Human Research Seminar Series

Informed Consent Process & HIPAA Authorization Requirements

Monday, February 11, 2013

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Science at the heart of medicine

Einstein Institutional Review Board (IRB)

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Informed Consent Process & HIPAA Authorization Requirements

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Overview

• The consent document
• The consent process
• Obtaining informed consent
• Documenting informed consent
• Special protections
• HIPAA
### Purpose of Informed Consent

- Respect for Persons (principle of autonomy from the Belmont Report)
  - Research subjects must be given the opportunity to choose what will or will not happen to them

### Informed Consent Document: Purpose

- The Informed Consent Document (ICD)...
  - Provides a written summary of all the information that the participant needs to make a decision to participate
  - Provides a description of what is expected during participation
  - Explains the rights of a participant
  - Serves as a guide for the verbal explanation of the study
  - Documents the subject's agreement to participate in the study
  - Serves as a reference for essential study information
Informed Consent Document: Requirements

- Introduction, with a clear statement that the project is research
- Confidentiality of records statement
- Compensation for injury statement (for greater than minimal risk studies)
- Whom to contact about the research/problems
- Purpose of the study
- Description of the study procedures, including use of randomization and placebo controls

Informed Consent Document: Requirements (Part 1)

- Statement that the study involves research
- Explanation of the purposes of the research
- Duration of the subject's participation
- Procedures to be followed, and identification of any procedures which are experimental
- Reasonably foreseeable risks or discomforts
- Description of any benefits to the subject or to others which may reasonably be expected
- A disclosure of appropriate alternative procedures or courses of treatment, if any
Informed Consent Document: Requirements (Part 2)

- Statement describing the extent, if any, to which confidentiality of records will be maintained
- An explanation as to whether any compensation and/or medical treatments are available if injury occurs (for research involving more than minimal risk)
- Whom to contact for answers to pertinent questions about the research and research subjects' rights
- Whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal will involve no penalty or loss of benefits, and the subject may discontinue participation at any time without penalty or loss of benefits

Informed Consent Document: Additional Elements

- Required as applicable/appropriate:
  > Reproductive Risks: Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo/fetus, if the subject is or may become pregnant) which are currently unforeseeable
  > Involuntary Withdrawal: Circumstances under which the subject's participation may be terminated by the investigator
  > Costs: Any additional costs to the subject that may result from participation in the research;
  > Voluntary Withdrawal: The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  > New Findings: Statement that significant new findings which may relate to the subject's willingness to continue participation will be provided to the subject
  > Size of Study: The approximate number of subjects involved in the study.
Other Consent Document Requirements

- Consent Language For Genetic Testing
  - NY State Civil Rights Law specifies consent language that is required (1) to do genetic testing as part of a research protocol and (2) to use stored specimens for future genetic research.
  - Einstein IRB Policy ‘Collection and/or Study of Human Specimens,’ consent guidelines and future use templates are found at: http://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/specimens.pdf

The Process

- The informed consent process is the foundation of the research study. It establishes a relationship of trust between the participant and the research team and allows for the exchange of essential information to assist the participant in making an autonomous decision about participation during the evolution of a trial.
The Informed Consent Process

- Ongoing course of actions to ensure the participant’s **continuing informed agreement** to continue with study participation.
- The process **promotes a dialogue** and provides information that evolves with the progression of the study and the needs of the participant.
- It is a fundamental mechanism to ensure **respect for persons** through provision of thoughtful consent for a voluntary act.

The Evolving Consent Process

- Before participation
- Pre-consent contact (prior to enrollment)
- During the study
  - What could happen during the subject’s participation that may change a subject’s willingness to continue?
- When does the process end?
The Evolving Consent Process: 
Before Participation

• Advertisements (flyers, media ads, internet ads, press releases)
  > IRB approval is required
  > Specific guidelines apply, see:
    http://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/advertisement.pdf and
    http://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/Compensation.pdf
  > Advertisement form available at:
    http://www.einstein.yu.edu/docs/administration/institutional-review-board/forms/advertisement.doc

The Evolving Consent Process: 
Pre-Consent Contact

• Initial contact is over the phone, including:
  > Pre-screening (determination of preliminary eligibility)
  > Telephone surveys
  > To provide pre-study information to prospective subjects
The Evolving Consent Process: During Participation

- Providing information to keep the participant informed and to assess willingness to continue to participate:
  > On-study visits (communication, education, study-related instructions, abnormal lab results)
  > Amendments (add or change procedures, new consents)
  > Adverse events
  > New findings (risks, newly approved drug for same indication)
  > Change in subject health status

The Evolving Consent Process: End of Participation

- Normal study completion
- Subject voluntarily withdraws consent
  > Effect on patient safety
- Investigator terminates/withdraws subject from study
  > Patient safety
  > Patient doesn’t meet all inclusion/exclusion criteria
  > Patient violates protocol requirements
The Process of Consent

• Potential benefits of an effective process:
  > Increased protocol compliance
  > Enhanced subject safety
  > Increased retention rate
  > Increased reliability of data
  > Decreased subject-related protocol deviations

Who May Obtain Informed Consent from Participants?

• Those who are qualified to enroll subjects:
  > Must have completed the CITI educational requirement, which is required by YU/Einstein and Montefiore.
  AND
  > Must be knowledgeable about the study and capable of answering any questions that the research participants have.
  AND
  > Are considered Key Personnel and are listed in the IRB Research Application (or added as Key Personnel via an amendment).
  • Check your research application.
Obtaining Informed Consent

- Obtain consent prior to initiation of any research procedures.
- Adequate time must be given for the potential subject to make an informed decision. (The subject decides how much time is adequate.)
  > Consider allowing the subject to take the consent home for review and discussion prior to signing.
- The consent form must be read and the information understood.

Obtaining Informed Consent (continued)

- A potential subject may choose to include others (e.g. family members) in the decision making process;
- The informed consent dialog addresses the subject’s questions and concerns;
- The study team needs to assess the accuracy of information received and verify the subject's understanding;
- No research intervention, be it as non-invasive as a questionnaire or invasive as a liver biopsy, may be done prior to obtaining consent, unless consent is waived by the IRB.
- Signed ICDs can be faxed or scanned under some circumstances.
The Consent Discussion

- Consider the subject’s:
  - Maturity
  - Educational level
  - Cultural beliefs
  - Psychological, emotional, and physical limitations
  - Motivations
  - Vulnerability – pain, emotional distress
- Also must consider the type of study (end stage cancer, HIV, drug, device, sensitive info)
- **Ask open-ended questions to assess comprehension** (e.g. “Can you go over the main points of what I said? I want to make sure I explained everything to you correctly and didn’t forget anything.”)

Finally…

- The subject must sign and **personally date** the informed consent document.
- The person obtaining the consent must sign and **personally date** the informed consent document.
- A copy of the consent document **must** be given to the person signing the consent document.
- The consent **process** should be documented.
- The time of consent should be documented.
- The **original, signed** consent form is maintained by the investigator.
Documentation

• “If it wasn’t documented, it wasn’t done.”
• Documentation should be:
  > Attributable
  > Legible
  > Contemporaneous
  > Original
  > Accurate

Einstein IRB Documentation Requirements

• Federal Law requires written documentation that consent was obtained prior to participation in the study for drug and device studies. Institutional policy extends this requirement to all research that is more than minimal risk or that involves patients:
  > in significant pain
  > who have an altered mental status
  > who may not be capable of giving informed consent
  > in labor
Einstein IRB Documentation Requirements (continued)

- The documentation should include:
  > The title of the study
  > That the inclusion/exclusion criteria for enrollment in the study have been met
  > That the purpose, procedures, risks, benefits (if any), voluntariness, and alternatives were discussed, understood, and accepted
  > A statement that the person signing the consent was given a copy of the informed consent form
  > The date and time that the consent was obtained

Documentation

- Also:
  > A copy of the consent may be placed in the medical chart (check the institutional policy)
  > Document atypical circumstances.
- It is recommended that written documentation of consent always be completed.
- Template available: [http://www.einstein.yu.edu/docs/administration/institutional-review-board/forms/ic-note.doc](http://www.einstein.yu.edu/docs/administration/institutional-review-board/forms/ic-note.doc)
Reconsenting

- Subjects must be informed of any change in the protocol including important new information and new risks, and given the option to withdraw from the protocol.
  - Subjects currently enrolled in the study are not routinely required to sign the revised informed consent document. Such a decision is made by the IRB on a case-by-case basis.
  - Unless otherwise specified, they can be informed by phone, letter, or in person, with documentation in the research record.

