Basic Elements of Informed Consent

It is imperative that the informed consent document is written in language using lay terms that are easily understood by the participant. The basic elements of informed consent are:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subject
- a description of any benefits to the subject or to others which may reasonably be expected from the research
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and, in the case of drugs or devices (requiring IND or IDE) a note that the Food and Drug Administration and the company sponsor may inspect the records. In addition, regulatory agencies such as the Office of Human Research Protection, the Institutional Review Board and the New York State Department of Health may also need to be included.
- for research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- In the case of patient /subjects, a clear statement as to which procedures are experimental and which procedures would be performed for medical reasons if the patient were not a research subject. Payment for the costs for research and medically indicated procedures must be clearly defined (borne by the research, the subject, or third party payers).
- for FDA-regulated studies, the possibility that the Food and Drug Administration may inspect the records needs to be included in the statement regarding subject confidentiality.
- An explanation of whom to contact to voice concerns or complaints about the research
- Contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff

*Minimal risk means that the risks of harms anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(g)]
Additional elements of informed consent to be provided when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. (for example: Include when the research involves investigational test articles or other procedures in which the risks to subjects is not well known.)
- A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. For example: Include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.)
- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent. (For example: include when there are anticipated circumstances under which the investigator may terminate participation of a subject.)
- Any additional costs to the subject that may result form participation in the research. (For example: Include when it is anticipated that subjects may have additional costs.)
- The consequences of a subject’s decision to withdraw from the research. (For example: Include when withdrawal from the research is associated with adverse consequences.)
- Procedures for orderly termination of participation by the subject. (For example: Include when the protocol describes such procedures.)
- A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject. (For example: Include when the research is long term and interim information is likely to be developed during the conduct of the research.)
- The approximate number of subjects involved in the study. (For example: Include when the research involves more than minimal risk.)

Some General Instructions:

It is very important that the PI and research team keep in mind that informed consent is an ongoing dialog, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. The fundamental mechanism by which investigators ensure respect for persons involves providing a thoughtful consent for the voluntary act of participating in a research study. The consent process must be described in your protocol.

• The consent form should be written at an eighth grade level. Avoid dense paragraphs using lengthy sentences. Use ‘bullets' and tables to clearly explain topics. Charts and Tables breaking out research risks when many different treatments are involved are strongly recommended.

• All scientific, medical and technical terms should be replaced with lay terms (preferable), or explained in lay terms.

• Use departmental or general Winthrop letterhead stationery for the first page.

This document should always include a footer with the following information:
Title of study, version # and date, section for patient’s initials
• Standard and suggested wording is contained in the consent template below. Please carefully review all the language to ensure correct information specific to your project is relayed to potential participants.

• The signed consent form must be filed in your research study files and a copy must be given to the participant or the participants legally authorized representative.

• The pages must be numbered and the footer (preferably, but header can be used for the title only) must contain the most current consent version #, the title of the study and an area for the subjects initials. The version date on the consent form must match the version date approved by the IRB. The only time a consent form version date changes is if there are revisions made to the consent form and approved by the IRB committee. The first page of the consent form must be on Winthrop or departmental Winthrop letterhead.

• The IRB office will gladly 'pre-review' a consent form at anytime via email or fax (# 8590). If you would like an MS word version of this document, please contact the IRB office.

Please Note: An Approved Consent Form will have a watermarked stamp of the date of expiration on each page. You must **never** use a Consent form that has expired.

*Please note when using this document all items in italics are for informational use and should not be added to your consent form.

*Many sections of this document include instructional text in red and italicized and should be removed prior to submission to the IRB.*

Blue text in parentheses () should be replaced by information for your study, e.g., (PI’s Name)

**The following must be at the top of the first page**

**INFORMED CONSENT/AUTHORIZATION FORM**

- Research Study Title *(the title should be consistent with the title of grant application/protocol)*
- Name of Principal Investigator: *(please note there can be only one Principal Investigator)*
- Name of Sub- Investigators or Co-Investigators:
- Name of Pharmaceutical Company or Sponsor of study

*Do not use a font smaller than Times New Roman (11pt.)*

**Reminder:**

*This document should always include a footer with the following information; Title of study, version # and date, section for patient’s initials*
The consent form should be written at an eighth grade level. In addition, please avoid shifts in person (2\textsuperscript{nd} to 3\textsuperscript{rd} person).

