

# General Prospective Protocol Guidelines

*Note: There are no specific length recommendations/requirements for a protocol other than to use as much detail as possible in your writing. Your audience is the research and institutional review committee. The Consent form must be written for the research subject at a 6<sup>th</sup> grade education level.*

## Section I: Scientific Design

### A. Title

Descriptive title of your project – If applicable, include the phase (phase I, phase II, etc.), design (randomized, double-blind, placebo controlled, etc.), single or multi centered, the drug or device name, and the study population.

*For example: Single-blind randomized placebo controlled study to evaluate the safety and efficacy of ASA given as an adjunct treatment following acute myocardial infarction*

Principal Investigator(s)

Co-investigator(s)

Other study personnel (e.g. biostatistician, data entry, and clinical study nurse personnel)

### B. Table of Contents (*if >10 pages*)

### C. List of Abbreviations

A list of abbreviations used in the protocol.

### D. Brief Summary/Abstract

Briefly discuss the overall rationale for the study, the key elements, expected outcomes, and the long-term objectives of your research.

*For example: This study is being done to determine if ASA is safe and effective as an adjunctive therapy following acute myocardial infarction (MI). We expect to show ASA is safe in this scenario, and that patients given ASA as an adjunctive treatment have a lower in-hospital mortality rate, and have fewer complications than patients given placebo. This may have a long-term impact on our ability to achieve better overall outcomes and save more lives.*

### E. Specific Aims/Objectives

List the specific aims, hypotheses of your study, usually in numbered paragraphs. Relate the specific aims to your long-term objectives, and describe what your research intends to accomplish.

*For example:*

**Aim 1:** Evaluate the safety of patients given ASA versus placebo as adjunct therapy post MI stabilization.

*Hypothesis: ASA will prove equally safe as placebo for adjunct treatment post MI.*

**Aim 2:** Evaluate the mortality of patients given ASA versus placebo as adjunct therapy post MI stabilization.

*Hypothesis: The mortality rate will be lower in the ASA arm compared to the placebo arm.*

### F. Background and Significance

Describe the prior research that has been done on your topic. Provide a critical evaluation of previous research, identify the gaps in knowledge about your topic, and explain how your study will fill a gap in the current understanding of your topic. Include reference citations as appropriate.

*For example: Some retrospective studies have shown that ASA has a positive therapeutic effect post MI, but no randomized clinical trials have been done. Therefore, this study will determine whether ASA given post MI is safe and effective.*

### G. Preliminary Studies

Discuss the project's feasibility, and show that you have the resources, skills, and experience to complete your study as described in the protocol. Include information on any pilot studies that you have done.

*For example: The principal investigator has been practicing cardiology for 5 years in Hawaii, is well published in cardiac procedures (ref. 1 Dr. Jones et al), and has completed several randomized studies. In a small pilot study, ASA given post MI showed some promise in lowering in-hospital mortality.*

## H. Drug Supply, Packaging, Labeling and Storage

Describe how the study drugs are obtained, bottled, packaged, and stored until used.

*For example: ASA and placebo tablets will be made and donated by The Queen's Medical Center pharmacy. Tablets will appear identical in size, shape, and color. 90mg tablets of generic ASA and sugar tablets will be made using standardized pharmacological formulations. 20 tablets will be put into a bottle with a numbered label describing its purpose. Tablet bottles will be assigned a random number representing the sequence in which they should be dispensed. All study personnel will know the treatment group decode, but the patient will remain blinded. Tablet bottles will be stored in The Queen's Medical Center pharmacy until dispensed, and then the bottle of tablets will be kept with the patients other medications until all tablets have been used or the patient is discharged, at which time any remaining tablets will be disposed of according to hospital policy.*