Informed Consent – A Continuous Process
Non-Reading Participants

- A person who speaks and understands English, but does not read and write, can be enrolled in a study by “making their mark” on the consent document (when consistent with applicable law)
- Documentation that the ICD has been read and explained is required
- Thorough documentation of the consent activities is strongly recommended

Non-English Speaking Participants

- A fully translated document for populations commonly seen at this institution (Spanish)
  > The consent process should be conducted in the language of the participant. An interpreter (not family member) fluent in English and the subject’s language
  > Consent translation services (Spanish) are available through Bronx CREED’s Scientific Director and Research Core Director, Joel Zonszein, MD, at (718) 904-2883, or joel.zonszein@einstein.yu.edu.
- For a subject who speaks an unanticipated language, see the “Short Form Consent Process” slide.
Justification for Population Exclusion

• Scientific justification is needed for excluding non-English speaking subjects.
  > Insufficient funds to hire a translator is not an appropriate justification.
  > Lack of validation of the measures in the other languages is an appropriate scientific justification.

Short Form Consent Process

• The oral translation of informed consent information is permitted when a non-English speaking subject is unexpectedly encountered (does not apply to Spanish speaking subjects). Two documents are used:
  > A short-form (containing generic information about research) that is written in a language understandable by the subject
  > A written summary (the complete English consent) of what is presented orally
• A witness to the oral presentation, who is fluent in both English and the language of the subject, is required.
  > The witness cannot be a friend or family member of the subject.
Short Form Consent Process (continued)

- The subject must be given copies of the short form document and the summary
- At the time of consent:
  > the short form document must be signed by the subject
  > the summary (i.e. the English consent) must be signed by the person obtaining consent; and
  > the short form document and the summary must be signed by the witness.

Vulnerable Populations

- Vulnerable populations may consist of individuals who lack the capacity for self-determination:
  > Temporarily
  > Permanently
  > Related to maturity
  > Susceptibility to undue influence or coercion
Legally Authorized Representatives (Enrollment of Individuals Incapable of Consenting on their Own Behalf)

- Where feasible, prospective consent is preferred (e.g. before the incapacitation occurs).
- Only with (prospective) IRB approval.
- Generally limited to studies offering the prospect of direct benefit to participants and minimal risk studies.
- NYS’s Family Health Care Decisions Act (FHCDA) dictates the hierarchy of decision-making authority.
- If a subject regains decision-making ability, consent of the subject to continue participation is required.

Classes of the Population Requiring Special Protection

- Minors
- Patients in significant pain
- Patients who have an altered mental status (e.g. patients who are under the influence of sedatives or narcotics, etc.)
- Patients who may not be capable of giving informed consent (e.g. patients with mental retardation, dementia, acute psychiatric disorders)
- Women in labor
- Fetuses
- Prisoners
- Students, employees
Consent Forms for Research Involving Minors

- Ages 0-6
  - Parental Permission Form
- Ages 7-12 (capable of assenting)
  - Parental Permission Form
  - Child Assent Form
- Ages 13-17
  - Combined Parental Permission and Young Adult Assent Form
- Templates are available in PATS.

Signature Requirements for Research Involving Minors

- Generally the signature (permission) of one parent and signature (assent) of the child (aged 7-17) is required.
- The signature of both parents* is required for greater than minimal risk research with no prospect of direct benefit.
  - *Unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
Parental Permission: Is it Always Required?

- Parental permission may be waived in protocols designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. E.g.:
  > Where disclosure about the research to the parent may bring harm to the minor.
  > When the research involves procedures that NYS law permits on minors in the clinical setting without parental permission, e.g., abortion, STD treatment, etc.
  > NOTE: General counsel’s review is required.

Reconsenting - Minors

- When minors participate in a study over a period of time, they should be given the opportunity to (re)assent:
  > When they turn 7 and 13, and
  > Upon turning 18, individuals must consent to continuing in the research.
### Informed Consent Tips

- The consent conversation is private and should be performed in a location that ensures confidentiality;
- Only use consent forms that have been approved by the IRB and include the stamped dates of approval. Use the most recently approved consent form (print from PATS);
- Do not date the informed consent form for the subject;
- Maintain current and previously signed informed consent documents
- Document atypical circumstances
- Before the participant leaves the office, be sure the consent is complete and accurate (dates, initials, choices, etc.)

### ICD Stamp Samples

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Oral Consent  
(Waiver of Documentation of Consent)

- Requests for Oral Consent must be submitted to the IRB (via application or amendment) prior to use.
- Two waivers exist.
- Waiver #1
  > No more than minimal risk of harm to subjects
  and
  > Involves no procedures for which written consent is normally required outside of the research context

Oral Consent  
(Waiver of Documentation of Consent)

- Waiver #2:
  > For studies in which:
    - The only record linking the subject and the research would be the consent document
    and
    - the principal risk would be potential harm resulting from a breach of confidentiality.
  > Each subject is to be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
**Waiver of Informed Consent**

- **Requirements:**
  - No more than minimal risk.
  - Will not adversely affect the rights and welfare of the subjects.
  - Could not practicably be carried out without the waiver.
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- Similar criteria apply to HIPAA as well.
- Requests for a waiver of informed consent must be approved by the IRB.

**Health Insurance Portability And Accountability Act (HIPAA)**

- The Act establishes the conditions under which Protected Health Information (identifiable health information) may be used or disclosed by covered entities for research purposes.
  - Einstein, Montefiore, and NBHN (JMC/NCB) are all covered entities.
Core Elements Of HIPAA Authorization

- The Authorization Form templates on the Einstein IRB website and in PATS contain all of the required elements.
- Modification or use of another model requires review by legal counsel prior to use.
- The research participant must be given a signed copy of the HIPAA authorization form.
- Combined models (consent and HIPAA Authorization) require approval by the HIPAA Security Officer.

Alteration or Waiver of Research Participants’ Authorization

- A request for a waiver or alteration of HIPAA Authorization can be submitted to the Einstein IRB for review and approval.
- The criteria are listed in the Waiver/Alteration Form in the application forms (iRIS, PATS, and the MS-Word paper forms).
Exemptions from HIPAA Authorization

- Use of PHI preparatory to research, e.g., review of data to determine the feasibility of a study.
- Research on protected health information of decedents.
- Use of a limited data set

Questions?

- Any future questions, please contact the Einstein IRB
- East Campus:
  > Jackie Rowan, QA Coordinator
  > 718-430-2268
  > jacqueline.rowan@einstein.yu.edu
- West Campus:
  > Kathleen O’Connor, QM Analyst
  > 718-920-4151 x228
  > koconno@montefiore.org
# Einstein IRB Contact Information

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<th>East Campus IRB</th>
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  Bronx, NY 10467  
  • Phone: 718-798-0406  
  • Fax: 718-798-5687 |

Website: [http://www.einstein.yu.edu/irb](http://www.einstein.yu.edu/irb)  
Includes: Policies and Procedures,  
Submission Guidelines, Forms,  
and Educational Materials
Informed Consent Guidelines

Ethical Principles of Informed Consent

The principle of respect for persons requires that people be given the opportunity to choose what will or will not happen to them. Freely given informed consent must be obtained from every decisionally capable, potential adult subject before any research procedures begin, unless the IRB has waived some or all of the consent requirements.

This policy provides guidance for conducting a proper informed consent process and ensuring adequate documentation in the research record, in compliance with institutional policy, Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46) and FDA regulations (21 CFR 50 & 56).

Informed consent is not just a form or a signature, but a process of information exchange that takes place between the prospective subject and the investigator before, during, and sometimes after the study, which includes:

1. Subject recruitment materials;
2. Verbal instructions;
3. Written materials;
4. Question and answer sessions;
5. Agreement documented by signature.

I. WHO MAY ENROLL SUBJECTS

The Principal Investigator is required to submit to the IRB for each protocol the names of the individuals authorized to obtain informed consent from the subjects in the study. All of these individuals must be knowledgeable about the study and must have completed the training program required by Einstein and Montefiore. The PI must obtain the IRB's approval prior to adding additional individuals to the authorized list. The PI remains responsible for ensuring that adequate informed consent is obtained from each subject enrolled in the study protocol.

The prospective participants or their representatives must be given sufficient information to make an informed decision whether or not they want to participate and have the opportunity to have their questions answered. Consent must be informative, interactive, understandable, voluntary, and free of coercion or undue influence.

II. DOCUMENTATION REQUIREMENTS

FDA regulations (312.62(b) state "The case history of each individual shall document that informed consent was obtained prior to participation in the study" for studies
utilizing either an experimental drug or device or an approved drug in an unapproved fashion. Institutional policy extends this requirement to all research that is more than minimal risk or that involves patients

1. who are in significant pain,
2. who have an altered mental status,
3. who may not be capable of giving informed consent,
4. who are in labor.

A. Minimal Risk Research

For behavioral studies, observational studies, and clinical studies, the presence of the properly executed informed consent document in the study file is adequate.