**Introduction**

**Every Consent Form must include an introduction**

A research study is designed to answer specific questions, sometimes about a drug or device’s safety and effectiveness. Being in a research study is different from being a patient. As a patient you and your doctor make decisions together about your health care. Conversely, when you are a research participant, the Doctor (known as the Principal Investigator, Study Doctor or Research Doctor) and the research staff follow the rules of the research study as closely as possible, without compromising your health.

Before agreeing to participate in this research study, it is important that you read this consent/authorization form. It describes the purpose, procedures, and the possible benefits and risks of the study. It also describes any alternative procedures that are available to you and your right to withdraw from the study at any time. This study is a clinical trial (research study involving human patients). Clinical trials include only patients who choose to take part; your participation is entirely voluntary. Please take your time to make your decision. You may want to discuss your decision with your friends and family. If you decide to participate, you will receive a signed and dated copy of this form to keep for your records.

**Introduction (for studies that involve children)**

By regulatory definition, “children” are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In New York State, a person under 18 years old is considered a “child,” and may not legally give consent, except for emancipated minors. (45 CFR 46.408(b); 21 CFR 50.55(e) (2))

A research study is designed to answer specific questions, sometimes about a drug or device’s safety and effectiveness. Being in a research study is different from being a patient. As a patient you and your doctor make decisions together about your health care. Conversely, when you are a research participant, the Doctor (known as the Principal Investigator, Study Doctor or Research Doctor) and the research staff follow the rules of the research study as closely as possible, without compromising your health.

This research study involves children who cannot legally consent to take part in this study. When a child cannot legally consent, his/her parent or legally authorized representative is required by law to sign the consent form. Use the following only if IRB Committee has required Assent of Minor. However, your child (age) must also agree (assent) to participate in this research study and sign the attached Assent of Minor form. If your child does not assent to participate, your child will not be included in this research study.

This consent/authorization form gives you detailed information about this research study. This information will help you decide if you would like to give your permission for your child to take part in this study. This consent/authorization form may have words or information that you do
not understand. If you should have any questions, please ask the study doctor. This study is a clinical trial (research study involving human patients). Clinical trials include only patients who choose to take part; your participation is entirely voluntary. Please take your time to make your decision. You may want to discuss your decision with your friends and family.

After you have read this consent/authorization form and discussed it with the study doctor, you will be asked to sign (and date, for FDA regulated studies) this form if you agree to allow your child to participate in this study. Your signature will show that you have been informed about the study and that you give your consent (permission) to have your child take part in this study. You will be given a signed (and dated for FDA regulated studies) copy of the consent form.

**Funding**

*Source of Funding can be included under your Introduction section if preferred*

*If your study is Sponsor-supported, use the language below:*

The study is being supported by (Sponsor’s Name) which is providing funding to Winthrop University Hospital and the Principal Investigator to cover costs related to your participation in this study. These funds may also be used to further the research or educational interests of the Investigator and/or the Institution.

*If your study is investigator-initiated, use the language below:*

This research study is sponsored by the Department __________ at Winthrop University Hospital.

*The following language should also be added if a Consultative or Financial Relationship exists for the Principal Investigator and/or any investigators in the study. If so, disclose in a separate paragraph in the consent form the name and precise nature of the relationship:*

**Consultative or Financial Relationships**

**Examples:**
- Dr. X is a paid consultant to the company sponsoring this study.  
- Dr. X is a paid consultant, paid member of the Advisory Board, and receives payment for lectures from the company sponsoring this study.  
- Dr. X is an unpaid consultant to the company sponsoring this study.  
- Dr. X is a founder of the company, has stock in the company, and is a paid consultant to the company sponsoring this study.

