

Chapter 12

CONSENT AND ASSENT

A. Consent

General Rule: The administration of informed consent is an ongoing educational process that takes place between the investigator and the prospective subject; it is not just a piece of paper that must be signed. The consent document does not substitute for discussion.

Informed consent is a person's documented, voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventative procedure.

Investigators must obtain legally valid informed consent from each subject or from the subject's authorized representative for any nonexempt research. Subjects document their consent by signing a written statement.

In most cases, written consent forms should be prepared below the 8th grade reading level. Even this may be too high if the subjects have lower educational backgrounds or verbal skills. Sometimes combining oral and written presentations increases the comprehension if one presents the information in a clear, brief and direct manner. It is also suggested that comprehension increases if the subjects have more time to review the information presented in the consent form.

In order to facilitate the review process by the CAMC/WVU IRB, it is requested that all informed consent documents utilize the following standardized format. The standard headings in bold type must be included in all informed consent documents submitted to the IRB. The standard clauses are already printed for your convenience.

B. Instructions for Preparation of Consent

Format and Style

The consent form must adhere to the following requirements.

- a. Use departmental letterhead of the principal investigator, if applicable.
- b. Use typewriter or printer ribbon dark enough for legible copies. Larger-than-normal type size may be necessary for some populations-such as children, the elderly, or the visually impaired.
- c. Number the pages (i.e., 1 of 4, 2 of 4, etc.)
- d. Divide the consent form into sections and use descriptive headings (e.g., "Purpose", "Risks and Discomforts," "Confidentiality"). Section titles may appear on a separate line or be underlined at the beginning of a paragraph.

- e. Use the first person, as though the subject were explaining the study to someone else (e.g., "I understand that...", "Dr. X will do...to me"). You may speak to the subjects in the second person only in a separate cover letter, cover page or narrative. A consent form to be signed by a parent, a guardian or authorized representative should be written in the first person, but refer to the subject in the third person (e.g., "I understand that my child will...", "Dr. X will do...to my child").
- f. Use lay language throughout. Explain the nature of the project, the nature of the subject's participation, and the nature of the risks and benefits involved in language clearly understandable to the anticipated subjects. **Try to keep language on an eighth-grade level.** If the study plans to enroll non-English speaking patients, a separate consent form in that language must be prepared and approved by the IRB.
- g. The Board does *not* allow separate signature pages; at least some portion of the text must be on the signature page.

Contents

The consent form must contain all applicable items listed below (items 1-13).
The Board may waive any of these requirements upon the written request of the investigator.
Explain why the provision is unnecessary or inappropriate.

- (1) The words "**Consent Form**" at the top of the page.
- (2) The complete title of the study **at the top of the first and last page.**
- (3) **Introduction or Research Study**
 - a. Include the following statement or its equivalent:
"I have been asked to participate in this research study."
 - b. Inform participants if the research is being done to fulfill requirements for a doctoral dissertation, master's thesis or classroom assignment.
 - c. Identify any external sponsor or funding agency.
"This study is being funded by (sponsor name)."
- (4) **Purposes**

Explain why the study is being conducted. ***For drug or device studies, no claims may be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation or that the drug or device is in any way equivalent or superior to any other drug or device.**
- (5) **Procedures**
 - a. Describe the procedures to be followed, specifically identifying any experimental procedures.
 - b. State the expected duration of the subject's participation.

- c. State the approximate number of subjects to be recruited in the study overall, and locally, as appropriate.
- d. Explain the randomization process and the likelihood of the subject's being assigned to an alternative.
- e. Explain any special circumstances under which you would terminate the subject's participation.
- f. If questionnaires or interviews are involved, inform subjects that they can see them before they sign the consent form and that they do not have to answer all of the questions.
- g. Subjects *must* be informed that appropriate care will be available or an appropriate referral will be made if a particular problem or disease is discovered and if they have an adverse physical or psychological reaction to the study.

(6) **Benefits**

- a. Describe any anticipated benefits to the subject or to others (such as generalizable knowledge).
- b. If students are to receive class credit, other opportunities must be available to earn extra credit and the consent form must so state. For example:
"I understand that I will earn extra credit for participating in this study. I also understand that other options are available for earning the same extra credit."