B. All Other Research

The following should be documented in the research file by the person designated to conduct the consent process:

1. The title of the study
2. That the inclusion/exclusion criteria for enrollment in the study have been met
3. That the purpose, procedures, risks, benefits (if any), voluntariness, and alternatives were discussed, understood, and accepted.
4. That the participant was given a copy of the informed consent.
5. The date and time that the consent was obtained.

II. THE CONSENT PROCESS

The consent process contains four main components:

1. Information: "The reasonable person" standard should be used. This means that enough information is given to enable the person to decide whether or not to participate in the research. The person should clearly understand the range of risk, the potential benefits, if any, and the voluntary nature of participating in the study. Although each research study involving human subjects has unique elements, federal regulations and institutional policy require that all consent documents contain the following information elements:

   1. Introduction (with clear statement that this is research).
   2. Confidentiality of records statement (the mechanism for maintenance of confidentiality and who will have access to the research records and medical records).
3. Compensation for injury statement (for greater than minimal risk studies).
4. 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.
5. Purpose of study.
6. Description of study procedures (identifying any that are experimental), including use of randomization and placebo controls, if applicable.
7. For studies of investigational articles, a statement that the purpose of the study includes evaluation of the safety and/or effectiveness of the test article.
8. Duration of the subject's participation.
9. Potential risks, discomforts, and inconveniences of participation, especially for tests that carry significant risk of morbidity/mortality.
10. Potential benefits of participation, clearly presented and not overstated.
11. Alternatives (medical treatment or other courses of action, if any). If none, a statement such as, "You may choose not to participate in this study."
12. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw from the study at any time without penalty or loss of benefits to which the subject is otherwise entitled.
13. If applicable, the following information should be included in the consent form:
   a. Reasons for involuntary termination of participation.
   b. A statement that the particular treatment or procedure may involve risks to the subject (or to the fetus, if the subject is or may become pregnant) that are currently unforeseeable.
   c. Potential costs to participants.
   d. Consequences of withdrawal (adverse health/welfare effects.
   e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
   f. Number of subjects (if it may have an impact on the decision to participate).
   g. Payments (incentives and/or expense reimbursements)

2. **Comprehension:** The manner and context in which the information is conveyed is as important as the information itself. The individual's ability to understand is based upon that person's level of intelligence, rationality, maturity, and language. The presentation of the information must be adapted to each person's capabilities.
3. **Voluntariness:** Subjects must be told that they have the right to decline participation and to withdraw from the study at any time after it has begun.

4. **Signatures:** Signatures should be dated.

### III. NON ENGLISH-SPEAKING RESEARCH PARTICIPANTS

1. The informed consent document must be "in language understandable to the subject" 45 CFR 46.116 and 117, and 21 CFR 50.20. Subjects who do not speak English should be presented with a fully translated consent document written in a language that is understandable to them. The Einstein IRB generally requires Spanish translations of consent documents for studies that plan to enroll 5 or more subjects with a potential for direct benefit to the participants. Studies providing an adequate scientific justification precluding Spanish translation may have the requirement waived. The translation can be obtained through a translation service of your choice (see Appendix). An 'Affidavit of Accuracy' is required. Alternatively, the translation can be prepared "in house". This requires that one individual translate the document into the appropriate language and another individual convert the translated document back into English. The two English documents can then be compared side by side for accuracy and completeness. For the "in house" translation, submit to the IRB the translated and back translated consents together with the names and qualifications of the individuals involved in the process.

2. If a non-English speaking subject is unexpectedly encountered, the investigator must rely on oral translation. The oral presentation of informed consent information is permitted, in conjunction with a short form written consent document in the language understandable to the subject (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation, who is fluent in both English and the language of the subject, is required. This cannot be a friend or family member. The subject must be given copies of the short form document and the summary. At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (i.e. the English language informed consent document) should be signed by the person obtaining consent; and (iii) the short form document and the summary should be signed by the witness.
   1. The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of 46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened
3. It is the responsibility of the IRB to determine which of the procedures at 46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

IV. ILLITERATE ENGLISH-SPEAKING PARTICIPANTS AND THOSE WITH PHYSICAL DISABILITIES

"A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended." (FDA Information Sheet, 9/98)

V. INCLUSION OF MINORS

See IRB policy for Enrollment of Minors in Research

VI. WAIVER OF INFORMED CONSENT ALTERNATIVE CONSENT MECHANISM

WAIVER OF DOCUMENTATION OF INFORMED CONSENT

A waiver of informed consent, alternative consent mechanism, or waiver of the documentation of informed consent is permitted under the regulations. A CONSENT WAIVER FORM is included in the IRB Research Application. All waivers require IRB review and approval.

VII. INFORMED CONSENT TEMPLATES

1. The Individual Informed Consent Document (consent form).

This template is required for:
1. Adults (aged 18 years and over), capable of understanding.
2. Family members or legal guardians for instances in which the subject lacks the capacity to consent.
3. The template applies to both 'minimal risk' research and 'more than minimal risk' research.
4. For Non English-Speaking populations and those who are unable to read English, the investigator is required to use this form and the Short Form Consent Document.

2. The Simplified Informed Consent Document

This template is required for potential subjects with an altered mental status, or who may not be capable of understanding the Individual Informed Consent Document (consent form). Depending on the nature of the study, an Informed Consent Document signed by a family member may also be required.

3. Consent Forms for Research Involving Minors

Depending on the age of the subjects, the following consent documents must be used:

1. Ages 0 - 7 years old: *Parental Consent Template.
2. Ages 7-12 years old, capable of assenting:
   a. Parental Consent Template and
   b. Child Assent Template
3. For adolescents ages 13-17 years old: Parental and Young Adult Template
4. The use of a single form with appropriate sections for adults, young adults, and parental permission is permitted.

*The baseline Parental Consent, Individual Consent, and Young Adult Consent Template are one document. Sections should be tailored to meet the needs of your study population.
Appendix

The Einstein IRB will generally accept any certified translation by a professional translator. The following list is provided for your convenience but does not represent a specific endorsement by the IRB:

- **Bronx CREED Translation Service:** The Bronx Center to Reduce and Eliminate Ethnic and Racial Health Disparities (Bronx CREED) and the Institute for Clinical and Translational Research offer an English-to-Spanish translation service. For investigators without external funding there will be no charges. For investigators with external funding budgeted for translation, charges, if any, will be determined on a case-by-case basis. All publications, presentations, and posters should acknowledge their NIH grant for this service. The primary translator, Ms. Yovana Coupey, received her translation certification from the NYU School of Professional and Continuing Studies and also currently serves as Course Leader of the Medical Spanish Program. To request translation services, contact Bronx CREED’s Scientific Director and Research Core Director, Joel Zonszein, M.D. at (718) 904-2883 or joel.zonszein@einstein.yu.edu.

- **Inlingua Language Centers,** 609-921-2080
POLICY FOR THE USE OF PATIENT MEDICAL RECORD INFORMATION IN RESEARCH AND RECRUITMENT OF RESEARCH PARTICIPANTS

POLICY STATEMENT

It is the policy of MMC and AECOM that patients have the basic rights of confidentiality and privacy with respect to their health information. In general, this right requires that patients grant consent for someone other than their health care providers to review their records. In order to conduct some types of research, however, it may be desirable or necessary to waive the requirement to obtain patient consent for access to health information, as outlined below.

GENERAL PRINCIPLES

1. No permission is needed from the IRB/CCI or from Quality Improvement for a clinician to review his or her own individual patient records in order to examine patterns of care, patterns of outcomes or the specifics of any interventions.

2. Record reviews for the purposes of Quality Improvement and Continuous Quality Improvement are necessary to ensure quality of clinical services and must be conducted without individual informed consent.

3. Research using truly anonymous data does not require informed consent or a HIPAA authorization.

4. Individual consent is not required prior to chart review when all identifying information will be protected (i.e. anonymized and de-identified or coded), and the CCI/IRB finds that the knowledge to be gained is of sufficient importance.

DEFINITIONS

A. Anonymous (De-Identified) Data: Uncoded health information that cannot be linked back to the subject either directly or indirectly.

   For information to be considered de-identified, the following direct 18 identifiers must be removed: name, address, employer, relatives’ names, date of birth, telephone and fax numbers, e-mail addresses, social security number, member or account number, certificate/license number, voice/fingerprints, photos or other number, code or characteristics.

B. Anonymized: Health information that can be linked back to the subject only through a coding mechanism that is unknown to the researcher and that is held confidentially by a third party.

C. Limited Data Sets: A limited data set is the same as a de-identified data set (see Section B above), except that the following data elements are allowed: zipcode, city,
and state, date of birth and other dates. If a limited data set is to be used a Data-Use Agreement is required.

D. **Data Use Agreement:** Is the means by which covered entities obtain assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. The agreement is to be submitted to the CCI/IRB with the 'Request for Waiver/Alteration or Exemption from HIPAA Authorization and Informed Consent Form', and must contain the following:

1. Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a Data Use Agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).

