ROCHESTER REGIONAL HEALTH LETTERHEAD

Or letterhead specific to the Principal Investigator)

Consent Form

(Project Title)

(Name of principal investigator and co-investigators)

(Name of Sponsor, if applicable)

(Note 1: The sections below appear in an order that promotes subject understanding, but sections may be re-ordered as appropriate)

(Note 2: Starred (*) sections may be deleted if they do not apply, however, the IRB may require that they be included.)

2/18 All pages are to have page number in x of y format.

2/18 All pages are to liave line number for tracking purposes

Introduction

This part of the consent form must state that this is a research study and it should indicate why the person is being asked to participate. It should state which department is conducting this study. It should say that subjects should read the form carefully and instruct them to ask the investigator and/or person obtaining consent any questions that they may have before making a decision whether or not to participate. Especially for long-term studies, complex procedures and studies with greater risk, this section should emphasize that the form contains important information and that subjects should keep their copies to refer to as the study proceeds.

The introduction is an opportunity to reinforce the voluntary nature of subjects' participation ("You are being asked to participate..." "You are invited to participate..."). The introduction may be used to provide background on why the study is being conducted and its importance and the importance of subject participation. The importance, however, should not be overstated or exaggerated.

Purpose of Study

This section of the consent document must, briefly and simply, inform the subject of the purpose (aim/goal) of this study. It may be appropriate to inform the subjects if the study is being undertaken just locally or on a larger scale, e.g., city-wide, regionally, nationally, or internationally.

Description of Study Procedures

- This section should contain a complete description of the procedures that are necessary to complete the study. All experimental procedures must be described and any related by non-experimental procedures should be stated. The subject's time commitment must be explained in terms of the length of study, visits required, and any other activities (e.g. diaries, telephone follow-up) required for completion. Use lists, tables, and charts to show complex schedules and study designs.
- Note: any questionnaires, diaries or study-related material must receive IRB approval prior to use in the protocol.

For medical studies, this section would include explanations about medications being given, the amount of blood drawn, invasive and/or non-invasive procedures, length of hospital stay, follow-up procedures and the like.

- All scientific/medical/technical terms should be defined or explained in lay terms.

- Avoid the use of undefined medical abbreviations such as EKG, SMA-12.

- If the study involves a randomization, the randomization procedure should be explained along with the changes of receiving each of the arms. For example; if the study offers a fifty/fifty chance of randomization into one of two arms, a recommended wording for the section may be "You will be randomized, chosen by chance like the flip of a coin to be placed into one of the two available groups". If the odds of randomization should be outlined, for example "…1 in 3 chance, etc."

- If the study involves the use of a placebo, define placebo. A suggested wording may be; "placebo, a substance made to resemble the study drug but which contains no active ingredient"

- If the study is double/single blinded, explain the meaning for the subject.

- If there are explicit exclusion or inclusion criteria for the study, e.g., allergies, pregnancy, medical conditions, use of certain medications, etc. they can be included in this section.

(Note: the risk of pregnancy is not an acceptable criterion to exclude women of child-bearing potential. Contraceptive measures and pregnancy testing can be used, with removal from the study if positive. Note: the contraceptive measures allowed under the protocol should be clearly defined. Abstinence is not considered an effective method of birth control and should not be included as such. Additionally, condoms and diaphragms should state that they are to be used with spermicide.)

- Use tables and/or charts to show complex schedules

Risks of Participation

This section should contain a sufficient description of the risks to enable subjects in deciding if they want to participate. Information on probability of the risks and the magnitude and reversibility of harmful effects is helpful to this process.

List any:

- Potential behavioral and psychological risks, such as triggering bad memories, learning disturbing things about oneself, nervousness about being observed, etc. need to be delineated.

- Legal and social risks, if any, need to be stated as well as risks to confidentiality or privacy.

- Specific risks to confidentiality and or privacy

- Side effects for each drug, device or procedure. Specify if side effects are reversible and/or treatable, and what monitoring will occur to detect/control side effects. Indicate that all drugs have side effects. If appropriate, you may state that this subject may experience all, some or none of the side effects listed. Potential side effects should be listed as a range of occurrence, (for example: "Likely (occurring in 10% or greater of the study population)", "Less Likely (occurring in 5 – 10 % of the study population)" and "Rare (occurring in 0 – 5 % of the study population)".

- For drug studies, this section may point out that there is always the risk of previously unknown side effects occurring.

- It may be useful to instruct subjects to report any side effects.

- If the study involves blood draws, mention that this might cause pain and bruising at the site where the blood is taken; and sometimes, it causes people to feel lightheaded or even to faint.

- If a sample consent form has been provided by a study sponsor/group, all the risks from the sample consent must be included in the Rochester Regional Health consent form.