## Section II: Investigational Plan

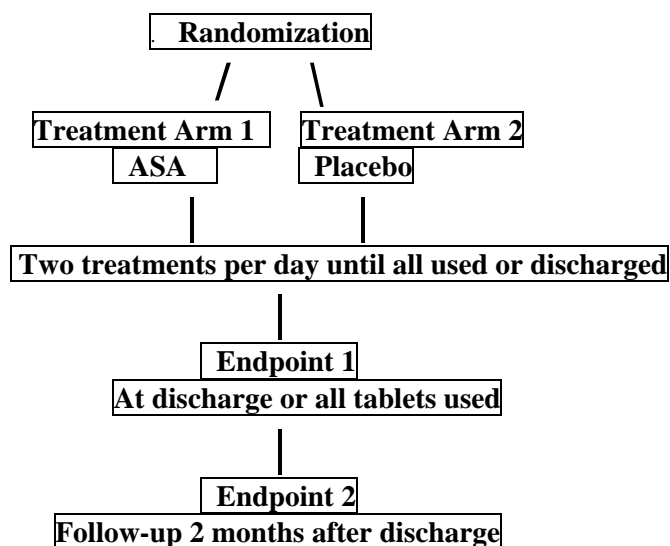
### A. Overall Study Design and Methods

Describe the study design (observational, randomized, cross-sectional etc.) and procedures (who, what, where, when, and how the research will be carried out). Describe any novel methods that will be used, and explain their benefits over existing methods. Include a description of any collaborative agreements you may have with other investigators or service providers. If appropriate, discuss any foreseeable difficulties and limitations of your proposed research, and provide a brief explanation of any alternative approaches to accomplishing your specific aims.

Be sure to highlight any procedures, situations, or materials that may be hazardous to study personnel, and thoroughly explain the precautions you will take to protect your study personnel. Briefly discuss recruiting techniques; this topic will be covered more extensively in Section II, Human Subject Information. Define your subject population for analysis and provide sufficient detail to allow reviewers to evaluate the proposed research methods.

*For example: The proposed study is a single-blind randomized placebo controlled study to evaluate the safety and efficacy of ASA given as an adjunct treatment following acute myocardial infarction. Subjects will be treated once admitted to the hospital and stabilized according to standard guidelines. ASA or placebo will be randomly assigned to 500 subjects (250 per arm) that give informed consent and meet the inclusion/exclusion criteria. Study drug will be given as adjunctive therapy and only the subjects will be blinded to the treatment arm. If the attending physician believes there is any danger to the patient the study drug will be stopped. No additional procedures will be done as a result of this study. Data will be continuously reviewed by the principle investigator for safety.*

It is recommended that you include a schematic diagram of the study design, for example;



## B. Selection of Subjects

Define the population, and provide a list of inclusion and exclusion criteria. Provide sufficient detail to allow reviewers to evaluate the proposed research methods.

*For example: Subjects admitted to The Queen's Medical Center with a primary diagnosis of acute myocardial infarction will be screened to determine if the eligibility criteria are met. If eligible, consent will be sought from potential subject. Subjects  $\leq$  18 years of age and women who are pregnant, nursing, or of child bearing potential will not be enrolled. Subjects who received prior aspirin therapy will not be excluded from the study.*

*Inclusion criteria:*

- 1. Adult > 18 years of age*
- 2. Subject admitted with acute MI*
- 3. Subject is able to provide informed consent*

*Exclusion criteria:*

- 1. History of CHF, ACS, or known cardiac birth defect*
- 2. Women who are pregnant, nursing, or of child bearing potential*

## C. Observations and Measurements

List and describe when assessments will be done, and list the type of procedures to be done, or clinical data to be collected. Also include enrollment assessments and information that will be collected at screening. You may wish to refer to Appendix A.

*For Example:*

*All assessments will be done by the attending physician and principal investigator. Specific assessments will be done at screening and discharge (see appendix A). Continual assessments will be done during the hospital stay for: vital signs, laboratory values, physical examinations, and adverse events.*

## D. Data Collection Plan

Describe the overall data collection plan. Define the types of data collection instruments that will be used, and list which data fields will be collected. Data collection forms should be included in Appendix G. Specify if a computerized database will be used. If known, describe what hardware and software will be used (e.g. data will be entered into an Access database on a laptop computer). Explain precautionary steps taken to assure data security.

*For Example: The investigators named in this protocol will oversee all data collection. The case report form shown in Appendix G will be used by the study nurse to collect data about the subject throughout the hospital stay until the subject is discharged. A computerized database will be developed to facilitate the analysis. Research data will be organized as described in the following 'Database Content' section. The principal investigator will oversee and audit the data entry activities weekly for compliance with security and system usage procedures, as a quality assurance measure. The principal investigator will also control access to the research data and provide oversight for all research using it. Protected health data will only be reviewed by personnel named in this protocol.*

*Database Content: The research database will contain the following patient identifiers, demographic information, medical history, clinical assessments and treatments collected during the hospital stay.*

<i>Medical Record Number</i>	<i>MI onset date/time</i>	<i>Physical exam normal no/yes</i>	<i>Adverse experiences</i>
<i>Account Number</i>	<i>Admission date/time</i>	<i>BP, Pulse, weight</i>	<i>Medical History</i>
<i>Patient Name</i>	<i>Discharge or death date/time</i>	<i>Concurrent Illnesses</i>	<i>Prior ASA therapy no/yes</i>

## E. Statistical Methods

Provide evidence that you have considered the statistical aspects of your study, such as the sample size, how you will analyze your data, and what constitutes statistical significance (e.g.  $p$ -value < 0.05). If applicable, describe how randomized treatments are to be assigned. For double-blinded studies, specify guidelines for breaking the random code in an emergency to determine what treatment was given. It is highly recommended that you consult with a biostatistician for this section.

