costs to the subjects. This should match any terms defined in the contract with the sponsor, if applicable:

Taking part in this research may lead to added costs to you, such as: Describe these costs.

Include for research where insurance will be billed. This should match any terms defined in the contract with the sponsor, if applicable:

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

# Will being in this research benefit me?

If there are possible benefits to the subject:

We cannot promise any direct benefits to you or others from your taking part in this research. However, possible benefits to you include \_\_\_\_\_. Describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, describe them. Possible benefits to others include \_\_\_\_\_. Describe any benefits to others.

If there are no expected benefits to the subject but possible benefits to others/ scientific knowledge:

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_. Describe any benefits to others.

# What other choices do I have besides taking part in this research?

If there are alternatives:

Instead of being in this research, your choices may include:

List the major approved alternative options such as drugs / devices / procedures

Consider, based on the indication and population, whether an alternative might include no active treatment but support and management of pain and other symptoms to be as comfortable as possible through the remainder of life

For student subject pools, describe alternatives for course credit.

If there are no alternatives:

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

[Include for research involving prisoners. Otherwise, delete.] Taking part in this research will not improve your housing or correctional program assignments. Taking part in this research will not improve your chance of parole or release.

# What happens to the information collected for this research?

Your private information include only if applicable and your medical record will be shared with individuals and organizations (if applicable) that conduct or watch over this research, including:

* The research sponsor
* People who work with the research sponsor
* Government agencies, such as the Food and Drug Administration or the Department of Health and Human Services
* The Institutional Review Board (IRB) that reviewed this research
* Temple University
* Temple University Health System and its affiliates
* List others with whom private information will be shared
* When the procedures include communicable disease testing, include any disclosures mandated by state-law.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

For controlled drug/device trials (except Phase I drug trials**),** pediatric device surveillance trials, and NIH-funded clinicaltrials add the following language verbatim: (If the research does not require listing on www.clinicaltrials.gov, but will be listed anyway, you may use this language or a variation of this language. The IRB does not require this information when not required by FDA/NIH, even if the study will be listed.)

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.

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

[Include if a HIPAA authorization is required. Note, self-reported medical history does not require HIPAA Authorization. HIPAA Authorization is required only if medical/psychological records are being accessed, otherwise delete.] Federal law provides additional protections of your personal information. These are described in an attached document titled “Authorization to use and disclose your protected health information.”

[Include for research involving prisoners. Otherwise, delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

***What is a Certificate of Confidentiality?***

[Include this section if the NIH has issued a Certificate of Confidentiality for this research (e.g., any new or ongoing research funded by the NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information).]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps protect your identifiable information and biological samples. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[You may use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].

# Who can answer my questions about this research?

Use the following language verbatim:

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (215) 707-3390 or [irb@temple.edu](mailto:irb@temple.edu) if:

1. You have questions, concerns, or complaints that are not being answered by the research team.
2. You are not getting answers from the research team.
3. You cannot reach the research team.
4. You want to talk to someone else about the research.
5. You have questions about your rights as a research subject.

# What if I am injured because of taking part in this research?

[Delete this section if the research involves no more than minimal risks to subjects.]

[Pick the option that applies to your research and delete the other options. If the research is an industry- or sponsor-funded, please contact TCRI-CRORA, Lisa Landsberg, at 215-707-7303 or email at [Lisa.landsberg@temple.edu](mailto:Lisa.landsberg@temple.edu) regarding the appropriate option. This should match any terms defined in the contract with the sponsor, if applicable.

[Option 1: For studies funded by an outside sponsor/agency not conditioned on first billing third party payers for research-related injury] If you are injured or become ill as a result of this research [drug or device] or a procedure required to be done only as a part of this research, immediately notify the research team and they will arrange for you to get immediate medical care. The sponsor, [add sponsor’s name], will pay for the physician fees and medical expenses for the treatment of your injury or illness. By signing this consent form, you are not waiving any of the legal rights that you otherwise would have as a participant in a research study. If you have a research related injury, please contact Dr. [NAME] at (xxx) xxx-xxxx during regular hours and at (xxx) xxx-xxxx after hours and on weekends and holidays.

[Option 2: For studies funded by an outside sponsor/agency when the sponsor conditions its obligation to pay for a research-related injury on a primary effort to obtain payment from a third party payer] If you are injured or become ill as a result of this research [drug or device] or a procedure required to be done only as a part of this research, immediately notify the research team and they will arrange for you to get immediate medical care. The sponsor, [add sponsor’s name], will pay for the physician fees and medical expenses for the treatment of your injury or illness which are not covered by your commercial (private) insurance. If your insurance is funded by federal or state government funds, your insurance will not be billed. If you have a research related injury, please contact Dr. [NAME] at (xxx) xxx-xxxx during regular hours and at (xxx) xxx-xxxx after hours and on weekends and holidays.