- Studies using questionnaires should state that the patient is free not to answer any question which may make them feel uncomfortable.

Number of Participants*

The number of local patients expected to enter the study should be stated along with the total number of patients if the study is multicenter. This is actually an additional 'risk" consideration. Therefore, the total number of subjects is important to consider before beginning the study. For example, a small number of subjects may compromise confidentiality by making it easy to identify them (This statement may also be placed in the Risks section above.)

Benefit of Participation

List any direct benefits to the subject or to others which may reasonably be expected from the research. It may be prudent to state that there is no guarantee that the patient will receive any benefit from their participation in the protocol (so state). Benefits which may be stated include the possible development of commercial products or greater understanding of conditions such as theirs. It may be permissible to state that a project may yield results that could possibly benefit a sub-population (e.g. AIDS patients, low birth weight babies, students and so forth).

New Study Findings*

New findings developed during the course of the research may change subjects' willingness to continue to participate. If so, subjects need to be informed that these findings will be provided to them. This may require new consent forms or addenda.

Alternatives

Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. Usually, medical studies have alternatives, e.g. 'standard' treatment, no treatment, other research studies, etc. If a test drug/device is available "off protocol" (i.e., approved for use) that needs to be stated. Other types of studies may have alternative actions such as other options to earn course credit (e.g., reports and papers) or availability of non-research services.

For minimal risk studies that have no alternatives (e.g., some survey research), it may be stated that "the alternative is not to participate" or you may delete this section if it does not impact the information needed to decide about participation.

Costs*

Any additional costs that may result from participation in the study must be listed. The following are examples of acceptable wording:

"There is no cost to you to participate in this research study."

Or, for medical studies:

"How much you will have to pay depends on whether or not you have insurance and what costs your insurance will cover. You or your insurance carrier will be responsible for the costs of clinic visits, any hospital admissions, laboratory tests, x-rays, and other tests. Insurance coverage cannot be guaranteed for tests and treatments related to this study."

Payments*

If subjects are to be paid for participation or reimbursed for expenses, specify the amount, schedule of payment, and conditions for payment. Payment should be based on a prorated system. This means that payments are earned/given as the study progresses and that subjects do not have to complete the entire study to receive a payment. (Note: for clarity, do not use th e word "compensation" to refer to incentive payments or reimbursements for expenses). Note too, that advertisements may mention, but must not emphasize payments; and all advertisements must first be approved by the IRB. If medications, tests and therapies are to be provided free as part of the study, specify.

Circumstances for Dismissal from the Study*

List the circumstances, if any, under which the subject's participation may be terminated without their consent. The following are examples of acceptable wording:

"If you do not keep appointments for study visits or fail to complete study activities, e.g. taking study medications or completing forms."

"If you do not follow the instructions you are given." Note: do not use the phrase "fail to follow the protocol or research procedures" as subjects do not have this information.

"If your disease becomes worse or if your doctor feels that staying in the study is harmful to your health, further treatment would be discussed at that time."

"If new scientific developments occur that indicate the study is not in your best interest."

"If the Principal Investigator, Rochester Regional Health Institutional review board, or the study sponsor decides to stop or cancel the study."

Compensation for Injury

All research conducted in whole or in part at Rochester Regional Health must contain the following statement:

"Rochester Regional Health, in fulfilling its public responsibilities, has provided professional liability insurance coverage and will be responsible for any injury only in the event such injury is caused by the negligence of Rochester Regional Health."

Confidentiality of Records

Confidentiality of Records and HIPAA Authorization (Data Privacy Statement)

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and who it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing the consent document for this study, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. If you do not want to allow these uses, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor/investigator and staff will use your medical records and information created or collected during the study to conduct the study.

- The study doctor/investigator and staff will send your study-related health information ("study data") to the sponsor (if applicable) of the study and its representatives ("sponsor"). Because the sponsor conducts business related to clinical research in many countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will represent the terms of this Data Privacy Statement in all countries.

- The study data sent by the study doctor/investigator to the sponsor does not include your name, address, social security number, or other information that directly identifies you. Instead, the study doctor/investigator assigns a code number to the study data and may use your initials. Some study data sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (e.g. date of birth). If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor/investigator.

- The sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs.

- The sponsor may add your study data to data from other studies in research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.

- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, and the Rochester Regional Health Institutional Review Board overseeing this study at Rochester Regional Health.

- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.

- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the Rochester Regional Health Institutional Review Board overseeing this study at Rochester Regional Health, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.

- The sponsor works with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your study data in the same way as the sponsor.

- The sponsor will not disclose personal health information to insurance companies unless required to do so by the law, or unless you provide separate written consent to do so.

- Your medical records and study data may be held and processed on computers.