### a. Power/Sample Size Considerations

Provide details of the sample size calculation (assumptions, power level, alpha level, etc.). The assumptions used in the calculations should correspond to existing knowledge as stated in the Background and Significance.

**b. Statistical Analysis Plan**

Describe the statistical methods to be used for addressing each specific aim (e.g. descriptive statistics will be produced, chi-square test will be used for comparing proportions, and t-test for comparing means). Also list the computer software that will be used for the analysis.

**F. Publication and Presentation Plans**

List any meetings or conferences where you plan to present the results. List any journals you're planning to submit to for possible publication.

**G. Timeline**

Write a short paragraph stating when you expect to complete the study. Include certain milestones (e.g. subjects identified within 1 month, data collection completed within six months, analysis will be completed within one month after data collection ends, publication 2 months thereafter, completing the study by June 2007). You may wish to refer to Appendix A.

### **Section III: Human Subject Information**

Note: All clinical research studies performed at the Queen's Medical Center (QMC) must comply with Federal, State, and Local regulatory guidelines. The format and content of this section should follow the QMC RIRC guidelines.

**I. Human Subjects**

**a. Inclusion/Exclusion criteria:**

Provide number, age range, and health status of the subject population. Identify criteria for inclusion or exclusion.

**b. Gender/Minority/Pediatric Inclusion**

All protocols must include documentation of the inclusion of women and minorities in the research protocol, or else state why their inclusion is neither applicable nor feasible.

**c. Recruitment and Consent**

Describe how subjects will be recruited for the study, e.g. from investigator or sub-investigator clinical practices, referring physicians, advertisement, etc. Explain how information will be disseminated to subjects (advertisements: handouts, brochures, etc.). *Note that any advertisements must be approved by the QMC RIRC, and a copy must be included in the protocol.*

**J. Risks and Benefits**

**a. Describe risks and assess likelihood and seriousness.**

**b. Describe procedures for protecting against or minimizing potential risks.**

**c. Describe potential benefits and importance to the subjects and others.**

**d. Discuss why risks are reasonable in relation to benefits.**

**e. Consent form process**

*Explain who will be responsible for obtaining consent, when consent will be obtained, and how it will be obtained.*

*If investigators have a financial interest in the study, or if they are compensated for the study, then the consent form MUST include this information.*

## K. Data and Safety Monitoring Plan

Note: all protocols at the Queen's Medical Center with moderate to significant risk **must** have an RIRC approved Data and Safety Monitoring Plan developed and on file with the Queen's Medical Center's RIRC. **Contact the QMC RIRC to determine your study's risk level.**

You may use your Sponsor's Data Safety and Monitoring plan, or, in the absence of specific Sponsor guidelines, use the following:

### a. Adverse Event (AE) Reporting:

Adverse events anticipated in this [insert level of risk from the Manual of Human Subject Research [risk definition guidelines](#)] risk study that involves [insert a synopsis of testing and interventions] include [describe adverse events]. We will monitor for these adverse events by [describe types and frequencies of tests, etc., that will be used to monitor for adverse events (e.g. vital signs, physical exams, lab tests, etc.)]. If ever an adverse event occurs, [describe your plan to report adverse events such as the following] research staff will report such to the Investigator who will then advise the RIRC, and the NIH and/or sponsor as indicated [you need to identify your sponsor or others who you will report adverse events to]. Unanticipated non-serious adverse events will be reported within 30 days and serious adverse events will be reported 24 - 48 hours as per Queen's Medical Center RIRC guidelines. In absence of moderate or serious adverse events, as is appropriate with [state your study's risk level] risk studies, reports of study progress will be submitted to the RIRC on an annual basis [or specify more often if the SAC, Safety Advisor, or RIRC require more frequent reports or reviews]. Once reviewed, reported adverse events will be tallied by the RIRC secretary for RIRC reporting purposes.

### b. Risk Minimization:

All study procedures will be performed according to protocol and RIRC-approved recruitment/consent procedures and the enrollment inclusion/exclusion criteria previously listed will be closely adhered to. Possible risks associated with participating in this study include [list physical, emotional, socioeconomic, insurability, or stigmatizing risks in detail as they will be in your RIRC application].

