

**CONSENT FORM TEMPLATE**  
*Including language for HIPAA Compliance*

*The Health Insurance Portability and Accountability Act (HIPAA), effective as of April 14, 2003, requires all informed consent forms for all studies to be modified for HIPAA compliance. HIPAA does not remove any current requirements of informed consent as per federal regulations. The HIPAA authorization has specific requirements that must be included with the research informed consent. The specific requirements for valid authorization are 45 CFR 164.508(c):*

- *A description of the information to be used or disclosed*
- *Who may use or disclose the information*
- *Who may receive or request the information*
- *Purpose of the use or disclosure*
- *Expiration date or event*
- *Individual's name, signature and date*
- *If consent signed by legal representative, a description of that person's authority*
- *Right to refuse to sign authorization. Note: The provision of research-related treatment may be conditioned upon the patient providing an authorization for the use/disclosure of their PHI for such research. If this is applicable, the patient must be informed that refusal to sign authorization means that the patient cannot obtain the research-related treatment. Otherwise, a statement that treatment, payment, continued enrollment in health plan or eligibility for benefits will not be conditioned upon the individual's provision of authorization*
- *Right to revoke authorization and what must be done.. Note: if research-related treatment was provisioned upon the authorization, the patient must be informed that revocation of authorization means that the research-related treatment will no longer be available.*
- *Re-disclosures not protected*
- *Access to PHI temporarily held while study in progress.*

*Consent forms must be maintained for at least 6 years after signature. Place in medical records and/or keep with research files.*

*Please use this template to include what is appropriate for your study, and delete those that are not. Some text paragraphs may not be needed for your study. This template is meant to provide as many possibilities and suggestions as may arise. Throughout the template, you will need to provide more study-specific information. These are usually indicated by brackets [] or italic font.*

THE QUEEN'S MEDICAL CENTER  
HONOLULU, HAWAII

**INFORMED CONSENT TO TAKE PART IN A  
CLINICAL RESEARCH STUDY**

**[should have a readability level targeting the 6<sup>th</sup> grade reading level]**

6-13-00 Note: FDA prefers the use of 3<sup>rd</sup> person "you".

Please do not use "I/you understand that" in any place on the consent form.

Title of Study:

Principal Investigator:

*Address*

*Phone*

Sponsor:

*Address*

INFORMED CONSENT

You are being asked to take part in this research study *because [ describe major reasons of patient to be a candidate of study]*. This is a research study that will *[in general terms what will this study do]*

Before you decide whether or not to take part in this study, you must understand the purpose, how it may help, any risks, and what you have to do. This process is called informed consent. The researcher(s) will talk with you about the study and the informed consent form. The consent also gives you information about what health information will be collected as part of the research study and how that information will be used or disclosed. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form. If you sign this form you are agreeing to take part in this study and to allow the use and disclosure of your medical records and health information collected in connection with your part in this study. You will be given a **signed** copy to keep. If you do not sign this consent form, you may continue to receive care, but not as part of this study."

Before you learn about the study, it is important that you know the following:

- Taking part in this study is of your own free will.
- You may decide not to take part in the study or stop being in the study at any time without it making any difference to your care now or in the future, or to any benefits that you are allowed.
- If the study changes in any way which could make a difference to your taking part, you will be told about the changes and may be asked to sign a new consent form.

## PURPOSE OF THE STUDY

This research study is being done to:

- 1) *[what are the major objectives]*

*OR*

- 2) The purpose of this research study is to .....*[explain and describe nature and purpose]*

*OR*

- 3) This is an experimental (research) treatment. It may not help you and it may hurt you.

*[1. Include the number of subjects that will be involved in the study.*

*2. Include the number of sites taking part in the study.]*

## PROCEDURES

### Screening

If you decide to take part in this study, you will be asked to sign this consent form.

*[1. Describe what will happen (lab or diagnostic tests, exams, etc) that will be done before being enrolled in the study.*

*2. Amount of blood to be taken for screening.]*

### Study Treatment

You will be randomized (chosen by chance, like a toss of a coin) to.....