- If research related procedures are performed within the Rochester Regional Health (RRH) (i.e. laboratory tests, imaging studies and clinical procedures), the results will be placed in your Electronic Medical Record (EMR). Once placed in your EMR, results are accessible to appropriate RRH staff who are not part of the research team.

Your personal health information may no longer be protected by HIPAA privacy rule once it is disclosed by your study doctor/investigator to these other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor/investigator or Rochester Regional Health. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing written notice to the study doctor/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor/investigator or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. The sponsor will still use study data that was collected before you cancelled your authorization. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

Your authorization for the use and disclosures described in this Data Privacy Statement (DPS) does not have an expiration date.

Note: If there is not a sponsor for the protocol, remove such reference in the HIPAA statement. Additionally, if the HIPAA statement is altered (either by the request of the sponsor or other regulatory site, the DPS must be reviewed and approved by the IRB prior to use in the consent form.

Contact Persons

The consent form must address three (3) areas for subjects' questions, namely, questions about the research itself, questions about research related injury, and questions about subjects' rights. Examples of acceptable wording for this section:

For more information concerning this research you should contact (specify name) at (telephone number) (Note: this person is usually the principal investigator)

If you believe that you may have suffered a research-related injury, contact (specify name) at (telephone number) who will give you further instructions. (Note: this person is usually the PI, or, if the PI is not a physician, some prearranged medical contact.)

If you have any questions about your rights as a research subject, you may contact the IRB Administrator of the Rochester Regional Health Institutional review board at 585-922-5640.

Where Can I Find Additional Information About This Research Study or the Research Results?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. It may be many years; however before research results are posted.

Voluntary Participation

Recommended wording for this section:

"Participation in this study is voluntary. You are free not to participate or to withdraw at any time, for whatever reason with no impact on your care or treatment for your condition. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner."

Signatures / Dates

The signature of the subject and/or subject's legal representative indicates an agreement to participate. The date (which should be in the subject's writing) is meant to indicate that consent was obtained prior to the subject being involved in any research procedures. With few exceptions, the subject's signature and date of signature are required by the federal regulations for human research subject protection and is the Rochester General Hospital's research policy.

The signature of the subject's patient representative indicates permission to participate is granted by a person legally empowered to give consent to research. For some research, this is appropriate (e.g., coma studies) and for some it is not appropriate (e.g., survey research)

The signature of the person obtaining consent indicates that the form has been read by or read to the subject, that an appropriate explanation of the research was given, that questions from the subject were solicited and answered to the subject's satisfaction, and that, in this person's judgment, the subject demonstrated comprehension of the information. While this signature is not required by the federal regulations, the Institutional review board does require this signature for all research that presents greater than minimal risk to subjects. The date of signature should also be recorded when this signature line used.

The signature of a witness attests to the fact that the subject has indicated to the witness that the research has been explained to them, that the subject has read (or had read to

them) the consent form and that all of the subject's questions were answered. In the witness judgment the subject is voluntarily signing the consent form. This signature is not required by federal regulations; however, the IRB may require this signature for some research that presents greater than a minimal risk to subjects. The witness should be used when subjects may not completely understand the process (e.g. diminished capacity, vulnerable populations, children or for persons with decreased competency). This is both a protection for subjects as well as investigators. The date of signature should also be recorded when this signature line is used.

Recommended wording for this section:

"Patient/Patient Representative

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I will receive a signed copy of this form for my records and future reference.

_____	_____	_____
Print Name	Signature	Date
_____	_____	_____
Patient Representative – Print	Signature	Date

Relationship if other than the subject: _____

PERSON OBTAINING CONSENT

I have read this form to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

_____	_____	_____
Print Name	Signature	Date

For studies with <u>minors</u> (over the age of 7 and under age 18), two forms may be used (an 'assent' with the child's signature line and a 'permission form' with the parent's signature line) or, if appropriate, one form with both signature lines. Note: Some research with children may require the permission of both parents. In this type of

research, two parental signature lines would be needed for documentation. IRB policy requires parental permission for all research involving minors as subjects.

OR FOR STUDIES WITH MINOR SUBJECTS WHO CAN GIVE THEIR ASSENT INCLUDE BOTH OF THE FOLLOWING SIGNATURE LINES:

Patient/Child Assent (for children over the age of 7)

It has been explained to me that I am going to be in a study. Information about me will be collected as part of the study. My parent or guardian is giving permission for me to be in this study. I have been allowed to ask questions about being in the study. My questions have been answered in a way I understand. I agree to be in this study.

_____	_____	_____
Child Print Name	Signature	Date

Parent/Guardian

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give permission for my child to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____	_____	_____
Parent/Guardian Print Name	Signature	Date

Continue with the standard "Witness" and "Person Obtaining Consent" sections.