2. Identify who is permitted to use or receive the limited data set.

3. Stipulates that the recipient will –
   a. Not use or disclose the information other than permitted by the agreement or otherwise required by law.
   
   b. Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
   
   c. Hold any agent of the recipient (including subcontractors) to the standards, restrictions and conditions stated in the data use agreement with respect to the information.
   
   d. Not identify the information or contact the individuals.

E. **Identifiable data:** Health information that can be linked back to the subject through a coding mechanism that is known to the researcher.

F. **Identified Data:** Health information that is recorded along with the subject's identifying information.

G. **Health Information:** Any information, whether oral or recorded in any form, that relates to the physical or mental health or condition of an individual, the provision of health care to an individual, or payment for the provision of health care to an individual.

H. **Research:** A systematic investigation designed to develop or contribute to generalizable knowledge.

I. **Quality Improvement:** The systematic collection and analysis of outcome data, under the auspices of the institution’s or department’s Quality Improvement processes, for the purpose of identifying and attempting to reduce and eliminate error or less than optimal processes for the benefit of patients.
PROCEDURES  ALL PROPOSED RESEARCH REQUIRES REVIEW BY THE IRB/CCI TO DETERMINE IF RESEARCH IS EXEMPT, QUALIFIES FOR EXPEDITED OR FULL REVIEW, AND TO DETERMINE THE APPROPRIATENESS OF THE HIPAA AND/OR INFORMED CONSENT WAIVER/ALTERATION OR EXEMPTION.

A. Collection of Data Preparatory to Research:

1. In order for Principal Investigators or their designees to review medical records (written or electronic) in the course of preparation of a research protocol, the Principal Investigator must submit the ‘Informed Consent and HIPAA Exemption Form’ to the appropriate IRB/CCI. The IRB/CCI must find that:
   a. Use or disclosure is sought solely to review health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
   b. No identified health information is to be removed from the covered entity by the researcher in the course of the review.
   c. The health information for which use or access is sought is necessary for the research purposes.

2. The Principal Investigator is required to provide assurance that confidentiality will be maintained and that improper disclosure or misuse of patient information, whether intentional or due to neglect, is a breach of confidentiality which can result in the loss of access to clinical information and may result in disciplinary action by the employer, such as revocation of faculty appointment or dismissal.

3. The Principal Investigator must present a copy of the IRB/CCI exemption approval to Medical Records or the applicable department. If the records are electronic or maintained on a computer database, the investigator must comply with applicable institution’s policies and procedures.

4. No permission is needed from the IRB or from Quality Improvement for a clinician to review his or her own individual patient records in order to examine patterns of care, patterns of outcomes or the specifics of any interventions. For any other purpose, permission must be obtained from the IRB.

B. Use of Anonymous (De-Identified) Data:

1. Research using data that are anonymous is generally exempt from IRB/CCI review and does not require informed consent or a HIPAA authorization as long as all 18 identifiers (see definition of “Anonymous Data,” above) have been removed. The Principal Investigator is responsible for obtaining written approval from the CCI/IRB by submitting the ‘Informed Consent and/or HIPAA Authorization Waiver/Alteration or Exemption Form.’
2. Research using anonymized data generally qualifies for expedited review by the CCI/IRB and does not require informed consent. If any identifiers remain, the patient must sign a HIPAA authorization, or the research must qualify for a waiver of HIPAA authorization. The Principal Investigator is responsible for obtaining written approval from the CCI/IRB by submitting the ‘Informed Consent and/or HIPAA Authorization Waiver/Alteration or Exemption Form.

C. For Use of Montefiore Medical Center Electronic Records Only

1. Use of Encryption to Create De-identified Protected Health Information or Limited Data Sets

2. Any individual or department wishing to create or utilize de-identified protected health information or a limited data set in connection with the conduct of research must seek approval in advance from the IRB for use of electronic records.

3. Removing Identifying Data from Electronic Records.
   a. For purposes or creating an encrypted electronic record data set, the program FieldEncrypt may be utilized. The IRB/CCI will decide whether the encryption key is to be kept by the IRB/CCI to permit merging new data with the old database in the future, is to be destroyed at the time of database creation, or is to be given to the Principal Investigator. NOTE: If the Principal Investigator wishes to use a method of encryption other than FieldEncrypt, prior approval must be obtained from the IRB.
   b. The principal investigator should provide to the IRB/CCI the member of the research team who will review the paper records and de-identify the protected health information or create a limited data set.
   c. The IRB/CCI is then given custody of the de-encryption key or at its discretion the de-encryption key is permanently destroyed.

4. Determination of Field’s Encrypted
   a. It is the responsibility of the IRB/CCI taking into consideration the recommendation of the principal investigator, to determine the fields within the database which must be encrypted and whether the dataset must be encrypted to the level of de-identification or a limited dataset.

D. Use of Identifiable Data Without Informed Consent:

All research using identifiable data must be approved by the IRB/CCI. A detailed protocol must be submitted for review by the IRB/CCI, and the IRB/CCI must find that:

1. The research is methodologically sound;

2. The research poses an important question; and
3. The review/disclosure of patient medical information is in compliance with state and federal statutes (e.g. AIDS, Substance Abuse, etc.).

In order for the research to qualify for a waiver or alteration of informed consent and HIPAA authorization, the IRB/CCI must find:

The research (and use or disclosure of the health information) involves no more than minimal risk to the subjects, including the privacy risk. The determination of minimal privacy risk to the subject is based upon the following criteria:

There is an adequate plan to protect the identifiers from improper use and disclosure;

1. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research unless there is a health or research justification that makes retention necessary or such retention is otherwise required by law; and

2. There are adequate written assurances that the health information will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the proposed research or for other research for which use or disclosure of the health information is permitted by law;

3. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

4. The research could not practicably be carried out without the waiver or alteration of the consent/authorization (because of difficulties locating subjects or because obtaining consent would contaminate the data), and without access to and use of the health information;

5. The research could not practicably be carried out without access to and use of the health information;

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

7. The privacy risks to individuals are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research.

All individuals who will have access to the health information must sign a copy of the Confidentiality Agreement (attached hereto) that provides assurance that the health information will not be re-disclosed to any other person or entity.

The Principal Investigator must include in the protocol the specific steps to be taken that will protect subject confidentiality (e.g. the records will be secured in a locked file cabinet, identification of the limited number of individuals who will have access to the data, encryption of records, use of codes, etc.).
The CCI/IRB will determine whether appropriate safeguards exist to protect the confidentiality of data and patient records, and will direct what additional measures, if any, need to be implemented by the Principal Investigator.

All information from which the subject’s identity could be ascertained must be removed from the data and maintained in a separate, secure location.

The Principal Investigator must present a copy of written CCI/IRB approval to Medical Records or, in the case of access to computer databases, the investigator must comply with applicable institution policies and procedures.

E. Retrospective or concurrent review of health information for the purpose of contacting subjects to participate in research:

Research in which health information will be reviewed for the purpose of contacting subjects must be submitted to the IRB for approval prior to review of health information. Section C 1 & 2 above also apply.

For initial contact of subjects (when the investigator is not part of the treatment team), the following conditions must be met:

Written CCI/IRB approval must be obtained in advance of any subject contact.

1. The Principal Investigator or a research collaborator must contact each subject’s physician, explain the study to him/her, and request that he/she assist in the recruitment of the patient into the study.

2. The initial recruitment contact with the subject must be made by a member of the subject’s treatment team and not by the Principal Investigator or a member of the research team. If the subject’s physician has died or left the institution, contact shall be made by the Chairman or Chief of Service of that department or his/her designee.

3. If the patient’s physician agrees to assist in the recruitment process, the protocol submission to the CCI/IRB must include a proposed recruitment letter for review and approval by the CCI/IRB that will be signed by the potential subject’s physician.

4. The Principal Investigator may send the letter (signed by the subject’s physician and approved by the CCI/IRB) to the potential subject seeking his/her participation in the study. A sample letter is attached hereto Information on the envelope should be limited to the name of the institution and should not include reference to the department.

5. The letter to potential subjects must contain the following elements: (i) the nature of the research; (ii) the fact that participation is voluntary; (iii) the patient’s medical care will not be affected if he/she decides not to participate; (iv) a
description of who will contact the potential subject and how contact will be made (e.g. by phone, letter, etc); (v) a phone number the potential subject should call, or a postcard to be returned, if he/she is not interested and does not want to be contacted; (vi) disclosure that the patient’s medical information is known to the researcher.

6. The letter to the potential subjects may not contain the following information: (i) the patient’s diagnosis; (ii) the disease category of the study; (iii) any information from which the reader could learn any health information about the potential subject.

F. Review of Patient Databases from AECOM, MMC, the North Bronx Healthcare Network (Jacobi and NCB) and Other Institutions:

1. In order to access Montefiore’s electronic databases, the investigator must comply with this policy as well as Institutional Administrative Policy and Procedure.