*1. Describe what the chances are of getting which treatment.*

*2. Describe what will happen, in chronological time sequence what will happen for the study.*

*3. Include dosage of drugs.*

*4. Include the amount of blood or sample to be taken. Try to use tablespoons or teaspoons*

*5. What tests/procedures will be done, how long they will take, and in some cases, who will be present/*

*6. Identify which part of the study is experimental.*

*7. Explain where the subject will be and who will be there.*

### Follow-up Visits

*[1. Describe sequence of follow-up visits, office visits. Subject must understand that a study follow-up visit may be different than the standard follow-up visit, especially if the attending doctor is not the study doctor.*

2. *Include the amount of blood or sample to be taken. Try to use tablespoons or teaspoons*
3. *What tests/procedures will be done. Identify which are experimental.*
4. *How long will patient be in study?]*

#### Stopping Your Part in the Study Before the End (Withdrawal or Early Termination)

The following procedures will need to be completed if you stop taking part before the study ends.: *[describe any tests, procedures, follow-up visits, return of medications, etc., the subject must have for early termination or withdrawal from the study]*

## RISKS

Taking blood may cause some soreness, bleeding and bruising, and (very rarely) infection where the needle enters the body.

1. *Describe risks and complications of drugs, treatment, equipment*
2. *Explain that there may be risks that are not known yet with this drug/procedure.]*

You cannot be in this study if you are pregnant, nursing, or trying to get pregnant, since this research may have unknown risks to the embryo or fetus (unborn child). You must use safe and useful birth control.

For female subjects, it is very important that you do not become pregnant during this study. If you are a woman who is able to become pregnant, and choose to have sex during this study, you must agree to use a medically acceptable method of birth control throughout the study. Certain brands of contraceptives that you take in pill form are not acceptable for this study because the study drug may change (or decrease) the strength of the contraceptive. Your study doctor can tell you which brand is OK for you to use. Men should use a condom to decrease the chances of both HIV transmission and pregnancy. Medically acceptable birth control methods include:

- condom and spermicide
- diaphragm and spermicide [or list what is acceptable]

Even if you use a medically acceptable birth control method, you could still become pregnant or make someone pregnant. Not having sex is the only certain way to prevent pregnancy. There is a slight chance that a pregnancy test could be wrong. If the pregnancy test is wrong, and you get the study drug while pregnant, the study drug may harm an unborn baby. The effects of the (study drug) on an unborn baby are not known. Do not breast-feed while taking (study drug). If you feel that you might be pregnant, you should tell the study doctor immediately. If you have gotten someone pregnant while on study drug, the study doctor should also be told.

1. *May need to describe in more detail the kinds of birth control that is OK to use, or other information or that if get pregnant to let the doctor know immediately.*
2. *Describe any other risks to pregnant women, embryo or fetus.*
3. *What about breastfeeding?*
4. *What about men. Do they need to use a condom or abstain from sex. Can they get a woman pregnant.]*

*Suggested part of text for telemedicine studies:*

There is a small chance that the sending of medical information could be interrupted or distorted by technical problems, that the sending of information could be picked up by unauthorized persons; that the electronic storage of medical information by this telemedicine could be looked at by unauthorized persons.

## BENEFITS

Taking part in this study may help you feel better but no guarantee can be made and it is possible that no good response will happen. You may have a good response to the treatment....*[Describe other benefits or non-benefits]* Knowledge gained from this study may help other people in the future.

## OTHER TREATMENT

You may choose to not take part in this study without it making a difference in the care that you get now or in the future.

*[1. Describe other treatments, options available. Include the option to not do any.]*

## CONFIDENTIALITY

**Federal Privacy Regulations provide safeguards for privacy, security, and authorized access to health information.** The confidentiality of all study-related records will be kept according to all applicable laws. Information gained during this study and information known about you will be confidential (private) to the extent permitted by state and federal law. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed.

## USE AND DISCLOSURE (RELEASE) OF YOUR HEALTH INFORMATION

By signing this form you are authorizing the collection, use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you as part of this study. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. Your personal health information is health information about you that could be used to identify you. This information may include information about AIDS or HIV infection, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

There is no expiration date to this authorization.

Who may receive, use or release information:

Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- *[Name of PI, and co-investigators]* and his/her research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

Who may receive the information by the above groups:

The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (*if applicable*)
- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health,
- Representatives of outside groups hired by QMC Research Department for audits to make sure studies are done as required.
- *[Collaborators at other institutions]*
- *[Outside data analysts]*
- *[List any other class of persons or organizations not affiliated with QMC to whom the subject's information might be disclosed]*

There is a possibility that your information may be released again by the sponsor of the study or governmental agencies described above and no longer covered by federal privacy rules.