(7) **Risks or Risks and Discomforts**

- a. Describe any reasonably foreseeable risks or discomforts to the subject.
- b. For studies involving radiation, state the nature of the radiation and the risks involved.
- c. If the research could possibly put at risk: (1) an unborn child, or (2) a man or woman's ability to procreate or (3) a woman's ability to conceive or carry a child, the following statement(s) revised to meet the needs of your particular study should be included in the consent form:
"If I am pregnant, I cannot participate in this study. If I am a woman who could have children, it will be necessary to have a urine (or serum) test to see if I am pregnant before I start this study. If I am a sexually-active male or female, I agree to take precautions to avoid the possibility of impregnation because it is not known how this drug (treatment, device, etc.) will affect an unborn child. If I do not know what birth control methods are effective, I will ask my doctor. If I am a woman and become pregnant during the course of the study, I will notify the PI of this fact as soon as possible."
- e. For studies involving more than minimal risk, explain that the treatment or procedure may involve risks that are currently unforeseeable.

- f. For studies involving more than minimal risk, explain the availability of medical treatment if injury occurs.

(8) **Financial Considerations**

- a. Explain any costs/additional charges associated with participation. For studies involving clinical treatment, this includes expenses associated with the study that would not ordinarily be incurred with standard treatment for the subject's condition. Outline the projected costs to be "covered" by the study sponsor versus costs that will not be "covered/uncovered" by the study or the insurance provider. Indicate who is to bear the expense of tests, procedures, hospitalization, outpatient visits, etc. done solely for research purposes.
- b. For studies involving more than minimal risk, state whether or not costs for medical treatment will be provided if injury occurs as a consequence of the research.
- c. For studies involving more than minimal risk, state whether or not any money will be paid voluntarily as compensation for injury (e.g., for lost wages or for pain suffering) that occurs as a consequence of the research.

For example:

"If I am injured as a result of this research, compensation for my injuries will not voluntarily be provided by the investigator, Charleston Area Medical Center, West Virginia University, or other affiliated entities."

- d. Describe any monetary rewards or payments for participating; include an explanation of the extent to which payment will be made if the subject withdraws or is removed from the study prior to its completion.

(9) **Alternatives**

You must disclose alternative procedures or courses of treatment and their consequences, including nonparticipation in the study and no treatment whatsoever.

(10) **Contact Persons**

- a. In studies involving more than minimal risk, state whom to contact in the event of a research-related injury.
- b. Provide the name(s) and telephone number(s) of the principal investigator(s).
- c. Inform subjects that if they have questions concerning their rights as subjects of research. The following statement is recommended:
If I have any questions regarding my rights as a research subject, I may contact the CAMC/WVU Institutional Review Board at 388-9970.

(11) **Confidentiality**

- a. The following statement is mandatory:

"I understand that any information about me obtained as a result of my participation in this research will be kept as confidential as legally possible."

- b. State that research records may become part of a participant's hospital or medical records.
- c. For all drug and device studies, the following statement is mandatory:
"I understand that my research records, just like hospital records, may be subpoenaed by court order or may be inspected by the sponsor, federal regulatory authorities, including the Food and Drug Administration, without my additional consent."
- d. Explain any foreseeable circumstances which the investigator might be required to give information about the subjects to third parties (e.g., mandatory reporting of infectious diseases, mandatory reporting of information concerning child abuse).

(12) **Voluntary Participation**

- a. State that participation is voluntary.
- b. State that refusal to participate or withdrawal from the study involves no penalty or loss of benefits to which the subject is entitled, that grades and class standing will not be affected (for students or trainees), that status on the team will not be affected (for athletes), that job standing will not be affected (for employees or subordinates).
- c. State that the subject's questions about the research have been answered.
- d. For studies involving more than minimal risk, the following statement (or its equivalent) is mandatory:
"In the event new information becomes available that may affect my willingness to participate in this study, this information will be given to me so that I can make an informed decision whether or not to continue my participation".
- e. Include a statement telling subjects they will receive a copy of the signed consent form.