2. If electronic databases are accessed, the investigator must comply with the applicable institution’s policies and procedures.

G. Access to or Disclosure of Health Information in Connection with Quality Assurance / Quality Improvement Activities:

1. Access to or disclosure of health information in connection with bona fide quality assurance and/or quality improvement activities of the institution is not subject to IRB/CCI oversight. Approval must be obtained from the institution’s or department’s Quality Improvement process.

Approved by CCI/IRB Joint Conference Committee 6/19/03.

PATIENT INFORMATION CONFIDENTIALITY AGREEMENT

For a printable version, click here. Name: __________________________ Position: __________________________ I recognize that, in the course of my duties as an investigator or agent of an investigator at Montefiore Medical Center (MMC), Albert Einstein College of Medicine (AECOM), Yeshiva University (YU) or the North Bronx Healthcare Network (NBHN), I may gain access to MMC, AECOM, YU and/or NBHN patient information, which is required by law to be kept confidential and which may be disclosed only under limited conditions. I agree that:

1. I will keep confidential all patient information to which I gain access.

2. I will access and use patient information only in connection with a research protocol that has received IRB/CCI approval.

3. I will not redisclose patient information except to the extent required by applicable laws, including but not limited to federal laws governing drug and alcohol treatment programs and state laws governing HIV information.
4. I will not discuss patient information in public places or outside of work.

5. I will access information only concerning patients for whom IRB/CCI approval has been given, and will not access information for other patients of Montefiore.

6. I will take all necessary precautions to ensure that the access and handling of patient information are conducted in ways that protect patient confidentiality to the greatest degree possible. This includes maintaining such information in a locked file cabinet.

7. Unless there is written consent from the patient/guardian, if, in the course of my review of patient information, I recognize the patient outside the scope of my practice (for example, if the patient is my acquaintance or neighbor), I will immediately stop reviewing the information and return the chart or, in the case of electronic records, close the applicable file. I will not record any information, even if such information does not identify the patient.

I understand that it is my obligation and responsibility to maintain the confidentiality of all patient information. Improper disclosure or misuse of patient information, whether intentional or due to neglect on my part, is a breach of patient confidentiality, which can result in the loss of access to clinical information for myself and my employer and may result in disciplinary action by my employer. If I am a member of MMC or the NBHN medical staff, improper access, disclosure or misuse of patient information may result in action being taken under the applicable medical staff bylaws, which may result in revocation of my medical staff appointment.

Signature: ____________________________
Date: ____________________________  Name ________________________________
Position ____________________________

SAMPLE RECRUITMENT LETTER TO POTENTIAL RESEARCH SUBJECTS

For a printable version, click here.

Dear ----: As your doctor, I am writing to let you know that a research study is being planned that may be of interest to you. It is possible that you may be eligible to participate in this study. Your eligibility can only be determined by the investigators of this study. Please be aware that, even if you are eligible, your participation in this or any research study is completely voluntary. There will be no consequences to you whatever if you choose not to participate, and your regular medical care will not be affected by that choice. If you do choose to participate, the study will involve [------- examples: blood tests, x-rays, biopsies, interviews, drugs, medical visits------]. In order to determine your eligibility and your interest in participating, [---name and role in study] will be [calling][writing] you directly. You may choose not to [speak with him/her] [respond to the letter]. If you do [speak][respond], any questions you have about the study will be answered. If you would prefer not to be contacted at all, please call [number] and provide your name, and the information that you would NOT like to be contacted about this research study. Of course, if you have any questions for me, please contact me.
MINIMAL RISK TEMPLATE

INSTRUCTIONS

Minimal Risk Template. This template should be used for all minimal risk studies with written consent. It will guide you through writing the consent form. There are two additional documents that will be helpful in writing the consent: “Optional Consent Language” and “Glossary Of Terms For Use In Preparing Informed Consent Documents.” These documents can be found on the IRB website, http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx.

The template lists the required sections as bold underlined headings. There are many optional elements that may or may not apply to your study such as genetic testing, future use of specimens, or certificate of confidentiality. We note in this template where they should be inserted if they apply. Suggested language is in the “Optional Consent Language” document on the website: http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx.

Consent language. We have provided suggested language for required and optional consent elements, but this language can be tailored to fit your specific study. We have also provided simple descriptions in lay language of common research terms and medical procedures in a document called “Glossary Of Terms For Use In Preparing Informed Consent Documents” (available at http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx). We encourage you to use these descriptions but they are suggested, not required.

You should keep your consent form BRIEF. We have provided guidance for the target length of each section. You should use clear, simple language at no more than an 8th grade reading level.

IRB Policies. This template occasionally refers investigators to relevant IRB policies that cover human subjects research including, for example, deception and compensation. IRB policies can be found on the IRB website (http://www.einstein.yu.edu/administration/institutional-review-board/policies.aspx).

Instructions for use of the template.

- DELETE THE INSTRUCTION PAGE BEFORE SUBMITTING THE CONSENT DOCUMENT TO THE IRB.
- DO NOT ADJUST THE MARGINS OF THE CONSENT TEMPLATE.
- For new studies, use the most updated version of the consent template available on the IRB website.
- Instructions within the template appear as comment bubbles. If the complete text of the instructions does not appear, click on the [ ] to view the text.
  - Optional sections have DELETE IF NOT APPLICABLE in the comment bubble. Delete the not applicable sections.
  - Comment bubbles will not appear in the IRB-stamped document and may be left in the document.
- The places you must insert your own study-specific language are in bolded in brackets [like this].
- NOTE: This consent form is written to the research subject. If you are asking someone else to provide consent, e.g., a parent or legal guardian of a minor or a legally authorized representative, change the words “you” and “your” to what is most applicable (e.g., “your child” or “the research participant.”)
ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORIE MEDICAL CENTER
JACOBI MEDICAL CENTER
NORTH CENTRAL BRONX HOSPITAL

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When the word “you(r) / “my” / “me” / “I” appears in this consent form, we mean the participant (you or your child); “we” means the research study doctors and research staff.

Introduction
You are being asked to participate in a research study called [insert study name]. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say “no” now or after you have started the study. If you say “no,” your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the “Principal Investigator.” [His/Her] name is [name]. You can reach Dr. [name] at:
Office Address:
City, State Zip
Telephone #:
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by [Specify who is paying for the study including treatments, medications and tests]

Why is this study being done?
The goal of this study is to …

Why am I being asked to participate?
You are being asked to participate in this study because you…

What will happen if I participate in the study?
Blood Draw
HIV Testing

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study under the protocol #12-1234. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:
Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg Room 1002
Bronx, New York 10461

Support for this research study is provided by [Specify who is paying for the study including treatments, medications and tests]
Informed Consent Process & HIPAA Authorization Requirements

MRI
Audio/Visual Recording
Genetic Testing
Specimen Banking for Future Use

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study. 

You will receive a total of [amount, e.g. $100] for [number e.g. 10] study visits. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Participants in this study may receive more than $600 in a calendar year for their participation. The IRS requires that we report this as income. Therefore, you must provide your social security number if you wish to receive these payments.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Taking part in this study will not involve added costs to you. All study drugs will be given free of charge by the sponsor, company or the drug makers. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

If you take part in this study, you or your insurance will pay for...

Are there any possible risks to me?

We will keep your information private, however, a risk of taking part in this study is that your confidential information might be shared accidently with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept private and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information [if relevant: and samples] will be kept as long as they are useful for this research.

The only people who can see your research records are the research team, the organization that funded the research, and the groups that review research. These groups are the Einstein IRB and the Office of Human Research Protection [if relevant: and the US Food and Drug Administration]. These persons who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Taking part in this study will not involve added costs to you. All study drugs will be given free of charge by the sponsor, company or the drug makers. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

If you take part in this study, you or your insurance will pay for...

Are there any possible risks to me?

We will keep your information private, however, a risk of taking part in this study is that your confidential information might be shared accidently with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept private and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information [if relevant: and samples] will be kept as long as they are useful for this research.

The only people who can see your research records are the research team, the organization that funded the research, and the groups that review research. These groups are the Einstein IRB and the Office of Human Research Protection [if relevant: and the US Food and Drug Administration]. These persons who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.
Certificate of Confidentiality

There may be other risks or discomforts if you take part in this study.

Blood Draw

MRI

If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Above, we have described all the risks we know about. However, because this is research, there is always the possibility that you [if relevant: or the embryo or fetus] will have a reaction that we do not know about yet and is not expected. [If relevant: If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.]

Conditions under which researchers may violate participant confidentiality

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include [describe any benefits to the participant which may reasonably be expected from the research].

You will not experience any direct benefit personally from participating in this study. We hope you will participate because the study will generate important data about [insert].

What choices do I have other than participating in this study?