**Background and Purpose of this Research Study**

*This section should give an explanation in lay language (8th grade reading level is required) of the basic reasons this study is being conducted.*

*Example:*

You are being asked to participate in a research study (state what is being studied). We hope to learn (state what the study is designed to establish or discover). You are being asked as a possible participant in this study because (state why the participant is eligible).
This research study is looking for (insert number of participants). We expect (state number) of participants to enroll in this study here (at Winthrop) and (state number) nationwide (insert nationwide if applicable).

**Duration of Study Involvement**

This research study is expected to take approximately… (Days, weeks, months, etc.) Your participation in this study may last up to _______. You will be asked to return to the office _______ times.

**Study Procedures**

Consider inserting a chart or calendar, actual images can be very helpful to participants. Chronological descriptions are also helpful.

Include the following, as applicable, in this section of the consent in lay language:

- **Clearly identify what is experimental in this study** (e.g. Although ___________ and __________ are often part of standard medical care, these procedures are only being done for the purpose of the study and are not part of your routine care).
- **Indicate whether or not the drugs or devices are being used in ways that are not FDA approved**
- **State the purpose(s) of the procedures. Suggestion: refer to your protocol to assist you in identifying all protocol-related procedures.**
- **Indicate whether or not all participants will receive the same therapy**
- **Describe the process of randomization if applicable. If there are multiple study groups, clarify this by listing the groups as follows:** If you decide to enroll into this research study you will be assigned by chance to one of the following groups: Group A - receives xxx Group B - receives xxx. Neither you nor your doctor can determine or will know into which group you will be assigned. However, in case of an emergency….
- **Describe the use of placebo, if applicable.**
- **If there is a washout period, explain this in lay terms, including the length of time.**
- **If there is a follow-up period, state so and the expected length of time.**
- **Identify invasive procedures, where applicable.**
- **For labs, state what specimens will be obtained and the estimated amount. The total amount should be calculated and presented to the participant in lay terms, e.g., the number of tablespoons of blood drawn.**
- **If samples will be sent out for analysis, include a statement:** Your samples will be sent outside of WUH for analysis.
- **If samples, such as tissues or blood, will be destroyed at the end of the study add the following:** Any samples left over after analysis will be destroyed when the study is completed.
- **If samples will be saved for future research, insert Tissue Sampling for Future Use Text below.**
- **If contraception is recommended, insert Reproductive Risk Text for both women and men below.**
**Some studies involve deception and may need to include the following statement:**

As part of this experiment you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be given an explanation of what information was withheld from you at the end of your study participation.

**Risks Involved if you Take Part in this Study**

You should list possible side effects or complications that could occur. Comprehension is usually inversely related to the amount of information presented, so include only the things that you think are important for a potential participant to remember. The IRB committee prefers the use of table formats to summarize risk information. Be sure to include risks of being in a placebo or observation group.

**Example of table format:**

Risk and side effects related to *(name of drug)*

<table>
<thead>
<tr>
<th>Likely</th>
<th>Less likely</th>
<th>Rare but serious</th>
<th>Unlikely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When applicable provide a list of drugs and/or food that must be avoided.

*Note: It is appropriate to explain that even if the subject declines participation in the study, the same study procedures, treatments, etc. given as standard care would still carry the same risks.*

We cannot be sure how you will respond to the *(medications or procedures)* used in this study. The researchers will discuss possible difficulties and the chances that they will happen. Unknown problems may also happen. Problems may range from a minor inconvenience or may be so severe as to result in death *(indicate highest severity level if death is not applicable)*. You should report any problems to your doctor or to the director of this study *(PI name and phone number)*.

**Tissue Sampling for Future Research**

Research using tissue is an important way to try to understand human disease. However, prior to granting your tissue to be used for future research projects, there are several things you should know before allowing your tissues to be studied.

Your tissue will be stored *(insert how samples will be stored - and if appropriate how samples will be linked)* e.g., under diagnosis and medical record or code number and unlinked.

*If linked:* You have the right to refuse to allow your tissue to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified sample, e.g., as part of your routine clinical care, but not for additional research.