For example:

"My participation in this study is voluntary. I may refuse to participate or may discontinue participation at any time during the entire duration of the study without penalty or loss of benefits to which I am otherwise entitled. If I terminate my participation, I may receive standard medical care and no prejudice will be shown toward me for medical care or participation in future research studies. In addition, my participation may be terminated by the investigator or sponsor without regard to my consent if I need additional medication, my failure to follow directions, experience a medication-related injury, or for administrative reasons.

Any time my participation is terminated, I will be asked to go through the termination procedures for my own safety. I have read and understand this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily consent to participate."

(13) **Signature Lines**

Include lines for the following signatures and dates for each:

- a. The subject and/or the subject's authorized representative, if applicable.
- b. The investigator.
- c. The person obtaining consent other than investigator.
- d. The attending physician (if applicable and if it may be different from the investigator).
- e. A witness to the subject's signature if the form is to be read to the subject or signed by the subject's authorized representative.

The Board must approve all consent forms. Once the Board has approved a consent form, you must use the IRB stamped consent form; the Board must approve any changes. Only the most current IRB stamped consent form must be used.

C. Waiver or Alteration of the Consent Process

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent (45 CFR 46.11[c]) provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or is subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:
 - a. federal, state or local benefits or services which are not themselves research programs; or,
 - b. procedures for obtaining benefits or services under these programs; or,
 - c. possible changes in or alternatives to these programs or procedures; or,
 - d. possible changes in methods or levels of payment for benefits or services under those programs;
2. The research could not practicably be carried out without the waiver or alteration.

OR

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3. The research presents no more than minimal risk of harm to subjects;
The waiver or alteration will not adversely affect the rights and welfare of the subjects;
The research could not practically be carried out without the waiver; **AND**

Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Reasons for requesting that a consent be waived or altered should be explicitly stated in a cover memo accompanying the research proposal and protocol.

In exceptional cases, you may obtain the Board's permission to depart from the usual procedure. Alternative procedures include the following:

1. Oral Narrative with Short-Form Consent Document

In rare instances, such as studies of subjects in emergency situations, the Board may approve the use of an oral narrative coupled with a short-form consent document.

The procedure for the oral narrative with short-form consent document must include the following elements:

- a. A narrative that contains all the information and elements of the standard consent form may be read to the subject verbatim or may be paraphrased. (The narrative may be in the first or second person.)
- b. The subject (or the subject's authorized representative) signs only a short-form consent document which states that the subject willingly agrees to participate in the research described in the narrative.
- c. A witness must be present when the narrative is read to the subject. The witness signs the narrative and the short-form consent document to verify that the oral and written information were the same.
- d. The investigator signs the narrative and the short-form consent document.
- e. The investigator gives the subject signed copies of the narrative and the short-form consent document.

If you wish to use an oral narrative coupled with a short-form consent document, you must submit a letter (addressed to the IRB) in which you request this procedure and explain why it is appropriate. The Board requires the following items:

- the narrative that will be read to the subjects
- the short-form consent document

2. Oral Consent Process and Waiver of Signed Consent Form for Impaired or Illiterate Subjects

In rare instances, such as with impaired (e.g., blind or dyslexic) or illiterate subjects who are fully capable of consenting but are not capable of reading or signing a consent form, the Board may approve the use of an oral consent process. In such cases, the investigator reads a narrative to the

subject in the presence of a witness, and the witness signs a form to verify the subject's oral consent.

The procedure for the oral consent process must include the following elements:

- a. The narrative must be read or paraphrased from a document that contains all elements of the standard consent form. (The narrative may be in the first or second person.)
- b. After the narrative is read, the subject indicates consent orally.
- c. A witness must be present when the narrative is read to the subject. The witness signs the narrative and a "Verification of Oral Consent" form to verify that the narrative was presented essentially as written and that the subject consented.
- d. The investigator signs the narrative and verification form.
- e. The investigator gives the subject a signed copy of the narrative and the verification form.

If you wish to use the oral consent process, you must submit a letter (addressed to the IRB) in which you request this procedure and explain why it is appropriate. the Board requires the following items:

- the narrative that will be read to the subjects
- the verification of oral consent form that will be signed by the witness and the investigator.