[Option 3: For investigator-initiated or NIH/government-funded studies] If you are injured as a result of taking part in this research, immediately notify the research team and they will arrange for you to get immediate medical care. There is no commitment by Temple University, Temple University Health System or its subsidiaries to provide monetary compensation or free medical care to you in the event of a research-related injury. If you have a research-related injury, please contact Dr. [NAME] at (xxx) xxx-xxxx during regular hours and at (xxx) xxx-xxxx after hours and on weekends and holidays.

# Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

Describe reasons why the subject may be withdrawn. Include all reasons for withdrawal described in the protocol. For example:

It is in your best interest

You have a side effect that requires stopping the research

You need a treatment not allowed in this research

You become pregnant

The research is canceled by the FDA or the sponsor

You are unable to take the research medication

You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

# What happens if I agree to be in this research, but I change my mind later?

Include if there are procedures for orderly termination of taking part in the research.

If you decide to leave this research, contact the research team so that the investigator can: Describe the procedures for orderly termination by the subject.

Include if there are potential adverse consequences to a subject who withdraws:

If you decide to leave the research early, there may be risks with this decision. These may include: Describe the adverse consequences.

[Include for FDA-regulated research. Otherwise, delete.] If you stop being in this research, already collected data may not be removed from the research database. You will be asked whether the investigator can collect data from your routine medical care. [Note: The consent document cannot give the subject the option of having data removed.]If you agree, this data will be handled the same as research data. [Note: If a subject withdraws from the interventional portion of a research and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to this research the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review research data related to the subject collected prior to the subject’s withdrawal from this research, and may consult public records, such as those establishing survival status.]

[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

# Will I be paid for taking part in this research?

If subjects will be paid:

For taking part in this research, you may be paid up to a total of $\_\_\_\_\_ [if the payment is in gift cards, include this]. Your compensation will be broken down as follows:

Describe payment schedule in terms of amount

Describe when payments will be made

Describe the amount of payment if the subject drops out

Federal tax law requires to you to report this payment as income to the Internal Revenue Service if you are compensated more than $599.00 (in total) this year for participating in research. You may be asked to tell us your social security number or other identifying information (e.g., full name). If payments for this study are more than $599.00, we will report them to the Internal Revenue Service and send you a Form 1099-MISC.

[Include the following 2 sentences if the research data is being stored in a de-identified manner.]This information will not be associated with the information or data you provide for this research. It will be stored separately from your data, it will not be linked in any way, and your identifying information will be destroyed within 1 year of study completion.

If you do not give us your social security number or other identifying information you may take part in this research if you agree to not be paid.

If subjects will not be paid, either delete this section, or include the following statement:

You will not be paid for taking part in this research.

If the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit, include the following statement: (Modify if subjects will share in commercial profit.)

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

**What if this research has additional findings about me that were not related to the research questions?**[DELETE THIS SECTION IF THERE ARE NO POSSIBLE INCIDENTAL FINDINGS THAT COULD COME ABOUT DUE TO THE RESEARCH]

[Include if incidental findings may be communicated to the participant] This (provide imaging procedure (e.g. MRI)) is done for research purposes rather than for diagnosis. The (provide procedure)will not be routinely examined by health professionals for potential structural and functional clinical abnormalities. However, in the event an abnormality is detected by the investigators or the (administer of the procedure (e.g. MRI technician))*,* the (named procedure) will be further examined by a (name appropriate clinician (e.g. a radiologist)) and the investigator may encourage you to consult your physician. [add below language if applicable]

The blood, saliva, tissue that is obtained from you will be tested and/or stored for future use and potential laboratory, genomic and proteomic studies. The material will have your name, medical record number and other identifying information associated with it. Please indicate if you wish to be contacted in the future regarding any test results that may be obtained.

[Include if incidental findings will not be communicated to the participant] The (named procedure) we collect are for research purposes only and we cannot provide a (name appropriate clinician) clinical interpretation of the results. However, if your healthcare provider would like to use the (type of data e.g. scans) for comparison with another clinical (applicable types of data) that has already been obtained or may be obtained in the future, they may request these (type of data) if they are still available. [add the below language if applicable]

The blood, saliva, tissue that is obtained will be tested and/or stored for future use and potential genomic and proteomic studies. However, the material will be de-identified (will not have your name, medical record number or other identifying information associated with it). Therefore, we will not be able to contact you in the future regarding any test results that may be obtained.

# Statement of Consent:

Use one of the following signature blocks:

Example signature block for studies that only involve adult subjects able to consent

[Omit the signature page if there is no written documentation of consent.]

|  |  |  |
| --- | --- | --- |
| Your signature documents your consent to take part in this research. | | |
|  |  |  |
| Signature of adult subject capable of consent |  | Date |
|  |  |  |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |
| Printed name of person obtaining consent |

Example signature block for studies that may or will involve adult subjects unable to consent and may also include adult subjects that have capacity to consent

Add one of the following:

* All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
* All subjects unable to consent are required to assent.
* The assent of adult subjects unable to consent is not required.