*If unlinked:* Because your sample will not be linked to your name after they are stored, you cannot
withdraw your consent to the use of the sample after it has been taken.

Optional:
The results of the study of your sample will be used for research purposes only and you will not be told the results of the tests.

Or
You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests.

Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Winthrop University Hospital and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

Include the following language if samples in study will be used for genetic testing or if future research on samples will include genetic testing.

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators (may/will) do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Note: GINA will decrease the potential risk for loss of insurability and employability by protecting research participants from discrimination as a result of findings made through genetic testing. The Informed Consent document and process should outline these protections if there is a possible risk to the participant.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information

If investigators will not share the research results with the participant, the following language can be added:
The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

This document should always include a footer with the following information;
Title of study, version # and date, section for patient’s initials
If investigators will allow participants to choose whether they want to receive test results and/or will contact participants in the future, the following language (two choices of language) can be added:

Regarding informing you of the test results, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

______Yes I wish to be told the test results.
______Yes ____No I wish member(s) of my family to be told the test results.

Or

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Reproductive Risks

If applicable the following section is recommended when women of childbearing potential (non-pregnant) will be enrolled in an investigational study:

No birth control method completely eliminates the risk of pregnancy. If pregnancy occurs, there may be risk of miscarriage, birth defects or other unforeseen medical conditions.

For Female Participants:
If you are a woman and sexually active, you should not be pregnant or become pregnant or breastfeed while you are participating in this study. (Indicate for how long after the study the patient must not become pregnant). Since the drug used in this study is experimental, it may cause unknown risks to the unborn fetus or the baby of a nursing mother. Women of childbearing potential will be given a pregnancy test before entry into the study. (Indicate if this will be done at each subsequent patient visit).

Acceptable active methods of birth control must be used during this study. Examples are: oral contraceptive (birth control pills), subcutaneous implants (implanted under the skin), intrauterine
devices (IUD), barrier methods (diaphragm), surgical sterility (tubal ligation), transdermal birth control patch and abstinence (no sexual intercourse). Your doctor will discuss these options with you.

If you think you have become pregnant while participating in this study, it is important that you contact the study doctor immediately. You will be taken off the study drug and withdrawn from the study optional based on study. You must also inform the study physician if you become pregnant within____months after your participation in this study ends.

*If there are risks associated with men fathering a child, add appropriate language:

For Male Participants:
If you are male and you are sexually active, you should practice an acceptable birth control method. Examples are: barrier methods (condoms), surgical sterility (vasectomy), and abstinence. Your doctor will discuss these options with you. You must continue using these methods for up to ____months after your participation in this study ends.

The study physician must be notified immediately if your partner becomes pregnant while you are enrolled in this study. You will be taken off the study drug and withdrawn from the study optional based on study). You must also inform the study physician if your partner becomes pregnant within____months after your participation in this study ends.

**Audio/Video Photos**

*For audio/video/photos the following paragraphs may be appropriate:

One aspect of this study involves making [audio or video recordings/photographs] of you. [Then describe why the recordings/photographs are being made, who has access to the recordings, how they are labeled and if or when the recordings/photographs will be destroyed. Depending on whether or not you would include the subject’s data in the study if s/he refused to be recorded/photographed, choose one of the following two statements to add to this section:]

*If audio or video recording/photographs are optional, (i.e., you would still enroll the subject in the study if he/she refused to be recorded/photographed), use this statement: You should initial below to indicate your preferences regarding the optional [audio or video recording/photographs].

You give permission to [make/take] [audio or video recordings/photographs] during this study.  
_____ Yes  _____ No

If audio or video recording is required as part of the study, (i.e., you simply would not enroll the subject in the study if s/he did not want to be recorded), use this statement:

_____ Your initials here indicate that you know that [audio or video recordings/photographs] of you will be [made/taken] during this study.