Right to Withdraw or Stop Taking Part in the Study

You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study, or choose to withdraw from the study, or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.

If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

### Access to Your Information

As is usually the case, you may see the information in your medical record; however, the records and information related only to the study that are kept separately will not be available to you until the study is finished. If you wish to review your study records after the completion of the study, you should request this from the study doctor.

*For Certificate of Confidentiality, possible text:*

This research study is covered under a Certificate of Confidentiality given by the Department of Health and Human Services. The Certificate protects the researchers (study doctors, and staff) from being forced to release any research information (data) in which you are identified, even under court order or subpoena, for criminal (related to a crime), administrative, or legislative proceedings. The information can be released if you or your guardian requests it in writing. This protection is not absolute. It does not, for example, apply to any state requirements to report certain communicable diseases, or to release information in cases of medical necessity. The researcher(s) must report cases of suspected child or elder abuse to the appropriate authorities.

## COSTS

- [1. Outline what the sponsor pays for, and what the patient pays for.*
- 2. Patients should not pay for any tests/exams/etc that are research-study-specific.*
- 3. If the patient must pay for all charges, clearly state that their insurance company may not pay for the costs since the treatment/device/etc is considered investigational (still under research).*
- 4. Will the patient be paid any money for taking part in the study?]*

The study doctor(s) will be paid by the sponsor for your taking part in this study.

OR

This study is being sponsored by a grant from [name of grant funding agency]. Part of the researcher's and his/her research team's salaries are being paid by this grant.

*If there are no funds to cover any costs the following is suggested text:*

Any procedure or test related only to this research study and not normally be done will be explained to you, and is explained in this consent form. All costs for doctors fees, medication (including drugs to treat any side effects), laboratory tests, x-rays or scans, and hospital costs will be charged to you as if you were not part of this study. The sponsor of this study and the study doctor do not have any funding (money) to pay for any of these costs. Your insurance company may not pay for some (or all) of these tests and procedures because this is a research study. If your medical insurance does not cover any of these costs, you will be responsible for payment. Because these costs can be very high, you should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage and get an estimate of your share of the cost.

*If there are no funds to cover any costs the following is suggested text:*

Any procedure or test related only to this research study and not normally be done will be explained to you, and is explained in this consent form. *[Explain whether insurance will or will not pay for these costs. If insurance will not pay, who will be responsible for cost*

*and what the range of cost will be.]* The sponsor of this study and the study doctor do not have any funding (money) to pay for any of these costs. Because these costs can be very high, you should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage and get an estimate of your share of the cost.

## TREATMENT AND COMPENSATION FOR INJURY

If you are injured as a result of being in this study, you will get

- [1. Will patient get immediate medical care and treatment including hospitalization.*
- 2. Who pays for this immediate treatment?*
- 3. Will money be given to patient to cover these expenses?*
- 4. Or will costs of medical treatment be paid for by the patient directly or through medical insurance and/or other forms of medical coverage?*
- 5. Who must the subject contact in case of a research related injury.]*

*If there is no funding to cover this, the following is suggested text:*

If you have an injury or illness (get sick) as a result of being in this study, immediate emergency medical care and treatment which may be needed will be available at the usual charge. The sponsor of the study and the study doctor do not have any funding (money) to pay for treating the injury or illness. Your insurance company may not pay for some (or all) of the treatment of the injury or illness as a result of being in this study. If your medical insurance does not pay for these medical costs, you alone will be responsible for payment. There is no way of knowing what the costs will be. You should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage.

If you are injured or become sick directly from taking part in this study, *[the sponsor or entity responsible]* will pay for the reasonable costs of medical treatment for your injuries. Please be sure to:

- 1) Talk with study doctor or the study nurse of the injury right away, and
- 2) Carefully follow all study directions.

The sponsor, The Queen's Medical Center and the study researchers have not set aside any other kind of compensation (payment) for lost wages or other damages or losses resulting from any injury that you may get from taking part in this study.

## REMOVAL FROM THE STUDY

You take part in this study of your own free will. You may be taken off the study without your consent for any of the following reasons:

- Your condition gets worse;
- You do not keep your study visits or take the drugs as you are told;
- You have a bad side effect to the drugs;

- You get pregnant;
- *[list reasons]*

If you are taken off the study, you may be asked to return for follow-up visits as described below.

### NEW FINDINGS

You will be told of any important new information learned during the study that may change your willingness to continue in this study.