3. Waiver of Signed Consent Form to Preserve Subject Anonymity

In many instances-especially in research involving only the use of educational tests, questionnaires, surveys, interviews, or observation-the principal risk to the subject would be a breach of confidentiality. When data was recorded so that subjects can not be identified, the only record linking the subject and the research would be the consent document. In such cases, the Board may waive the requirement of signed consent if it finds the risks resulting from a breach of confidentiality warrant such action. In these cases, after the subject has read a narrative that contains all elements of the standard consent form, he or she may provide explicit oral consent or implicit consent by voluntary participation in the research.

The procedures for the waiver of signed consent must include the following elements:

- a. All subjects must receive an information sheet, signed by the investigator and containing all elements of the standard consent form. Subjects must have an opportunity to read it before deciding whether to participate. The information sheet may be in the form of a narrative or cover letter and may be in the first or second person.
- b. The subjects may manifest their consent orally or-especially if anonymity is desired-their consent may be implicit from voluntary participation.

If you wish to obtain a waiver of signed consent, you must submit a letter (addressed to the IRB) in which you request this procedure and explain why it is appropriate. The Board must have a copy of the information sheet that will be read by the subjects.

4. Other Waivers or Alterations

The Board may approve substantial alterations to or waive any essential element of written informed consent only if all of the following conditions apply:

- a. The research involves no more than minimal risk to the subjects.
- b. The waiver of alteration will not adversely affect the rights and welfare of the subjects.
- c. The research could not practicably be carried out without the waiver or alteration.
- d. Whenever appropriate, the subjects will receive additional pertinent information after participation.

These conditions apply, for example, to any research that would involve participants in research *without their prior informed consent* or that would involve *deception* of subjects through incomplete or misleading information in the consent process.

Protocols in which the investigator seeks a waiver or alteration of the consent process under this provision may be eligible for expedited review by two board members.

D. Assent

Assent is the agreement by an individual not competent to give legally valid informed consent to participate in research.

General Rule: Written informed consent is required.

When potential research subjects are not competent to give legally valid informed consent, respect for personal autonomy mandates that the investigator obtain their voluntary assent to participate in addition to obtaining the informed consent of a parent, guardian, or other authorized representative.

Assent is generally required whenever:

- subjects are children between the ages of 7 and 18; or
- intellectually or emotionally impaired subjects are not legally competent to give their informed consent.

Subjects manifest their "assent" to participate by signing an assent form which, like the consent form, explains the nature of the research project, the nature of the subjects' participation, and the nature of the risk and benefits involved.

Format, Style and Content

The format, style and content of the assent form are essentially the same as for a consent form, except

- a. the language should be appropriate for the age and capacity of the subjects;

- b. certain provisions may be omitted if they would be confusing or would not be meaningful to the subjects.

The Board must approve all consent forms. Once the Board has approved a consent form, you must use that form. The Board must approve any proposed changes.

E. Waiver of Alteration of the Assent Process

When an intervention or procedure involved in the research may directly benefit the subject and is available only through participation in the research, the consent of the subject's parent(s) or guardian(s) is sufficient, and the subject's assent is not required. You should nevertheless solicit the assent of the subject; in such cases you may use a short-form assent document. You may give the subjects a signed copy of the consent form or narrative and a signed copy of the short-form assent document.

If you wish to use a short-form assent document, you must submit a letter (addressed to the IRB) in which you request this procedure and explain why it is appropriate. The Board requires the following items:

- the narrative that will be read to the subject, if different from the consent form to be signed by the subject's parent(s), guardian(s) or legally authorized representative;
- the short-form assent document.

F. Distribution and Storage of Informed Consent Documents

A copy of the consent form must be given to the subject or subject's family/representative. The copy with the original signatures and dates must be retained in the investigator's file for a minimum of three years after completion of the study and are subject to audits conducted by the FDA, sponsor, JCAHO and IRB.

JCAHO requires that a copy of the signed consent form be contained in the front of the patient's chart and that the front cover of the chart be clearly labeled as a "Research Subject". Documentation of the person obtaining the patient's informed consent and the date it was obtained must be recorded in the patient's medical record. It is recommended that this be noted in the appropriate "Progress Notes". The Investigator must make progress notes at least every three days in the research patient's chart. Before the study begins, the PI/Study Coordinator must document on the chart any patient education to the subject.

It is also recommended that documentation be maintained as to why a subject refused to participate once patient screening or the informed consent process begins.