**Benefits**

*This document should always include a footer with the following information:*
Title of study, version # and date, section for patient’s initials
Describe direct benefits, if any. Include one or more of the following, as appropriate to the specific study:

- This research study includes procedures that may change the treatment you would otherwise receive. We hope knowledge gained will be of benefit to you.
- There is little chance you will benefit from being in this research study. However, we hope to gather information that may help people in the future.
- There is no direct benefit to you expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future.
- This research study is designed to select by chance which treatment you will receive. It is not known if the treatment you will receive will be of benefit to you. There may be no direct benefit from agreeing to participate in this study.
- At this time, there is no direct benefit for you.
- Results of this study are for research purposes only. However, this study may help others in the future if xxxx can be established

### Alternatives

Explain any Alternatives in lay language. Explain whether or not the research therapy can be obtained off the study. If there is no alternative other than not participating, (e.g., some cancer research) indicate that there may be alternate palliative treatments that are not curative. Choose one of the following as may be applicable;

- The therapy offered in this research project is available to you without enrolling in this study.
- Because it is experimental, this drug or device or therapy is only available to you in the context of this research.
- There are no alternatives to participation in this study, except that you may choose not to take part in this study.
- You do not have to take part in this study to receive treatment for _____ (disease). If you decide not to take part in this study, there are other therapies such as________ to treat your ______.

### Confidentiality

This section of the consent form describes how your information in this research study will be used, shared and safeguarded in relation to this study. Your information will only be used in accordance with this authorization/informed consent form and as required or allowed by law. Please read it carefully before signing it.

### Authorization to Use Your Health Information for Research Purposes

The federal privacy regulations, Health Insurance Portability and Accountability Act (HIPAA) requires that we get your permission to use personal identifiable health information about you that is either created by or used in connection with this research study. This permission is called an Authorization. The personal identifiable health information (PHI) we will use includes the entire research record and supporting information from your medical records, results of laboratory tests, and both clinical and research observations made during your participation in the research.
What Personal Information Will Be Used or Disclosed?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct identifier.

Who May Use or Disclose the Information?

Your research records may be disclosed outside of Winthrop University Hospital, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to only research study personnel. However, the sponsor [Sponsor Name and any other entities (CRO)] may further release information resulting from this study. Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule (HIPPA), the information is no longer protected by the Privacy Rule and may be subject to re-disclosure.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Who May Receive or Use the Information?

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

(The name of the Sponsor), and/or the sponsor’s agents [e.g. CRO name], the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), regulatory agencies in other countries, and to Winthrop University Hospital. Please note, you must list EVERY person and organization (including data monitoring committees, government agencies, companies-such as a CRO, coordinating centers, management centers etc) who may use, receive and/or disclose protected health information. If you do not include a person or organization on this form, they may not use, receive nor disclose protected health information for research purposes.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage:

State here whether you are keeping data on a computer that will identify the subjects in the study. If you are, explain how you are protecting this information. Give details: for example, is the computer in a locked room, is it part of a network, is a password required for getting onto the system, who has access to these data, etc.

Certificate of Confidentiality

Include the language below if it applies to your study, if not continue with “access to my medical record...”

A Certificate of Confidentiality has been granted by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators (research staff) from being forced to release any research data in which the subject is identified even under a court order or subpoena. This protection is not absolute. For instance, it does not override any state requirement to report child abuse to the appropriate authorities.
Will access to my medical record be limited during the study?

While the clinical trial is ongoing, the Investigator or Winthrop University Hospital may refuse to permit you to access your personal identifiable health information obtained in the course of the clinical trial. However, you will have access to this health information following the completion of this clinical trial.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate in this study, your Authorization allowing us to use and disclose your identifiable health information will expire at the end of the research study, unless you withdraw your authorization sooner. State law does not allow you to say “indefinitely,” so instead you should list a date 50 or more years in the future. You always have the right to withdraw your Authorization by putting your request in writing to Dr. [PI] as stated below in the “Voluntary Participation and Withdrawal from Study” section of this form. If you withdraw your Authorization, you will also be removed from the study, but you will continue to receive any standard medical care and any other benefits to which you would normally receive as a patient at Winthrop University Hospital. However, if you do not send us this request in writing we may continue to use your personal identifiable health information that was collected up until your withdrawal from the research study to maintain the integrity of the study.

