Informed Consent Outline

Informed consent forms should be submitted according to the following outline.

- The form must explain to the subject all of the following elements in **lay terms** and in narrative form.

- The body of the consent document should be written in second person (i.e., "you", "your", "your child") followed by a subject statement of voluntary participation written in first person (i.e., "I hereby consent to participate").

- The use of short sentences, personal pronouns, clear page layout, and large fonts make documents easier to read. Consent forms not easy to read due to crowding or small type will not be accepted.

- The font must be at least 12 point although 14 point is preferred. Larger font should be used if subjects may be visually impaired and/ or for older populations. Be generous with spacing.

- Each page of the consent should be numbered and have a patient-initial line in the footer.

- The consent form language generally should not exceed an eighth grade reading level. Technical or scientific terms must be adequately explained or common terms substituted.

- The use of simple outlines, flow charts, diagrams, time lines, and other graphics are encouraged.

- The consent form may not contain any language that 1) suggests coercion or undue influence, 2) suggests a guarantee or assumption of success of the study, or 3) requires waiver of a subject's rights or releases any party from liability.

The example language (italics) provided below is for guidance. Statements in the actual

consent form should reflect specific and accurate information about your study. All of the sections must be present in the consent form.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY

PRINCIPAL INVESTIGATOR AND CO/SUB-INVESTIGATORS

Address
Telephone number

SPONSOR

Organization Name and Contact Name
Address
Telephone number

INTRODUCTION AND PURPOSE OF STUDY

Begin with a statement that the study involves research. Give an explanation of the purpose(s) of the research and why the potential research subject is eligible to enroll; an approximate number of subjects involved; and the expected duration of the subject's participation. If the study is to determine safety and effectiveness of a test article, it should be stated in the purpose.

1. *You are being asked to voluntarily participate in a research study.*
2. *The purpose of this study is:*

   Phase I studies:

   a. To test the safety and effects (good or bad) of <u>drug/intervention</u> for your _____

   b. To find the highest dose of this drug that can be given without causing severe side effects.

   Phase II studies:

   a. Test the effects (good and bad) and the safety of <u>drug/intervention</u> for your _____.

   Phase III studies:

   a. Test the effects (good or bad) and safety of a new treatment compared with the commonly used one for_____.

   b. Test the effects of a new treatment compared with no treatment.

3. *You are being asked to take part in this study because (eligibility criteria).*
4. *This research is being done because:*

   a. Currently we do not know which of these treatments are better.

 Patient initials_____

b. Currently, there is no effective treatment for your _____.

5. *You will be one of approximately (#) of people involved in this research project.*

6. *Your participation will last for approximately (length of time). (Where appropriate, state that the study will involve long-term follow-up).*

DESCRIPTION OF PROCEDURE

Describe all procedures to be followed, whether or not experimental. Specifically identify any that are investigational. Be specific and avoid technical terms. The information is intended for the patient's understanding of what is going to happen to him/her. If subjects are to be randomized, adapt the following language to your specific study:

> *It is not clear at the present time which (drug, treatment, device, etc,) is better. For this reason, the (treatment) given to you will be assigned based on chance, using a method of selection called randomization which is similar to flipping a coin. Neither you nor your doctor will choose what group you will be in. Your chance of receiving (one of, either, etc.) treatment is (equal, one in three, etc.)*

If the study is blinded, add the following statement:

> *Neither you nor your doctor will know which treatment you are receiving, but this information is available in the event of an emergency.*

POSSIBLE RISKS/DISCOMFORT/SIDE EFFECTS

Inform the subject of all foreseeable risks and discomforts, such as expected and possible rare side effects. There should be a clear itemization in the consent form of types of adverse experiences and the relative severity. Mild side effects should be those that do not require a therapeutic intervention. Moderate side effects require intervention. Severe side effects are potentially life threatening or fatal, disabling, or require prolonged hospitalization. Rare side effects occur in less than one in a thousand subjects, uncommon side effects in less than 1% of subjects, common side effects in 1 to 10% of subjects, and frequent side effects are those that occur in more than 10% of subjects.

Where possible, organize side effects in a listing format as 1) frequent and most common side effects, 2) less common side effects, and 3) rare side effects. Highlight or otherwise identify side effects that may be irreversible or long term. List both physical and nonphysical risks. Nonphysical risks should be included when they could affect the subject's decision about participation. Relevant nonphysical risks include: inability to work, risks related to insurability and employment, risks to confidentiality, travel or time commitments, and psychological effects.

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For a procedure that is not experimental and would probably be performed whether or not the subject was in the study (such as anesthesia or central line catheters), risks and discomforts do not need to be disclosed. Informed consent forms to be obtained should be disclosed (i.e., "You will also sign a separate consent form for your surgery which will explain the risks of anesthesia)".