SAMPLE CONSENT AND ASSENT FORMS

The following sample forms provide examples of format and language which the Board has previously approved or has developed to help investigators. You must adapt these examples to the particular procedures and subjects in each study; do **not** copy them mechanically.

Sample Form 1: Consent Form for Study Involving More Than Minimal Risk

Sample Form 2: Consent Form for Study Involving Only Minimal Risk

Sample Form 3: Assent

Sample Form 4: Short Form Assent

SAMPLE FORM 1

PROTOCOL TITLE

CONSENT FORM

INTRODUCTION

I, _____, willingly agree to participate in this research study, which has been explained to me by Dr. _____. This research study is being sponsored by (SPONSOR NAME) and conducted by the CAMC Health Education and Research Institute's Clinical Trials Center and _____.

I am being asked to participate in a clinical research study with _____, which is an investigational drug. Approximately 4000 patients will be tested in this study in approximately 400 sites worldwide.

My participation in this study is requested because I have had significant heart pain or heart attack within the last 12 hours. These symptoms might be caused by a partial blockage of one or more arteries in my heart and are referred to as unstable angina (chest pain). Blood clots are the most common cause of blockages in the arteries. Blood clots form when platelets, one of the components of blood, stick together. Presently, standard treatment for unstable angina includes aspirin and possibly heparin (a "blood thinner"). This standard treatment is effective in approximately 8 out of 10 patients treated. Therefore, we are in search of new treatments for patients with unstable angina that could be even more successful in limiting further damage to the heart.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the effectiveness and safety of the investigational drug _____ plus standard therapy (aspirin and heparin) compared to standard therapy alone. _____ prevents platelets from forming blood clots and may be helpful in reducing the time period needed for clots to dissolve. _____ may prevent further blockage of the artery by stopping formation of additional clots.

DESCRIPTION OF PROCEDURES

If I agree to participate in this study, I will be randomly assigned (like flipping a coin) to receive either active study drug _____, plus standard therapy (aspirin and heparin) or inactive study drug (placebo) plus standard therapy. The study drug will be given into a vein for 2 days minimum to 5 days maximum. If my doctor decides that I will need a heart procedure (which will open up the closed arteries of the heart) within the first 3 days of treatment, then the study treatment will need to be continued for at least 18-48 hours following the procedure, thus increasing the time to 5 days. Heparin will be given intravenously and aspirin will be given as a pill.

Before I begin treatment, my medical history and heart condition will be assessed and a physical exam will be performed (as well as a pregnancy test for females of childbearing potential). My blood pressure, pulse, weight and breathing, and my

heart tracing will be monitored frequently before, during and after I am given the study treatment. In addition, more frequent blood tests will be obtained during the drug administration to monitor the blood's ability to clot and to determine the blood concentration of _____ . Compared to routine cardiac care, an additional four (4) tablespoonfuls of blood may be required to perform these additional lab tests.

After initial treatment, the physician or hospital staff will be contacting me by telephone at 30 days to inquire about my state of health. A further follow-up at 6 months and 1 year will be done by phone or by mail.

Representatives of (SPONSOR) or the Coordinating Center staff may contact my doctor(s) and hospital(s) to obtain copies of my medical bills for up to six months following the date of my enrollment in this study.

Drug Treatment

I will be assigned with equal chances to one of these 2 groups:

- _____ with heparin and aspirin
- placebo (inactive study drug) with heparin and aspirin

The dose of _____ I will receive will be adjusted based on my kidney function. Neither my physician nor I will know the treatment group to which I have been assigned. However, if it becomes necessary for my safety, my physician will be able to find out which medication I am receiving.

Coronary Stent and Bypass Surgery

If my doctor decides that a coronary stent (a short wired tube to help keep the artery open) should be placed and ticlopidine or clopidogrel (anti-platelet clot-forming medications that might be given when a coronary stent procedure is needed) is initiated, then study treatment will be discontinued within 24-48 hours after initiation of ticlopidine or clopidogrel treatment. In the event of emergency bypass surgery, study treatment infusion will be stopped immediately.