**Significant New Findings**

Any new findings discovered during this research study that may affect your decision to continue to take part in this study will be shared with you by your study doctor as such information becomes available. At times, you may even be asked to sign another informed consent document.

**Research-Related Injury**

*The informed consent form must include language on participant compensation in the event of a research-related injury*

*Use this language for Non-Industry Sponsored Projects, including projects with federal funding (i.e., NIH funding, Investigator-initiated Studies)*

If as a result of your participation you experience physical injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available. No funds have been set aside for compensation; therefore you will be responsible for the costs of such medical treatment, either, directly or through your medical insurance and/or other forms of medical coverage.

*Use this language for Industry-Sponsored Projects (i.e., Pfizer):*

If you experience a research-related injury, medical treatment will be provided at no cost to you. The term “research-related injury” means an injury caused by the product or procedures required by the study that are different from the medical treatment you would have received if you had not participated in the study. *Your sponsor may request additional language in this section; please consult with the IRB office before adding any other language.*
Additional Costs and/or Payments

Clearly explain the costs which may be charged to the participant insurance co. versus the charges which will be paid for by the sponsor. (For Investigator-initiated studies, the charges may be incurred by the Department). This information should correspond with the protocol. Use suggested wording as appropriate:

There will be no cost to you for participating in this study. All study costs, including study medication and procedures directly related to the study, will be paid for by…

The following paragraphs are examples if there might be additional costs to the participant due to their participation in the research:

If you participate in this study, there may be additional costs to you. These may include the personal time that you will need to use to come to the doctor’s office for all of the study visits.

You will receive a reimbursement for expenses you may incur. or You will receive a compensation of ____ per completed visit for your time and travel expenses. You will receive this compensation after each fully completed scheduled visit and/or follow up phone calls. If you withdraw or are withdrawn from the study early, you will receive (please fill in as appropriate, i.e. pro-rated payment).

The study will pay for the services, supplies, procedures and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

If payment exceeds $600 include the following statement:
Winthrop University Hospital is required to report payments of $600 or more to the Internal Revenue Service (IRS). “This means that if you receive $600 or more from Winthrop University Hospital during any calendar year, these payments will be reported to the IRS and you will receive an IRS 1099 Form.” You may then be responsible for taxes on these payments.

If there are costs to participants, as outlined in the sponsored agreement, you should describe the costs to be paid by the participants. (e.g., If your insurer refuses to pay, you will be responsible for paying (include all that is applicable):

- Costs of the investigative drug, device or material;
- Applicable co-payments and deductibles related to the research item or service;
- Routine medical costs to conduct the study, including monitoring for side effects and study complications
Voluntary Participation and Withdrawal from Study

Your participation in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time during the duration of the study without penalty or loss of any care and without affecting your future medical care at Winthrop University Hospital.

For research studies that involve treatment use the following language:

You have the right to refuse to sign this Authorization/Consent document. If you do not wish to authorize the use and disclosure of your personal identifiable health information, (PHI), you will not be able to participate in this research study. However, any standard medical care and any other benefits to which you would normally receive as a patient at Winthrop University Hospital will not be affected.

For research that does not involve treatment use the following language:

You have the right to refuse to sign this Authorization/Consent form and refuse to take part in this research study. If you choose not to authorize the use and disclosure of your personal identifiable health information (PHI) or to take part in this research study, any standard medical care and any other benefits which you would normally receive as a patient at Winthrop University Hospital will not be affected.

If you withdraw from participating in this study, you may also want to withdraw your authorization for us to use your personal identifiable health information. Any identifiable health information that has already been used and disclosed to [Sponsor Name] or the [Data Coordinating Center] cannot be withdrawn. If you do decide to withdraw, we ask that you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing your authorization for the use and disclosure of your identifiable health information. Dr. [PI’s] mailing address is [address]. However, even after you have requested that we no longer use your personal identifiable health information, we may have to continue to use the information that has been collected prior to your withdrawal in order to ensure the research study can be completed as necessary. We are unable to take back anything we have already done or any information we have already shared with your permission.