For a procedure that is not experimental but would not be performed if the subject was not part of the study (such as stem cell leukophoresis for bone marrow transplant), risks and discomforts must be disclosed.

Where allergic reaction is a potential a statement should be made similar to:

> *As with all medication (devices), side effects may include allergic reaction. Allergic reactions may range from minor reactions, such as itching or rash, to major life-threatening reactions that can result in death.*

For unforeseeable risks:

> *Any treatment has possible side effects. Treatments used in this study may cause some or none of the side effects listed. In addition, there is a risk of uncommon or previously unknown side effects occurring.*

If there is risk posed by reproduction or sexual activity during treatment, this should be disclosed in the "Risks" section of the consent form. A statement that there may be unforeseen risks to the embryo or fetus may not be sufficient if animal data are not available to help predict the risks to a human fetus. Informed consent forms should disclose if mutagenicity and teratogenicity studies have not been conducted/ completed in animals. Subjects, both men and women, need to understand the danger of taking a drug whose effects on a fetus are unknown. Include a statement about possible sterility when appropriate (for both females and males) and if it is permanent*:*

> *Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. In animal studies, it has been found _____. You should not nurse your baby while on this study. You will need to use a medically proven form of birth control (contraception) method while participating in this study.*

POSSIBLE BENEFITS

Describe any health benefits to the subject, or to others, that may reasonably be expected. Avoid any suggestion of guarantee or assumption of success. If a placebo is used, disclose there will be no benefit to the subject if they receive placebo. Payment for participation may not be listed as a benefit.

There may be no direct medical benefit to you. The possible benefit of the study includes_____. It is hoped this study will result in a better understanding of_____that may help others in the future.

Phase III studies: The possible benefits of taking part in the study are the same as receiving the treatments without being in the study.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT

State appropriate alternative procedures or treatment (or none) to the subject, including those that are not experimental. Identify when the subject could receive the treatment without being in the study.

Other options to being in this study include _____, other investigational therapy, treatment to relieve symptoms, or no treatment at all. You doctor will provide detailed information about the proposed therapy and the benefits of each of the various treatments available.

COMPENSATION AND COSTS TO SUBJECT

State if the subject will be paid, including amount and schedule of payment(s). Payment should accrue as the study progresses and not contingent upon the subject completing the entire study. Identify what will be provided free of charge, such as drugs or diagnostic tests. Identify whether or not there will be additional cost to the subject as a result of participating in the research and if so, what that cost will be (i.e. transportation, drugs/devices, hospital charges, diagnostic & laboratory fees). Identify any potential costs for injury and any compensation available. Identify continuing medical care and/or hospitalization will be provided at the usual charges established to provide the care and who will be responsible for the costs. Also add the following language:

Your insurance company may not pay for investigational treatments; you should discuss coverage with your insurance company before agreeing to participate in this research study.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

State that the subject may decline to participate or discontinue participation at any time without penalty or loss of benefits.

Your participation in this study is voluntary. You have the right to choose not to participate or withdraw from the study at any time. Deciding not to participate or later withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled and will not affect your ability to receive

medical care from your doctor or the hospital, now or in the future. You will be informed of any significant new findings that may affect your treatment or your willingness to continue in the study.

State the medical consequences of a subject's decision to withdraw from the research as appropriate. When withdrawal from a research study may have deleterious effects on the subject's health or welfare, explain why withdrawal procedures are necessary for the subject's safety and specifically state why these procedures are important to the subject's welfare. A statement that the subject will be asked to submit to tests prior to withdrawal does not adequately inform the subject.

State any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

State if permission to follow the subject after withdrawing from the study will be requested. Disclose that the subject does not have to permit follow-up after withdrawing and may withdraw permission at any time.

STATEMENT OF NON-WAIVER

It must be clearly identified that the subject is not giving up any legal rights. The following statement is required by the NSH IRB;

By signing this consent form, you have not waived any of your legal rights or released any party from liability for negligence.

CONFIDENTIALITY AND REVIEW OF RECORDS

Include the following:

(1) a description of the personal health information that will be used or disclosed that identifies the information in a specific and meaningful fashion;

(2) identification of all persons or entities who may use or disclose the information;

(3) identification of all persons or entities who may receive or review the information;

(4) the purpose of each use or disclosure of the information;

(5) an expiration date or event for the use or disclosure of the information or a statement such as "end of the study," "none," or similar language;

(6) an explanation that the subject may revoke, in writing, the authorization to use or disclose his/her personal health information, except to the extent the investigator has relied upon the authorization;

(7) an explanation that the subject may refuse to sign the authorization; however, for research involving treatment, the investigator may condition participation in the study on signing the authorization;

(8) a statement stating that the potential exists for the individual's information to be re-disclosed by recipients and no longer subject to protection under the HIPAA Privacy Standards; and

(9) If the research includes treatment of the individual, a statement that the individual's right to access and copy their health information may be restricted as long as the research is in progress and that the right to access will be reinstated upon completion of the research.