*Please Note: Template for use of certain types of tissues samples, genetic testing have not been included here.*

### WHO TO CONTACT

If you feel that you have been injured as a result of taking part in this study, *[list who must be called, and their phone number – it must be a 24-hour available phone number if this study involves any treatment or device]*

If you have any questions about your treatment, your rights as a volunteer or any other matter relating to this study, you may call \_\_\_\_\_ at \_\_\_\_\_ and talk about any questions that you might have.

If you cannot get satisfactory answers to your questions or you have comments or complaints about your treatment in this study, you may contact:

Research & Institutional Review Committee  
The Queen's Medical Center  
1301 Punchbowl Street  
Honolulu, HI 96813  
Phone: (808) 547-4512

**AGREEMENT TO TAKE PART AND CERTIFICATION and AUTHORIZATION OF PROTECTED HEALTH INFORMATION –**

I, or my legally authorize representative (the legal person who cares for me) have read and understand the description of this study such as the purpose and nature of this study, its expected length, the procedures to be done, reasonably known risks and discomforts, benefits to expect, other treatments I may have, release of my medical records, payment and medical treatment for injury, and removal without my consent for this research study.

I am taking part in this study of my own free will. I may withdraw (stop taking part) and/or withdraw my authorization for use and release of protected health information at any time after signing this consent form without it making a difference to my care now or in the future or any loss of benefits that I am allowed. My consent does not take away my legal rights in case of carelessness or negligence of anyone connected with this study. My signature means that I have read the information above or that it has been read to me, my questions have been satisfactorily answered, and at any time I have other questions, I can contact the researcher listed on the first page.

Specially Protected Health Information

I agree to the release of the following information should it be contained in my medical records: Acquired Immune Deficiency Syndrome (AIDS or HIV), alcohol and/or drug abuse treatment, or behavioral or mental health services.

cc: **Signed copy** of consent/authorization form to patient

_____ Subject's Name (Print)	_____ Subject's Signature	_____ Date/ Time
_____ Witness' Name (Print) (Witnessing Signature Only)	_____ Witness' Signature *****	_____ Date/ Time

I have explained this research to the above subject. In my judgment the subject is voluntarily and knowingly giving informed consent and has the legal capacity to give informed consent to take part in this research study.

_____ Investigator's Name (Print) (Individual obtaining Subject's consent)	_____ Investigator's Signature	_____ Date/ Time
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(Investigator: fax a copy of this signed page to Research Regulatory Office at 537-7897 within 24 hours of signing.)

[Please leave 2 inches at the bottom of this page blank. This is reserved for the RIRC stamping.]

**CONSENT TO TAKE PART and AUTHORIZATION OF PROTECTED HEALTH INFORMATION – IF SUBJECT IS UNABLE TO CONSENT:**

As a legally authorized representative of the subject, my signature indicates that I have read this form, or it has been read to me, I have had the study explained to me, I have had answers to my questions, and I am satisfied with the information that I have been given. I am giving consent for the subject listed below to take part in this study and authorize the use and release of their protected health information. I can withdraw (stop taking part) and or take away the authorization for the use and release of protected health information at any time after signing this form without it making a difference to the subject's care now or in the future or any loss of benefits that I am allowed. My consent does not take away legal rights in care of carelessness or negligence of anyone connected with this study. I will be given a signed copy of this consent form.

**Specially Protected Health Information**

I agree to the release of the following information if it is in the subject's medical records: Acquired Immune Deficiency Syndrome (AIDS or HIV), alcohol and/or drug abuse treatment, or behavioral or mental health services.

\_\_\_\_\_ is not able to consent  
Name of the Subject (print)

\_\_\_\_\_  
Name of Legal Representative (print)

\_\_\_\_\_  
Signature of Legal Representative

\_\_\_\_\_  
Description of legal authority to act on behalf of subject

\_\_\_\_\_  
Date/ Time

\_\_\_\_\_  
Witness' Name (Print)

(Witnessing signature only)

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Date/ Time

\*\*\*\*\*

Based on my clinical judgment, this subject is not able or is incompetent to independently consent to participate in this research study.

\_\_\_\_\_  
Investigator's Name (Print)

(Individual obtaining the Legally Authorized Representative's consent)

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date/ Time

(Investigator: Fax a copy of this signed page to Research Regulatory Office at 537-7897 within 24 hours of signing.)

*[Please leave 2 inches at the bottom of this page blank. This is reserved for the RIRC stamping.]*