We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.

If applicable, add here information about the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation.

Should it be decided that it is not in the best interest of the study or your health to continue in this study or if you have been unable to follow the study doctor’s instructions, your participation in this study may be terminated by the sponsor or the study doctor. At that time we may ask your permission to continue using any identifiable health information that has already been collected as part of the study prior to your withdrawal. However, as stated earlier, we may continue to use the information that has been collected prior to your withdrawal in order to ensure the research study can be completed as necessary.
The following reason may be given as reasons to end your participation in this study:

*The reasons listed below are examples. Please read through this section carefully and modify as necessary.*

- If you develop a side effect or medical condition that may place you at risk of further complications by continuing your participation or if you need a medicine not allowed on this study;
- If you become pregnant;
- If you are unable to take the study medication or perform required procedures as instructed;
- If you are unable to keep your scheduled appointments;
- If the study is cancelled by the sponsor or by the FDA;
- For other administrative reasons

It is important that you remember to send your request to withdraw your authorization for us to use your individually identifiable health information in writing to Dr. [PI]. If you do not send us this request in writing we may continue to use your identifiable health information that was collected up until your withdrawal from the research study.

**Contact Information**

If you have any questions or concerns about this study or experience any medical problems, you may contact [Dr. X] or one of (his/her) associates at [telephone #]. If you need assistance outside of normal office hours you can call (516) 663-0333 and ask the operator to contact the [X-physician on call].

If you have any concerns, complaints or questions about your rights as a research participant, or any other matter related to your participation in this project, you may call Winthrop University Hospital’s administrative office of the Institutional Review Board Committee (IRB) at (516) 663-2552. The IRB is a committee required by federal regulations and New York State law. It is an independent committee comprised of Winthrop University Hospital’s physicians and staff, as well as lay members of the community not affiliated with the institution. The IRB reviews all proposed research involving human subjects before any study may begin at Winthrop University Hospital.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Director of Patient Relations at Winthrop University Hospital (516) 663-2058

**Consent to Participate**

You have read this page and the preceding [type in the #] pages of this consent form. In addition, the study doctor has explained to you the procedures in this study and the potential risks and side effects. You have been given the opportunity to ask questions about this study. You are aware that if you decide not to participate or to withdraw your consent, this will not affect any further treatment at this study site or any treatment by the study doctor. You voluntarily consent to participate in this study. You will receive a copy of this signed and dated consent form. You have not waived any of your legal rights by signing this consent form.

*This document should always include a footer with the following information;  
Title of study, version # and date, section for patient’s initials*
A description of this clinical trial will be available on 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.

**Note: The process of obtaining informed consent must comply with the regulations of the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA)**

SIGNATURE OPTIONS (choose one block) - The Principal Investigator is responsible for ensuring all participants enrolling in this study have provided informed consent. The PI may authorize other appropriately trained individuals to obtain informed consent and sign as 'designee.' These individuals must be listed in the IRB protocol. The individual signing below should be the individual obtaining consent.

Option 1 - to be used if study includes competent participants only

<table>
<thead>
<tr>
<th>Participant’s Signature</th>
<th>Printed Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed Name of Investigator Conducting Consent Discussion</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Signature of Investigator Conducting Consent Discussion</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Printed Name of Person who obtained consent signature (If different from above)</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Signature of Person who obtained consent signature (If different from above)</td>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>

Option 2: if study may include participants who do not have the capacity to consent
If your study receives IRB approval to include incompetent participants, include the following lines to signature section as the IRB has indicated is appropriate. The IRB approval is required to add this section. In some case participant's signature may be obtainable, however a second signature may also be required.

