JMC Informed Consent Template

INFORMED CONSENT

Study Title

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family.

You are being asked to take part in this study because you have *type of* cancer or other reasons.

Why Is This Study Being Done?

The purpose of this study is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[Applicable text:]

*Phase 1 studies:* Test the safety of  *drug/intervention* and see what
 effects (good and bad) it has on you and your *type of* cancer.

 or

 Find the highest dose of a *drug* that can be given without
 causing severe side effects.

*Phase 2 studies:* Find out what effects (good and bad)  *drug/intervention*  has on you and your *type of* cancer.

*Phase 3 studies:* **Compare the effects (good and bad) of the**  *new drug/
 intervention*  **with** *commonly-used drug/intervention*  **on you and your**  *type of* **cancer to see which is better.**

This research is being done because\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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*[Explain in one or two sentences. Examples are:* “Currently, there is no effective treatment for this type of cancer,” *or* “We do not know which of these two commonly-used treatments is better.”*]*

How Many People Will Take Part in the Study

[If appropriate:]

About \_\_\_\_\_\_\_\_\_ people will take part in this study nationwide or worldwide.

What Is Involved in the Study? OR What will happen if I take part in this research study

[Provide simplified schema and/or calendar.]

BEFORE YOU BEGIN THE STUDY: (example)

[For randomized studies example:]

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an *equal/one in three/etc.*  chance of being placed in any group.

[For nonrandomized and randomized studies:]

If you take part in this study, you will have the following tests and procedures:

[List procedures and their frequency under the categories below. For randomized studies, list the study groups and under each describe categories of procedures. Include whether a patient will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard.]

• Procedures that are part of regular cancer care and may be done even if you do not join the study.

• Standard procedures being done because you are in this study.

• Procedures that are being tested in this study.

DURING THE STUDY:

 Tests and Procedures

 Restrictions, if any

How Long Will I Be in the Study?

**We think you will be in the study for**  months/weeks, until a certain event **.**

[Where appropriate, state that the study will involve long-term follow-up.]

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 and your regular doctor first.

[Describe any serious consequences of sudden withdrawal from the study.]

The researcher may decide to take you off this study if \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[List circumstances, such as in the participant’s medical best interest, funding is stopped, drug supply is insufficient, patient’s condition worsens, new information becomes available.]

What Are the SIDE EFFECTS OR Risks of the Study?

While on the study, you are at risk for these side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the  *intervention/drugs*  are stopped, but in some cases side effects can be serious or long-lasting or permanent.

[List by regimen the physical and nonphysical risks of participating in the study in categories of “very likely”, “likely” and “less likely but serious.” Nonphysical risks may include such things as the inability to work. Do not describe risks in a narrative fashion. Highlight or otherwise identify side effects that may be irreversible or long-term or life threatening.]

Risks and side effects related to the  *procedures, drugs, or devices*  we are studying include:

[List risks related to the investigational aspects of the trial. Specifically identify those that may not be reversible.]

Reproductive risks: Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse your baby while on this study. Ask about counseling and more information about preventing pregnancy. *[Include a statement about possible sterility when appropriate.]*

[Attach additional information about contraception, etc.]

For more information about risks and side effects, ask the researcher or contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with  *type of cancer*  in the future.

[For Phase 3 studies, when appropriate:]

The possible benefits of taking part in the study are the same as receiving
 *standard drug/intervention*  without being in the study.

What Other Options Are There? or what other choices do i have if i do not take part in this study?

Instead of being in this study, you have these options:

*[List alternatives including commonly-used therapy and* “No therapy at this time with care to help you feel more comfortable.”*]*

[If appropriate (for non-investigational treatments):]

**You may get** study treatments/drugs at this center and other centers
**even if you do not take part in the study.**

Please talk to your regular doctor about these and other options.

[Reference and attach information about alternatives.]

What about Confidentiality? or Will my medical information be kept private? (some examples of verbiage might include)

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Your role in this research study and any information collected about you in this study, including your medical records (known as Protected Health Information, or “PHI”) will be protected as required by state and federal laws (including HIPAA) that govern the confidentiality and privacy of medical, personal and genetic information. If you PHI is being used in this research study, you will be asked to sign a specific permission form called an “AUTHORIZATION” which explains who can see this information and how it can be used. Without your authorization, we may also use or disclose information related to your medical, personal or genetic condition if any information that could identify you has first been removed or a waiver (of Authorization) is approved by the IRB.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

[List relevant agencies like the National Cancer Institute, Food and Drug Administration, study sponsor, etc.]

What Are the Costs?

Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

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

[If appropriate:]

If, during the study, the  *study drug*  becomes commercially available, you may have to pay for the amount of drug needed to complete the study.

What Happens if I am injured because i took part in this study?

**It is important that you tell your study doctor,**  *name(s)*  **at**  *telephone number* , if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at the number above.

What Are My Rights as a Participant?

Taking part in this study is voluntary or your choice. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

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

[Or when a Data Safety and Monitoring Board exists:]

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

Whom Do I Call if I Have Questions about the study or my rights?

If you do not understand anything related to this study or have an injury, illness or problem related to your taking part in this study, please contact your physician at once.

(List of principal investigator and/or responsible investigators and their affiliation and contact numbers)

For questions about your rights as a research participant, contact the  *name of center*  Institutional Review Board (which is a group of people who review the research to protect your rights) at  *telephone number .*

OR CONTACT YOUR LOCAL IRB, (INSERT BLANK AREA) FOR NAME OF LOCAL IRB AND TELEPHONE NUMBER.

Where Can I Get More Information? if appropriate

You may call the NCI’s Cancer Information Service at

1–800–4–CANCER (1–800–422–6237) or TTY: 1–800–332–8615

Visit the NCI’s Web sites…

Cancer Trials: comprehensive clinical trials information http://cancertrials.nci.nih.gov.

Cancer Net™: accurate cancer information including PDQ http://cancernet.nci.nih.gov.

You will get a copy of this form. You may also request a copy of the protocol (full study plan).

[Attach information materials and checklist of attachments. Signature page should be at the end of package.]

A description of this clinical trial will be available on <http://clinicaltrials.gov>. This web site will not include information that can identify you. At most, the web site will include a summary of study results. You can search this web site at any time.

If there is storage of specimens include verbiage and check marks with yes and no and initials for appropriate statements.

Signature

I have read this informed consent form and have been given the opportunity to discuss and ask questions about this research study. i have also received a copy of this informed consent form and agree to participate.

Printed Name, Address, & Telephone No of Participants:

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 Signature of Participant Date

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Printed Name of Witness Signature of Witness Date

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Signature of Principal or Responsible Investigator Date