You can refuse to participate in the study. [If appropriate: If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.]

Your other choices are...

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. [This will not affect your care and you will continue to be treated at this facility.] However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?

We will not let you participate in the study any more if [indicate the circumstances in which the investigator or study sponsor will remove a participant]. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.
CONSENT TO PARTICIPATE
I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant       Signature of participant       Date

Printed name of the person conducting the consent process       Signature       Date
List and explain, in lay terms, all risks of participation in the study. Include risks from tests and assessments, procedures, and study treatments. Use only as much space as absolutely needed.

Describe in lay language any direct benefit the participant may receive as a result of participating. These may include (1) benefits related to what is being studied (e.g., a test, treatment or intervention) if it is shown to be effective; (2) benefits of study screening, tests, or monitoring that may maintain or improve the participant’s comfort, health or well being; or (3) services that are provided through the study such as counseling or advice. It should not include study reimbursement or incentives. Use only as much space as absolutely needed.

Explain any alternatives the patient may have, including other research studies and treatments. (1-2 sentences)

If there are alternatives:
Describe other treatments and/or diagnostic procedures that are available outside of the study. If the study treatment is available without taking part in the research study, include a statement to that effect. Also indicate if any standard diagnostic procedures or treatments may be withheld or delayed as a result of study participation.

For studies where the duration or manner of participation makes this appropriate. DELETE IF NOT APPLICABLE.
OPTIONAL CONSENT LANGUAGE

INSTRUCTIONS

There are many optional elements that may or may not apply to your study such as genetic testing, future use of specimens, or certificate of confidentiality. This document provides suggested text for these sections. Required language will be noted as such.

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1. Conditions under which the researcher may violate participant confidentiality
2. Blood Draw
3. MRI
I. IN THE “PROCEDURES” SECTION

Blood Draw

To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein and [INSERT NUMBER OF TUBES] tube[s] of blood will be drawn, about [TRANSLATE INTO TEASPOONS OR TABLESPOONS].

HIV Testing

Will there be testing for HIV?

Yes, HIV testing will be done during this research study. The following is important information about HIV, HIV testing and your test results:

- HIV causes AIDS and can be spread through sexual activity, sharing needles, by pregnant women to their fetuses, and through breastfeeding infants.
- There is treatment for HIV that can help you stay healthy.
- People with HIV or AIDS should adopt practices to protect people in their lives from becoming infected with HIV.
- HIV testing is voluntary and can be done anonymously at a public testing center. However, testing is required if you would like to be in this research study.
- The law protects the confidentiality of HIV related test results.
- The law prohibits discrimination based on your HIV status and services are available to address any discrimination.

MRI

Magnetic resonance imaging (MRI) is a test that uses a magnetic field and pulses of radio waves to make pictures of organs and structures inside the body. For an MRI test, the area of the body being studied is placed inside a special machine that contains a strong magnet. Pictures from an MRI scan are saved and stored on a computer for more study. Although the MRI you will have in this study is being done for research purposes only, it is possible that doctors may notice something that could be important to your health. If so, we will contact you to explain what was observed and tell you whether you should consult your doctor. We will make the MRI report available to your doctor, and if you want, we will talk with your private physician or refer you to someone for follow-up.

Audio or video recording

Will there be audio and/or video recording?

Comment [HT1]: Genetic testing and specimen banking language must be included for all blood draws.

Comment [HT2]: Use this header. State what will be recorded (e.g., will the subject’s face/name be identifiable; will family members, or others, be identifiable). Include the setting of the recording, how the recordings will be used (e.g., only for tabulation of finite criteria by the research team; for possible use as a teaching tool to graduate or other students who are not members of the research staff). State clearly when the recordings will be destroyed. If participants will be compensated, describe under “Will I Be Paid.”
Genetic Testing
If NO, use the first section. If YES, use the second section.

Will there be genetic testing?
This study will not involve genetic research or genetic testing. [However, DNA extracted from [specify, e.g., blood cells] will be stored for future research studies.]

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.

Will there be genetic testing?
Genes are made up of DNA, and have the information needed to build and operate the human body. Genetic factors are personal traits or characteristics that are inherited and run in families. Your blood or tissue sample will be tested for genetic changes that may relate to [an increased or decreased risk of developing a disease, an increased chance of disability, etc.] in you or your offspring. [State the specific test(s) to be done, e.g., specify phenotype.]. The information obtained from these tests will include genetic information about you. To protect your identity, we will give your sample(s) a unique code number. Since genetic information is shared by family members, the information from these tests may have implications for your family members, as well.

If there is a positive test result, you may want to have additional independent testing, and consult with a genetic counselor, clinical geneticist, and specialist physicians. Genetic consultation and counseling are not provided through the study. You should be aware that insurance companies sometimes use information from genetic testing to deny life insurance or disability coverage to applicants. The meaning of the results of this genetic research is not known, therefore we will not give you the results of these studies. You should be aware that insurance companies sometimes use information from genetic testing to deny life insurance or disability coverage to applicants. If you decide to participate in this research study, if your insurance company asks, you should state that you have not had a genetic test.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.
Specimen Banking (Future Use and Storage)
If NO, use the first section. If YES and IDENTIFIABLE, use the second section. If YES and completely DE-IDENTIFIED (no identifiers and no linking code), use the third section.

**Will any of my samples or data be used for future research studies?**

No. We will destroy the data/samples when the study is completed.

**Will any of my samples or data be used for future research studies?**

Yes. We will store your samples/data in a “biobank,” which is a library of data and specimens (tissue and blood) from many studies. These samples/data can be linked to you. In the future, researchers can apply for permission to use the samples/data for new studies to prevent, diagnose or treat disease, including genetic research. If the biobank shares your samples/data with other researchers, it will remove your name. If you agree to the future use, some of your de-identified genetic and health information may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your samples/data may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy remaining samples/data but if these were already shared with other researchers, we cannot get them back.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.

**INITIAL YOUR CHOICE BELOW**
I consent to be contacted in the future to learn about:

- ______(1) New research protocols that I may wish to join.
- ______(2) General information about research findings.
- ______(3) Results of tests on my samples that may benefit me or my family members regarding preventive or clinical care.
- ______(4) I do not agree to be contacted in the future, even if the results may be important to my health or my family's health.
**Will any of my samples or data be used for future research studies?**

Yes. We will store your samples/data in a “biobank,” which is a library of data and specimens (tissue and blood) from many studies. These samples/data cannot be linked to you. In the future, researchers can apply for permission to use the samples/data for new studies to prevent, diagnose or treat disease, including genetic research. Your samples/data may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information may be placed into one or more scientific databases. These may include databases maintained by the federal government.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.
II. IN THE “RISK” SECTION

If there are conditions in which researchers may violate participant confidentiality

Are there any times you would not keep my data confidential?

If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself [insert language describing conditions under which you may break confidentiality]

If you give us information that you may hurt someone else, we [insert language describing conditions under which you may break confidentiality and whether you will report this information to the authorities].

Blood Draw

Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

MRI

There are no known significant risks from an MRI. Some people are bothered by feelings of confinement (claustrophobia), and by the noise made by the machine during the procedure. You will be asked to wear earplugs or earphones while in the machine. You may not participate in this study if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to advise the MRI staff if you have had brain surgery for a cerebral aneurism, or if you have implanted medical or metallic devices, shrapnel, or other metal, such as metal in your eye.
GLOSSARY OF TERMS FOR USE IN PREPARING INFORMED CONSENT DOCUMENTS

A

ABDOMEN The part of the body that contains the stomach, liver, kidneys and some other organs.