RISKS AND DISCOMFORTS

Any drug treatment that reduces blood clot formation may be associated with an increased risk of bleeding. The most serious risk of bleeding is bleeding into the brain that may result in permanent disability or death. However, _____ has been studied in about 2000 patients and the rate of bleeding in the brain was very rare (approximately 3 out of 1000 patients treated) and comparable to the group that did not receive _____. Stomach or intestinal bleeding was observed in approximately 4 out of 100 patients. In cases where a decrease in the number of platelets has occurred (which could result in bruising or bleeding {such as nose or gum bleeding} for a longer than normal period of time), the platelet count has returned to normal within several days of discontinuing the drug without severe consequence.

I should not participate in this study if I have a history of brain and/or stomach/intestinal bleeding, or severe kidney dysfunction. My physician will carefully evaluate my eligibility for the study.

A risk exists for momentary discomfort, bruising, bleeding, inflammation or infection (rarely) at the site of needle insertion for blood drawing, or at the site of the venous injection. Allergic reactions requiring treatment have not been reported with _____. The possibility exists that complications and undesirable side effects, which are unknown at this time, could also occur. If I am pregnant, I will not be able to participate in the study because there may be a risk to the embryo, which is unknown at this time.

Heparin and aspirin are standard and commonly used treatments for patients with unstable angina. The most common risks for aspirin include stomach irritation and/or stomach bleeding. The most common risks for heparin include increased risk as well as allergic reactions such as fever, chills, and hives. My physician will explain to me any of these risks in more detail if I wish.

POTENTIAL BENEFITS

If I receive _____ and it proves to be effective, it may be of benefit to me by preventing heart damage caused by blockage of an artery. The dose of _____ used in this study was selected from previous studies as the best dose for _____ administration. It is possible, however, that I may not gain any direct benefit from participation in this study. However, while there is no guarantee that I will benefit, the knowledge gained from my participation may help others.

INJURY OR COMPLICATION (TREATMENT AND/OR COMPENSATION)

In the event that I suffer one of the possible side effects of this research drug (or procedure) as described elsewhere in this Consent Form, I understand that the Charleston Area Medical Center (CAMC) and the CAMC Health Education and Research Institute (CAMC Institute) have the necessary medical equipment and professional personnel available to treat or otherwise address the medication side effects, or procedure complications. Most minor side effects or complications can be managed right in the hospital/clinic treatment unit. Serious side effects or complications, however, might require (or prolong) hospitalization.

The fact that I am voluntarily participating in this medical research project does not automatically entitle me to receive monetary compensation or payment for the costs associated with research-caused side effects or complications.

Medical treatment will be paid (in excess of insurance payment) by (SPONSOR) for any injury that is a direct result of the treatment or study procedure. No other compensation is offered.

For more information concerning this particular research and research-related risks or injuries, I can talk with _____, Principal Investigator, at telephone number _____. In addition, if I have questions concerning my rights as a subject of this research study, I may contact the Office of the CAMC/WVU-PC Institutional Review Board at (304) 388-9970.

FINANCIAL CONSIDERATIONS

The investigational drug used in this study, _____, will be provided free of charge to me for this study. The regular cost of treatment and hospitalization for my angina, including treatment with heparin and aspirin, will be billed to my insurance carrier.

I understand that the following research-related tests will not be covered by (SPONSOR), CAMC or CAMC Institute, and will be my or my third party insurer's responsibility:

- Physical Examination
- 12-Lead ECG
- Platelet Count, Hemoglobin, Hematocrit
- Serum Creatinine
- CK/CK-MB and/or Troponin
- Pregnancy Test for Females of Childbearing Potential

I also understand that before I sign this consent form I and/or a Study Coordinator in CAMC Institute's Center for Cancer Research may contact the Charleston Area Medical Center Financial Counselors at the Memorial Division to assist me in contacting my private insurer(s) to determine whether or not these tests would be covered. By signing this consent form, I will be responsible for these and any charges not covered for the research-related tests.

ALTERNATIVES

If I choose not to participate in this study, I will receive the standard treatment for my unstable angina. This will probably include, but is not limited to, heparin and daily aspirin.