Additionally, state what measures are taken to protect the privacy of personal health information. State that confidentiality cannot be guaranteed. When appropriate, this section should include a statement disclosing that the study will be covered by a certificate of confidentiality (if this is the case).

Efforts will be made to keep your personal information confidential. Absolute confidentiality cannot be guaranteed, however confidentiality will be maintained to the extent permitted by local, state, and federal law.

Your personal health information will be used and disclosed to others for this research study. A decision to participate in this study means that you agree to the use and disclosure of your personal health information for the purposes explained in this consent form.

During the course of this study the research team may use the following health information: [provide description of all health information to be used and disclosed]. The following individuals or entities will have access to your personal health information as necessary to conduct this research study: [include list of individuals and entities, their relation to the study, and the purpose for their use (e.g., principal investigator conducting the study, sponsor representative monitoring the conduct of the study]). Your personal health information may also be disclosed to [include list of individuals or entities and the purpose for the disclosure (e.g., representatives from the sponsor (identify), the Food and Drug Administration (FDA), the Institutional Review Board, or (other regulatory agencies) to monitor the conduct of the study)]. There is the potential of further disclosure of your personal health information by these individuals or entities such that your information is no longer subject to protection under federal regulations governing the privacy of health information. This research may result in scientific presentations and publications, but precautions will be taken to make sure you cannot be identified in any way.

By signing this consent form, you authorize the use of your personal health information until [provide expiration date, or state "end of study" or "indefinitely"]. You have the right to revoke your authorization to use your personal health information. The revocation must be in writing and [insert method for revoking authorization (e.g., sent to investigator at _____)]. If you revoke your authorization it will not apply to prior uses or disclosures of your personal health information made in accordance with the purposes explained in this consent form.

[To be included only for research involving treatment - If you refuse to provide authorization to use and disclose your personal health information for this study, the investigator may refuse to include you as a participant in this study.]

Your right to access your health information used and disclosed for the study may be restricted as long as the research is in progress; however, your right to access will be reinstated, upon completion of the research study.

For applicable studies that are governed by the United States Food & Drug Administration (FDA), the following statement must be provided verbatim:

"*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time*."

STUDY CONTACT PERSON TO HAVE QUESTIONS ANSWERED
Use the following statement and insert appropriate information.

If you have further questions or want more information concerning the research study and/or research-related risks or injuries, you may contact (principal investigator) at (telephone number - 24-hour access) at any time.

INSTITUTIONAL REVIEW BOARD REVIEW STATEMENT AND CONTACT PERSON
Include the following statement:

An Institutional Review Board (research review board) at has reviewed this study in the context of certain federal regulations relating to experimentation involving human subjects. Approval of this study by the Institutional Review Board is not an endorsement of this study or its outcome. If you have any questions or

concerns about this study or your rights as a research subject, you should contact the Chairman of the Institutional Review Board at [telephone numer].

STATEMENT OF VOLUNTARY CONSENT

Subject may certify that they understand the statements in the consent document and are satisfied with the explanation provided. The subject should not be asked to certify completeness of disclosure (e.g., "This study has been fully explained to me", or "I fully understand the study"). The copy of the consent given to the subject needs to be a signed copy. The copy should be given to the subject in advance of signing so he/she has an opportunity to review the information prior to making a decision. It is not necessary to repeat information found in the consent form in the consent statement. Please note: the subject/guardian must date the consent.

I have read all of the above or have heard it read to me. I have had the opportunity to ask questions about this study and my questions have been answered to my satisfaction. A copy of this consent form has been given to me. I hereby give my consent to participate in this study. I further authorize the use and disclosure of my personal health information for the purposes described in this consent form.

_____ _____ _____

Subject (representative) signature Date Time (*if procedure is done in hospital*)

_____

Representative's authority to sign for the subject

_____ _____ _____

Witness Signature Date Time (*if procedure is done in hospital*)

INVESTIGATOR STATEMENT OF INFORMED CONSENT PROCESS

The clinical investigator is responsible for ensuring informed consent is obtained from each subject before that subject participates in the study. The investigator does not have to personally obtain the informed consent but is ultimately responsible for the consent process. Investigators must ensure that the individual obtaining consent is knowledgeable about the research and can present the information to the subjects appropriately. Use the following statement:

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I have explained to the person named above, the nature of the research described above. To the best of my knowledge, the person signing this consent form understands the nature, demands, benefits, and risks involved in participating in this study.

_____	_____	_____
Investigator Signature (or designee)	Date	Time (*if procedure is done in hospital*)

Patient initials_____