ABSORB Take up fluids; take into the body

ACIDOSIS Condition when the blood contains more acid than normal

ACUITY Cleanness, keenness, especially of vision, hearing

ACUTE New, recent, sudden

ADENOPATHY Swollen lymph nodes

ADJUVANT Helpful, assisting, aiding

ADJUVANT TREATMENT Added treatment

ADVERSE EFFECT Side effect of a drug that is undesirable; examples include discomfort or harm to an organ or tissue

ALLERGIC REACTION May include rash, trouble breathing, fever, and/or diarrhea

AMBULATE/-ATION/-ORY Walk, able to walk

ANAPHYLAXIS Serious, potentially life threatening allergic reaction including reduced blood pressure and difficulty breathing that may result in death

ANEMIA Decreased red blood cells; low red blood cell counts that can cause tiredness or fatigue

ANESTHETIC (general) A drug or agent used to produce unconsciousness and to decrease the feeling of pain; it puts you to sleep to allow surgery

ANESTHETIC (local) A drug or agent used to numb an area of your body to permit surgery or biopsy

ANGINA Chest pain from too little blood flow to the heart

ANGINA PECTORIS Chest pain from too little blood flow to the heart

ANOREXIA Condition in which individual will not eat; lack of appetite

ANTECUBITAL Area inside the elbow

ANTIBIOTIC Drug that kills bacteria and other germs
**ANTIBODY** Protein made in the body in response to foreign substance attacks the foreign substance and protects you from infection

**ANTICONVULSANT** Drug used to prevent or treat seizures

**ANTILIPIDEMIC** A drug that decreases the level of fat(s) in the blood

**ANTIMICROBIAL** Drug that kills bacteria and other germs

**ANTIRETROVIRAL** Drug used to treat HIV or other diseases caused by viruses

**ANTIVIRAL** Drug used to treat diseases caused by viruses

**ANTITUSSIVE** A drug used to reduce coughing

**ARRHYTHMIA** Any change from the normal heartbeat (abnormal heartbeat)

**ASPIRATION** Material entering the lungs following vomiting

**ASSAY** Lab test

**ASSESS** To learn about; evaluate

**ASTHMA** A lung disease associated with narrowing of the breathing passages in the lungs

**ASYMPTOMATIC** Without symptoms

**AXILLA** Armpit

**B**

**BENIGN** Not harmful, usually without serious consequences, but with some exceptions, e.g., benign brain tumor may have serious consequences

**B.I.D.** Twice a day

**BINDING/BOUND** Carried by, stuck together, transported

**BIOAVAILABILITY** The portion of a drug that enters the blood (relates to drugs taken by mouth)

**BLOOD PROFILE** Series of blood tests

**BOLUS** An amount given all at once

**BONE MASS/DENSITY** The amount of calcium in a given amount of bone

**BRADYARRHYTHMIAS** Slow, irregular heartbeats

**BRADYCARDIA** Slow heartbeat
BRONCHOALVEOLAR LAVAGE Wash out part of the lung with salt water to obtain lung cells for laboratory tests

BRONCHOSCOPY Insertion of a flexible tube through the nose and voice box to examine the inside of the lung

BRONCHOSPASM Narrowing of the breathing passages of the lung causing difficulty breathing and wheezing

C

CARCINOGENIC Capable of causing cancer

CARCINOMA Type of cancer

CARDIAC Refers to the heart

CARDIOVERSION Return of normal heartbeat by electric shock or drugs

CATHETER A tube inserted into the body for withdrawing or introducing fluids (i.e. a Foley)

CATHETER (indwelling epidural) A tube placed near the nerves in the spinal cord used to administer anesthesia during an operation

CENTRAL NERVOUS SYSTEM (CNS) Brain and spinal cord

CEREBRAL TRAUMA Damage to the brain

CESSATION Stopping

CHEMOTHERAPY Treatment of disease, usually cancer, by drugs

CHRONIC Continuing for a long time

CISPLATIN A drug used to kill cancer cells

CLINICAL Referring to medical care

CLINICALLY SIGNIFICANT Of major importance for treating or evaluating patients

CLINICAL TRIAL An experiment involving patients

COGNITIVE TESTS Tests of thinking abilities

COMA Unconscious state (cannot be awakened)

COMPLETE RESPONSE Total disappearance of disease

CONGENITAL Occurring before birth; being born with a particular problem
CONJUNCTIVITIS Irritation and redness of the thin membrane covering the eye

CONSOLIDATION PHASE Treatment phase intended to make a remission permanent follows induction

CONTRAINDICATED Should not be used

CONTROL Healthy volunteer; a person without the disorder or disease

CONTROLLED TRIAL Study in which the experimental treatment or procedure is compared to a standard (control) treatment or procedure

COOPERATIVE GROUP Association of multiple hospitals and doctors to perform clinical trials together

CORONARY Refers to the blood vessels that supply the heart

CORONARY HEART DISEASE Hardening of the arteries of the heart

CT SCAN (CAT) (computerized tomography) Computerized series of x-rays

CULTURE Test for infection or germs that could cause infection

CUMULATIVE Total sum of individual events, experiences, treatments

CUTANEOUS Relating to the skin

CVA (cerebrovascular accident) Stroke

D

DERMATOLOGIC Related to the skin

DIASTOLIC Lower number in blood pressure reading

DISTAL Toward the end, away from the center of the body

DIURETIC “Water pill” or drug that causes an increase in urination

DOPPLER Sound waves

DOUBLE BLIND Study in which neither investigators nor subjects know what drug the subject is receiving

DYSFUNCTION Improper function; poor function

DYSPLASIA Abnormal cells
ECHOCARDIOGRAM  Sound wave test of the heart
EDEMA  Increased fluid in body tissues; swelling
EEG (electroencephalogram)  Recording of the electric waves in the brain
EFFICACY  Effectiveness; how well something works
ELECTROCARDIOGRAM (ECG or EKG)  Electrical tracing of heartbeat
ELECTROLYTE IMBALANCE  Imbalance of minerals in the blood (i.e. potassium, sodium)
ELEVATION OF LIVER  Evidence of abnormal liver function, evidence of liver damage
FUNCTION TESTS  damage
EMESIS  Vomiting
EMPIRIC  Based on experience
ENDOSCOPIC  Insertion of a flexible tube with a light to examine an internal part of the body
ENTERAL  Given through the stomach or intestines
EPIDEMIOLOGIC  Referring to the study of the distribution and population characteristics of diseases
EPIDURAL  A tube placed near the nerves in the spinal cord used to administer anesthesia during operation
ERADICATE  Get rid of (such as a disease)
EVALUATE  Assess; examine for a condition or state
EXTERNAL  Outside the body
EXTRAVASATE  To leak outside of a blood vessel
FDAA  U.S. Food and Drug Administration, the branch of the federal government, which approves new drugs
FIBRILLATION  Irregular beat of the heart or other muscle
FIBROUS  Having many fibers, as in scar tissue.
G

GASTROINTESTINAL Relating to the stomach and intestines

GENERAL ANESTHESIA A drug or agent used to produce unconsciousness and to decrease the feeling of pain; it puts you to sleep to allow surgery

GESTATIONAL Related to pregnancy

GLUCOSE A sugar

GOUT A disease that causes a painful inflammation of the joints

H

HEMATOCRIT Amount of red blood cells in the blood

HEMATOMA A bruise; a black and blue mark

HEMODYNAMIC MEASURING Measuring of blood flow

HEMOGLOBIN A substance in the blood that carries oxygen

HEMOLYSIS Breakdown of red blood cells

HEPARIN LOCK A plastic tube filled with blood thinner that is placed in a vein to give injections or take out blood

HEPATIC Refers to the liver

HEPATOMA Cancer or tumor of the liver

HERITABLE DISEASE A disease that can be transmitted to one's children

HISTOPATHOLOGIC Pertaining to the microscopic view of diseased tissues or cells

HOLTER MONITOR A portable machine for recording heartbeats over a period of time

HYPERCALCEMIA Increased level of calcium in the blood

HYPERKALEMIA Increased level of potassium in the blood

HYPERNATREMIA Increased level of sodium in the blood

HYPERTENSION High blood pressure

HYPOCALCEMIA Reduced level of calcium in the blood

HYPOKALEMIA Reduced level of potassium in the blood

HYponATREMIA Reduced level of sodium in the blood
HYPOTENSION  Low blood pressure

HYPOXEMIA  A decrease of oxygen in the blood

HYPOXIA  A decrease of oxygen in the blood

I

IATROGENIC  Caused by a physician or by the treatment

IDE  Investigational device exemption, the license to test an unapproved new medical device

IDIOPATHIC  A disorder for which the cause is unknown

ILLICIT DRUGS/ SUBSTANCES  Illegal drugs

IMMUNE SYSTEM  The system in the body that reacts to foreign or occasionally one’s own proteins

IMMUNOGLOBULIN  A substance produced by the body that binds to a foreign substance

IMMUNOSUPPRESSIVE  Drug which reduces the body’s immune response, used in transplantation and diseases caused by disordered immunity

IMMUNOTHERAPY  Use of drugs to help the body’s immune (protective) system; usually used to destroy cancer cells

IMPAIRED FUNCTION  Abnormal function

IMPLANTED  Placed inside the body

IND  Investigational new drug, the license to test an unapproved new drug

INDUCTION PHASE  Beginning phase or stage of a treatment

INDURATION  Hardening

INDWELLING  Remaining in place in body, such as a catheter

INFARCT  Death of tissue because of lack of blood supply

INFECTION  Disease that is transmitted from one person to another

INFECTION  Disease that is transmitted from one person to another

INFUSION  Introduction of a substance into the body, usually into the blood through a vein
INGESTION Eating; taking by mouth

INTERFERON An agent, which acts against viruses, an antiviral agent

INTERMITTENT Occurring between two time points (regularly or irregularly), alternately stopping and starting

INTERNAL Inside the body

INTERIOR On the inside

INTRAMUSCULAR Into the muscle; within the muscle

INTRAPERITONEAL Inside the abdomen

INTRATHecal Injected into the space around the spinal chord

INTRAVENOUS (IV) Injected into a vein

INTRAvesical In the bladder

INTUBATION (TRACHEAL) The placement of a tube into the throat (trachea) to assist breathing