RESEARCH CONFIDENTIALITY

Some information obtained from my participation in this study cannot be held strictly confidential. In addition to the health care professionals caring for me, the U.S. Food and Drug Administration (FDA) or other local governmental agencies, my hospital's Institutional Review Board, the sponsor of this study, (SPONSOR), and their representatives may need to review my medical records. I will not be personally identified when material from my medical record will be used for publication or educational purposes. By signing this informed consent, I authorize the inspections of my medical records. Additionally, parts of my hospital records that pertain to my participation in this study in the first 6 months may be photocopied and sent to a central location for clinical review.

I understand that a record of my progress while on this study will be kept in a confidential form at the CAMC Health Education Research Institute's Clinical Trials Center located in the Medical Staff Office Building at Charleston Area Medical Center's Memorial Division complex.

VOLUNTARY PARTICIPATION

It is important that I am aware that participation in this research study is entirely voluntary and that I can refuse to participate in, or can withdraw from the study, at any time without penalty or loss of benefits to which I am otherwise entitled. In the event that I decide to withdraw from the study, I should notify the attending physician. Refusal or withdrawal will not influence my medical care.

My physician may decide to withdraw me from the trial without my consent if I have treatment failure (no beneficial effect), unacceptable side effects, or other illnesses that may affect the study treatment. The sponsor can decide to terminate the study early. Any significant findings discovered during this study, which may bear upon my condition, or my willingness to continue participation in this study will be provided to me and my physician.

In case of early withdrawal from the study, I will be contacted for follow-up safety assessments.

I have read the above information and I am aware of the purpose of the study as well as the potential benefits and risks of participation in the study. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing this form, I give my free informed consent

to be a participant in this study. I understand that _____ use in humans is relatively limited, and that there is risk of side effects to the drug. I will receive a signed copy of this consent form.

Print Patient Name

Signature of Patient

_____/_____/_____
Date

_____/_____
Time: hour/minute

Print Witness Name – if required

Signature of Witness – if required

_____/_____/_____
Date

_____/_____
Time: hour/minute

I, the undersigned, have fully explained the relevant details of this study to the patient named above and/or to the person authorized to consent for the patient.

Print Principal Investigator Name

Signature of Principal Investigator or designee

Date

Print Person Obtaining Consent Other Than Principal Investigator

Signature of Person Obtaining Consent Other Than Principal Investigator

Date

INTRODUCTION AND PURPOSE

I, _____, have been asked to take part in this research study because I am a family caregiver of an older adult. Nurse researchers in West Virginia University School of Nursing are carrying out this research. The first purpose is to learn how well the family caregiver-training program helps people give care to their older adult relative. A second purpose is to study how well consumers can learn from an instructor through Mountaineer Doctor Television (MDTV). With MDTV, the student and instructor can see and talk with each other through a special TV. _____ is the primary sponsor of this study. The _____ is also providing partial funding.

PROCEDURE

A total of 80-120 family caregivers, about 10-15 at each of eight community sites in southern West Virginia, will participate in a 10-hour, small-group training program. The instructor, a nurse specialist in aging, will present the program onsite at four (4) communities and through MDTV at four (4) other communities. A research-based book written for consumers serves as the text for the training program. The chapters and training classes focus on common problems of caring for frail older adults, such as managing pain, confusion, incontinence, skin care, falls, and daily functions.

I will take part in the study by going to five 2-hour training classes at the site in my community. I understand that the classes at my site will be taught by the instructor either being present or through MDTV. During each class, I will have the chance to ask questions about care giving and talk about my thoughts and feelings about care giving. I understand that I will get a free copy of the program's book on the first day of class.

I will also take part in the study by giving answers to questions on a survey at five times. The first time that I will answer questions is right after I sign this consent form to take part in the study. The second time will be at the start of the first class. The third time will be at the end of the last class. It will take about 30-45 minutes to answer the questions at each of these three times. The questions will ask information about my health, care giving knowledge, how I deal with events in my life, how I solve problems, and how satisfied I am with the quality of my life. There will also be questions about the quality of life and use of health care resources for the person receiving care. At about one month and again at about two months after the last day of class, I will be asked to complete a 5-minute phone interview to follow up on any care giving problems. I will be able to look at all the questions before I sign this consent form. If I agree to take part, I have the option not to answer every question.

RISKS

There are no expected risks involved in my attending this training program. The training program will not cover all problems caregivers may have, but I will be able to ask questions about my problems. I may feel discomfort in thinking about or discussing care-giving problems.