If participant is not competent to provide informed consent, please sign the appropriate line below:

<table>
<thead>
<tr>
<th>Individual with legally documented authority*</th>
<th>PRINTED NAME</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legally Court-Appointed Guardian</td>
<td>PRINTED NAME</td>
<td>Date</td>
</tr>
</tbody>
</table>
### Option 3

To be used if study includes competent participants who may not remain competent throughout the duration of the study. (may be used only when directed by the IRB Committee)

<table>
<thead>
<tr>
<th>Next-of-kin (state relation to participant)</th>
<th>PRINTED NAME</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed Name of Investigator Conducting Consent Discussion</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Signature of Investigator Conducting Consent Discussion</td>
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<td>Date</td>
<td></td>
</tr>
<tr>
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<td>Date</td>
<td></td>
</tr>
</tbody>
</table>

### Option 4

Use only if study may include minors and the IRB Committee has not required a separate Assent of Minor (age 7 - 17) as approved by IRB. * Please note the IRB reserves the right to require a separate ASSENT OF MINOR Consent Form.

If study may include minors add the signature line for assent. The parent or legal guardian should sign parent or guardian line and the minor should sign the Assent line.

<table>
<thead>
<tr>
<th>Participant's Signature</th>
<th>PRINTED NAME</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual with legally documented authority*</td>
<td>PRINTED NAME</td>
<td>Date</td>
</tr>
<tr>
<td>Legally Court-Appointed Guardian</td>
<td>PRINTED NAME</td>
<td>Date</td>
</tr>
<tr>
<td>Next-of-kin (state relation to participant)</td>
<td>PRINTED NAME</td>
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<tr>
<td>Printed Name of Investigator Conducting Consent Discussion</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Signature of Investigator Conducting Consent Discussion</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Printed Name of Person who obtained consent (If different from above)</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Signature of Person who obtained consent (If different from above)</td>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>
The study and what is involved when participating in this study has been explained to you. Any questions that you have asked have been answered.

__________________________________________________________________________________

Assent of minor  PRINTED NAME  Date

You agree to allow your child to participate in this research study.

__________________________________________________________________________________

Parent or Guardian Signature  PRINTED NAME  Date

Option 5: Use when subjects are minors (under the age of 7). Where assent is not relevant.

__________________________________________________________________________________

Parent or Guardian Signature  PRINTED NAME  Date

Printed Name of Investigator Conducting Consent Discussion  Date

Signature of Investigator Conducting Consent Discussion  Date

Printed Name of Person who obtained consent signature  Date
(If different from above)

Signature of Person who obtained consent signature  Date
(If different from above)

Option 6: If your study involves neonates, pregnant women or fetuses, in accordance with federal regulations, your study may require the signature of both the pregnant woman and the father. Please check with the IRB Office before submitting your consent document for IRB review.

__________________________________________________________________________________

Parent or Guardian Signature  PRINTED NAME  Date

__________________________________________________________________________________

Parent or Guardian Signature  PRINTED NAME  Date

Printed Name of Investigator Conducting Consent Discussion  Date

Signature of Investigator Conducting Consent Discussion  Date

Printed Name of Person who obtained consent signature  Date
(If different from above)

Signature of Person who obtained consent signature  Date
(If different from above)

This document should always include a footer with the following information:
Title of study, version # and date, section for patient’s initials
Option 7: For subjects (not minors) who are not able to read this consent document themselves, the following must be completed (add to your consent form if applicable and approved by the IRB):

*please note if you are know that many of the subjects will be fluent in another language, you are required to have a translated informed consent document in the subject’s primary language.

I confirm that I have accurately translated and/or read the information to the subject:

________________________________________________________________________
Signature
_________________________________________________
Print Name

Date: __________________

I confirm that the consent document was translated and/or read to the subject by the individual signing above:

Name of Witness: ____________________________________________

Signature: ______________________________________________

Date: __________________

________________________________________________________________________
Printed Name of Investigator Conducting Consent Discussion                     Date

________________________________________________________________________
Signature of Investigator Conducting Consent Discussion                     Date

________________________________________________________________________
Printed Name of Person who obtained consent signature                     Date
(If different from above)

________________________________________________________________________
Signature of Person who obtained consent signature                     Date
(If different from above)