INVASIVE PROCEDURE Puncture, opening or cutting of the skin

INVESTIGATIONAL A method which has not been proven to be of benefit or a

METHOD Method that has not been accepted as standard care

ISCHEMIA Decreased oxygen in a tissue (usually because of decreased blood flow)

LETHARGY Sleepiness

LEUKOPENIA Low white blood cell count which can increase the possibility of infection

LIPID CONTENT Fat content in the blood

LIPID PROFILE Fat and cholesterol levels in the blood

LOCAL ANESTHESIA A drug or agent used to numb an area of your body to permit surgery or biopsy

LOCALIZED Restricted to one area; limited to one area

LUMEN The cavity of an organ or tube (e.g., blood vessel)

LYMPHANGIOGRAPHY An x-ray of the lymph nodes or tissues after injection of dye in lymph vessels (e.g., in feet)
LYMPHOCYTE A type of white blood cell important in immunity and defense against infection

LYMPHOMA A cancer of the lymph nodes (or tissues)

LUMBAR PUNCTURE (SPINAL TAP) Placement of a needle between the bones in the back to remove some of the fluid around the spinal cord

M

MALAISE A vague feeling of bodily discomfort; feeling bad

MALFUNCTION Not functioning properly

MALIGNANCY Cancer or other progressively enlarging and spreading tumor, usually fatal if not successfully treated

MEDULLOBLASTOMA A type of brain tumor

MEGALOBLASTOSIS Change in red blood cells

METABOLIZE Process of breaking down substances in cells to obtain energy

METASTASIS Spread of cancer cells from one part of the body to another

MI Myocardial infarction; heart attack

MINIMAL Slight

MINIMIZE Reduce

MONITOR Check on; keep track of; watch carefully

MOBILITY Ease of movement

MORBIDITY Undesired result or complication

MORTALITY Death or death rate

MOTILITY The ability to move

MRI Magnetic resonance imaging, body pictures created using magnetic rather than x-ray energy

MUCOSA/ Moist lining of digestive, respiratory, reproductive, and urinary tracts

MUCOUS MEMBRANE urinary tracts

MYALGIA Muscle aches
MYOCARDIAL Referring to the heart

MYOCARDIAL INFARCTION Heart attack

N

NASOGASTRIC TUBE Tube that goes through the nose into the stomach

NCI National Cancer Institute

NECROSIS Death of tissue

NEONATAL Referring to the newborn period

NEOPLASIA Tumor, may be benign or malignant

NEUROBLASTOMA A cancer of the nerve tissue

NEUROLOGICAL Related to the nervous system

NEUTROPENIA Decrease in the main part of the white blood cells

NIH National Institutes of Health

NON-INVASIVE Not breaking, cutting or entering the skin

NORMAL SUBJECT Healthy volunteer

NOSOCOMIAL PNEUMONIA Pneumonia acquired in the hospital

O

OCCLUSION Closing; obstruction

ONCOLOGY The study of tumors or cancer

OPHTHALMIC Referring to the eye

OPTIMAL Best; most favorable or desirable

ORAL ADMINISTRATION By mouth

ORTHOPEDIC Referring to the bones

OSTEOPETROSIS Rare bone disorder characterized by dense bone

OSTEOPOROSIS Softening of the bones

OVARIES Female sex glands; female organs that release eggs
PARENTERAL Injection of a drug into a vein or into the skin

PATENCY Condition of being open

PATHOGENESIS The mechanism of causing a disease

PERCUTANEOUS Through the skin

PERFORATION A tear or a hole

PERINATAL Referring to the pregnancy and newborn period

PER OS (PO) By mouth

PHARMACOKINETICS The study of the way the body absorbs, distributes, metabolizes, and gets rid of a drug

PHASE I Initial study of a new drug in humans to determine the limits of its tolerance and its safety

PHASE II Second phase of a study of a new drug intended to obtain initial information

PHASE III Large scale trials to confirm and expand information on safety and usefulness of a new drug

PHLEBITIS Irritation or inflammation of the vein

PLACEBO A substance with no active medication

PLACEBO EFFECT Improvement observed when a placebo is given

PLATELETS Small particles in the blood that help with clotting

POST-OPERATIVE After surgery

POTENTIATE Increase or multiply the effect of a drug or toxin by administration of another drug or toxin at the same time

POTENTIATOR An agent that helps another agent work better

PRENATAL Before birth

PRE-OPERATIVE Before surgery

PRN As needed

PROPHYLAXIS A drug given to prevent disease or infection

PROGNOSIS Chances for recovery
PROGRESSES Worsens; gets worse

PRONE Lying on the stomach

PROSPECTIVE STUDY Study following patients forward in time

PROSTHESIS Artificial limbs, such as arms and legs

PROTOCOL Plan of study

PROXIMAL Closer to the center of the body, away from the end

PULMONARY Referring to the lungs

Q

Q.D. Everyday

Q.I.D. Four times a day

R

RADIATION THERAPY X-ray or cobalt treatment

RANDOM By chance

RANDOMIZATION Chance selection, like flipping a coin

RBC Red blood cell

RECOMBINANT Formation of new combinations of genes resulting from the manipulation of genes in the laboratory

RECONSTITUTION Putting back together the original parts or elements; For Drugs: Preparation of a drug for administration by adding liquid to a dry, powdered drug

RECUR Happen again; return

REFRACTORY Not responding to treatment

REGIMEN Pattern of administering treatment

REGENERATION Regrowth of a structure or of lost tissue

RELAPSE The return of a disease

REMISSION Disappearance of evidence of cancer or other disease

RENAL Referring to the kidneys
REPLICABLE  Possible to duplicate
RESECT  Remove or cut out surgically
RESOLVE  Go away
RETROSPECTIVE STUDY  Study looking back over past experience
S
SARCOMA  A type of cancer
SEDATIVE  A drug to calm or make less anxious
SEDATION  A medicine to make someone calm, sleepy or less anxious
SEIZURES  Intense (very strong) uncontrollable movements
SEMINOMA  A type of cancer of the testes
SEQUELAE  A condition that occurs as a consequence of a disease
SEQUENTIAL  In a row
SERUM  Part of the blood without red or white blood cells or platelets
SOFTWARE  Computer program
SOMNOLENCE  Sleepiness
SPIROMETRY/PULMONARY FUNCTION TESTING  Measurement of how well you breathe and how well your lungs function
STAGING  Determining the extent of a disease
STANDARD OF CARE  The kind of treatment that the majority of doctors would agree is appropriate; the usual type of treatment
STENOSIS  Narrowing (of a duct, tube, or one of the heart valves)
STOMATITIS  Mouth sore; inflammation of the mouth
STRATIFY  Arrange into groups for analysis of results (e.g. by age, sex)
STUPOR  Stunned state in which it is difficult to get a response or the attention of the subject
SUBCLAVIAN  Under the collarbone
SUBCUTANEOUS  Under the skin
SUPINE Lying on the back

SUPPORTIVE CARE Care aimed at relieving the symptoms and not intended to improve or cure the underlying disease

SYMPTOMATIC Having symptoms (complaints related to the body)

SYNDROME A condition characterized by a set of symptoms

SYSTOLIC Higher number in blood pressure reading

T

TERATOGENIC Capable of causing malformations (abnormalities) in the unborn fetus

TERMINATE Stop

TESTES Male sex glands; male organs which produce sperm

THORACIC Relating to the chest

THROMBOCYTOPENIA A condition in which there is an abnormally small amount of platelets in the blood

THROMBOSIS Blood clot

T.I.D. Three times a day

TITRATION Gradual change of drug dose to determine the strength of the drug that is best

T LYMPHOCYTES Types of white blood cells involved in immune reactions

TOPICAL Surface; on the skin

TOPICAL ANESTHETIC Placed on an area of the skin to decrease pain in the area it is applied

TOXICITY An unwanted side effect resulting in injury to a tissue or organ

TOXICOLOGY TEST A test for illegal drugs, chemicals or poisons

TRANSDERMAL Through the skin

TRANSIENT Lasting or staying only a short time

TRAUMA Injury; wound

TREADMILL Walking machine often used to determine heart function
U

**UPTAKE** The taking in of a substance by a living tissue

V

**VALVULOPLASTY** A method of repairing a valve in the heart

**VARICES** Enlarged veins, usually in legs or the lining of the tube between the mouth and stomach (esophagus)

**VASOSPASM** Narrowing of blood vessels due to spasm of the muscle in the blood vessels

**VENIPUNCTURE** Putting a needle in a blood vessel to draw blood

**VERTICAL TRANSMISSION** Spread of a disease, as from mother to baby

W

**WBC** White blood cell