BENEFITS

By taking part in each class, I should learn something new about giving care to my older adult relative and about taking care of myself. I will receive a free copy of the training program book. Also, results of the study may benefit other family caregivers in the future.

CONTACT PERSONS

For information about this study, I can contact the Principal Investigator, _____ . For information about my rights as a research participant, I can contact the Research Review Specialist in the office of Research and Grants Administration at 388-9970.

CONFIDENTIALITY

I understand that any information obtained about me as a result of my participation in this study will be kept as confidential as possible. I understand that my research records may be subpoenaed by court order or may be inspected by federal regulatory authorities. In any publications that result from this research, neither my name nor any information from which I might be identified will be published without my prior written consent.

FINANCIAL CONSIDERATION

I understand that taking part in this study will cost me nothing. I understand that my voluntary participation in this research will not automatically entitle me to receive compensation for injury or payment for the costs associated with research-related injury. Without a showing of negligence on the part of the researchers, voluntary compensation for injury or costs associated with treating the injury will be left to the discretion of CAMC. I understand that nothing in this consent form causes me to give up any legal rights in the event that I might have to seek damages for injuries caused by negligence in this study.

VOLUNTARY PARTICIPATION

I understand that my participation in this study is voluntary. I am free to withdraw my consent to participate at any time. Refusal to participate or withdrawal from the study will in no way affect my receiving care at the health care site in my community. I have been given a chance to ask questions about this study and I have received answers about areas that I did not understand. Also, I understand that signing this form does not waive my legal rights in any way.

I willingly consent to take part in this study.

I have received a copy of this Informed Consent Form.

Signature of Participant

Date

Signature of Principal Investigator or
Investigator's Representative

Date

Signature of Person Obtaining Consent
Other than the Investigator

Date

Signature of Witness

Date

SAMPLE FORM 3

Student Assent Form

Research Project:

Principal Investigator:

Introduction: I, _____, have been asked to be in this research study. _____ are conducting this study, as part of the Health Science and Technology Academy (HSTA). HSTA is a program sponsored by the _____.

Purpose: The chief purpose of this project is to provide an educational research experience for 2 high school students who participate in HSTA. For their research, the 2 HSTA students want to see if preparing for and taking a science test in school causes students' blood pressures to go up.

Procedures: Up to 18 high school students who are taking Mrs. Marty Burke's science class (11:45 a.m. to 12:35 p.m.) will have their blood pressure measured on three different occasions in March 1998. The measurements will be taken several days before a science test; during the science test study period; and right before the science test. Two HSTA students and registered nurses will measure the blood pressure. Students who participate in the study also will be asked to state their age and race, and respond to general questions about activities that may increase blood pressure.

Confidentiality: I am promised that my name will not appear on any presentations or publications that result from this research.

Benefits: I understand that I will not receive benefits from participating in this research.

Voluntary Participation: I understand that I do not have to do this. No one will be mad at me if I refuse to do this or if I decide to quit later on. Also, I understand that my decision to participate or not participate will have no affect on my grade in my science class. I have been allowed to ask questions about the research, and all of my questions were answered.

I willingly agree to be in this study.

Signature of Subject

Today's Date

Signature of Principal Investigator
Or Investigator's Representative

Today's Date

SAMPLE FORM 4

TITLE:

ASSENT

(Children/Teenagers under 18 years of age)

I, _____, understand that I have T-Cell acute lymphoblastic leukemia (T-ALL) or advanced stage T-lymphoblastic lymphoma (T-NHL). I have had an opportunity to read this consent form and my physician has discussed this research project and explained the consent form in length to me, including the possible benefits and side effects of the treatment. I understand that participation in this study is voluntary and that if my parents or I wish to withdraw from this study, I will continue to be cared for with alternative methods of treatment. I have had an opportunity to ask questions about the research and agree to participate.

Patient Signature

Date

Physician Signature

Date

The undersigned physician, _____, M.D., hereby certifies that he/she has discussed the research project with the patient and has explained all of the information contained in the informed consent form appropriate for the patient's age and ability to understand, including possible benefits and side effects that may reasonably be expected to occur. The undersigned further certifies that the patient was encouraged to ask questions and that all questions were answered.

Physician Signature

Date