If assent will be obtained, add one of the following:

* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the subject sign the consent form, unless the investigator determines that the subject is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |  |
| --- | --- | --- | --- |
| Your signature documents your permission for you or the individual named below to take part in this research. | | | |
|  |  |  |
| Printed name of subject |  |  |
| Signature of adult subject capable of consent or adult subject’s legally authorized representative |  | Date |
|  |  |  |
|  |  |  |
| Printed name of adult subject’s legally authorized representative (leave blank if subject is capable of consent) |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |
| Printed name of person obtaining consent |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |
| --- | --- | --- |
| * I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.   OR   * The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted. | | |
|  |  |  |
| Signature of person obtaining assent |  | Date |
|  |
| Printed name of person obtaining assent |

If documentation of assent is by having the subject sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of assenting subject |  | Date |

Example signature block for research that may or will involve children as subjects and may also include adult subjects that have capacity to consent

Add one of the following for children:

* All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
* All children are required to assent.
* Assent of children is not required.

If assent of the child will be obtained, add one of the following:

* If assent is obtained, have the child sign an assent form, unless the investigator determines that the child is not capable of signing.
* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the child sign the consent form, unless the investigator determines that the child is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for you or the individual named below to take part in this research. | | |
|  |  |  |
| Signature of adult subject capable of consent, child subject’s parent, or individual authorized to consent to the child subject’s general medical care |  | Date |
|  |  |  |
| Printed name of adult subject capable of consent, child subject’s parent, or individual authorized to consent to the child subject’s general medical care |  |  |
|  |  |  |
| Printed name of subject  (not required if subject personally provided consent) |  |  |

If applicable (generally if the study is greater than minimal risk) add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of second parent  (Required unless this subject is an adult, the second parent is deceased, unknown, incompetent, or not reasonably available, or the parent providing consent has sole legal responsibility for the care and custody of the child) |  | Date |
|  |  |
| Printed name of second parent |  |

Always add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |  |
| --- | --- | --- | --- |
| * I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.   OR   * The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted. | | | |
|  |  | |  |
| Signature of person obtaining assent |  | | Date |
|  | |
|  | |
| Printed name of person obtaining assent | |

If documentation of assent is by having the child sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of assenting subject |  | Date |

Example signature block for witness signature

Add on as needed basis to the last page if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects. Do not add to every consent document unless every subject will have a witness to the consent process.

|  |  |  |
| --- | --- | --- |
| My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. | | |
|  |  |  |
| Signature of witness to consent process |  | Date |
| |  | | --- | |  | |  | | Printed name of witness to consent process | |  |  |

Example signature block for consent to continue participation in research for children who reach the age of majority or adults that regain capacity to consent during their participation in research

Previously, you could not legally agree to take part in research. You took part in research based on the permission of someone else. Now that you can consent for yourself, you are being asked for your consent to continue to take part. Please read the entire document before signing below.

|  |  |  |
| --- | --- | --- |
| Your signature documents your consent to take part in this research. | | |
|  |  |  |
| Signature of adult subject capable of consent |  | Date |
|  |  |  |
|  |  |  |
| Printed name of adult subject capable of consent |  |  |
|  |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
| |  | | --- | |  | | Printed name of person obtaining consent | |  |  |

Example signature block for consent to continue participation in research for adult subjects who have lost capacity during their participation in the research and are unable to continue providing consent

The study doctor has determined that the subject is no longer capable of providing consent and requires consent be provided by a legally authorized representative for the subject to continue participation in the research.

Add one of the following:

* All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
* All subjects unable to consent are required to assent.
* The assent of adult subjects unable to consent is not required.

If assent will be obtained, add one of the following:

* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the subject sign the consent form, unless the investigator determines that the subject is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Your signature documents your permission for the individual named below to take part in this research. | | | | |
|  |  | |  | |
| Signature of adult subject capable of consent or adult subject’s legally authorized representative |  | | Date | |
|  |  | |  | |
| Printed name of adult subject capable of consent or adult subject’s legally authorized representative |  | |  | |
|  |  | |  | |
| Printed name of subject  (not required if subject personally provided consent) |  | |  | |
|  |  | |  | |
| Signature of person obtaining consent |  | | Date | |
| |  | | --- | |  | | Printed name of person obtaining consent | | |  | |  |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |
| --- | --- | --- |
| * I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.   OR   * The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted. | | |
|  |  |  |
| Signature of person obtaining assent |  | Date |
| |  | | --- | |  | | Printed name of person obtaining assent | |  |  |

If documentation of assent is by having the subject sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of assenting subject |  | Date |