Risks associated with [name the test or procedure and then describe all risks; as in your RIRC application]. These risks will be minimized by [list procedures to minimize risk and you may include the following as well], by allowing only well-trained clinical research staff to perform study procedures and testing according to standard practice, and by making sure study participants clearly understand study procedures before and during the study protocol.

In addition to the above risks, side effects known to occur with [list tests and treatments involved in the study] include [list the side effects of each]. The possibility of these occurring will be minimized by [tell how you will do this].

### c. Monitoring of Study Implementation and Progress

Periodic assessments will be performed to assess recruitment and retention of study participants, data quality, and risk-benefit ratio. The recruitment goal for this study is [specify how many subjects should be recruited within how many months]. Data checks will be performed by [describe how the accuracy of data will be assessed and by whom]. Last, if more information about the study's risk-benefit ratio becomes available, the investigator will be responsible for notifying the RIRC, sponsor, the Queen's Medical Center, and study participants, as indicated.

### d. Study Termination

Criteria for early withdrawal of individuals from this study are: [list reasons and you may wish to add the following] and/or a participant's inability or unwillingness to adhere to study procedures. Criteria for early termination of the study include [list why you would stop the study completely: high proportion of serious side effect (list), early significant effect in a specific arm of the study, etc.]

#### **e. Confidentiality**

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

[Include what you wrote in your PHS398 or RIRC application and you may add the following.] Study participants will be assigned study numbers and specimen samples will be tagged with these numbers before laboratory analyses are performed. We will not use any identifying information in data analysis procedures or in research reports.

#### **f. Data Security**

Data will be organized, managed, and stored in [list where and how (e.g. lab notebook, software database, etc.)] by [indicate whom]. Security measures used to protect study data from loss or inappropriate use will include [list and describe. The Queen's Medical Center statisticians and RIRC Administrator can help you describe how you will assure data integrity (random quality checks, protection from inadvertent modification or loss, etc.) and protect the security (provisions for data storage sites and access, password protect, limited access to data sets, etc.) of your data. You may also include the following.] Hard copies of clinical information and data will always be kept in a secured place at the Queen's Medical Center or in our research office, and only study team members will be able to access them on an as-needed basis. Key personnel may not alter the data in any database without specific cause and approval of the Investigator. Study databases will be password protected. No data will be sent over the internet unless it is de-identified. Further measures to ensure data security will adhere to security standards set by the Queen's Medical Center and the RIRC [you can describe the applicable standards including password protection, de-identification, etc.].

#### **g. Record Retention**

It is the investigator's responsibility to retain study essential documents for at least 7 years after the last approval of a marketing application in their country and until there are no pending or contemplated marketing applications in their country or at least 7 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period if required by an agreement with the sponsor. In such an instance, it is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.

As per Queen's Medical Center policy, all data must be retained for 7 years, following the completion of a study. It is the Principal Investigator's responsibility to maintain all study data in a readable form. If the Investigator leaves Queen's, or Hawaii, s/he must make arrangements to store the data with the Research Planning and Development office.

## Section IV: QMC RIRC Informed Consent

### 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.*

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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: *Title*

Principal Investigator: *Name*

*Address*

*Phone*

Sponsor: *Name*

*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 institution*
- *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 is 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.

### **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 additional 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

**SIGNATURE PAGE**

**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)                      Witness’ Signature                      Date/ Time  
(Witnessing Signature Only)                      \*\*\*\*\*

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)                      Investigator’s Signature                      Date/ Time  
(Individual obtaining Subject’s consent)

(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.]**



## Section V. Attachments and Appendices

**A. Study Calendar** – List all visits (screening, treatment, endpoint, and follow-up) and the procedures to be done

Procedure	Screening	Day 1	Each Day of Stay	Discharge	2 Month Follow-up
Informed Consent	X				
Medical History	X				
Randomization		X			
Physical Exam	X	X	X	X	X
Vital Signs	X	X	X	X	
Hematology		X			
Urinalysis		X			
Chemistry		X			
12-Lead ECG	X	X	X	X	

**B. Budget Page** - Brief description of fees (i.e. chart archives fee may be imposed @ \$3 per chart, researcher hourly fee @ \$10 per hour, etc.) or balance/work sheet

**C. Curriculum Vitae of Principal Investigator**

**D. Roles of Personnel** - Also specify any privileges that will be needed (i.e. Allied Health Professionals credentialing, Care\*Link training and access required)

**E. References** - List only the literature cited within your Protocol's text.

Use the NIH format: names of all authors, title, book or journal, volume, page, and year.

**F. Data Guardian Approval** - Approval from Data Guardian(s), signed agreement letter should be attached.

**G. Data collection Forms** - Data collection tools, forms, or screen prints.