This format is provided as a SAMPLE FORMAT to assist you in writing a combined informed consent/authorization form. The form must be:

1. Typed
2. Written in second person
3. Written using **simple, lay language and avoiding use of all unnecessary medical terminology**
4. First page must be on AEHN stationery
5. Pages must be numbered, e.g., Page 1 of 6
6. Must include a footer that will be updated with each submission (Einstein IRB submission date: XXX)
7. Text marked by an asterisk cannot be changed;
8. Physician-initiated studies are required to be reviewed by a research/statistician person; e.g., MossRehab has a Peer Committee

**THIS IS INFORMATION ONLY AND SHOULD NOT BE PART OF THE CONSENT FORM:**

**INVESTIGATOR:** personally responsible for the conduct of the research project and for the actions of personnel under his/her supervision.

**CO-INVESTIGATOR:** assumes equal responsibility as the PI for the conduct of the study

**SUB-INVESTIGATOR:** any team member other than an investigator/co-investigator who may help in the design and conduct of the investigation, but does not actually direct its conduct. A sub-investigator can be any member of a research team (e.g., junior faculty, graduate student, resident, lab staff) designated and supervised by the investigator to perform study-related procedures and/or to make important study-related decisions.

**Person Holding Consent Discussion:** The person who signs here is attesting that he/she has explained the information about the research to the participant/participant representative and have answered any questions that he/she had about the research

**Witness:** A witness is required when the informed consent discussion with a prospective subject or their legally authorized representative is eligible and capable of providing a legally effective informed consent decision, but the individual is:

- Unable to read the consent form; or
- Physically unable to sign the consent form; or
- Non-English speaking and a short form consent and oral translation process will be used
TITLE OF PROJECT:

NAME OF PRINCIPAL INVESTIGATOR:

PRINCIPAL INVESTIGATOR'S PHONE:

AFTER HOURS PHONE:

SPONSOR:

Support/Funding Statement:
Funding to support the conduct of this study is being provided by [insert funding information or departmental support] a [insert description: pharmaceutical/device company, public agency/private not-for profit foundation, etc.].

Conflict of Interest Statement:
This statement will only be included if a potential conflict is identified. The Research conflict of Interest Committee (RCOIC) will suggest the necessary language for the statement.

If there is no potential conflict do not include this section in the consent document.

WHAT IS A CONSENT FORM?
You are being asked to take part in a medical research study. Before you can make a knowledgeable decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as informed consent and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign, and date this consent form, once you understand the study and have decided to participate. If you don’t understand something about the study or if you have questions, you should ask for an explanation before you sign this form;
- Being given a copy of your signed and dated consent form to keep for your own records.

The relationship that you have with the study doctor is different than the relationship you have with your family doctor. Your family doctor treats your specific health problem with the goal of making you better. The study doctor treats all subjects according to a research plan to obtain information about the experimental drug, device, or procedure being studied and with the understanding that you may or may not benefit from your participation in the study. You should ask questions of the study doctor if you want to know more about this.
PURPOSE OF THE STUDY
The purpose of the study is (explain in easy-to-understand language).

It is anticipated that about (identify total number of subjects to be enrolled) will take part in this study nationwide. Here at Einstein we hope to have (Include the number of patients to be Einstein sites).

DESCRIPTION OF PROCEDURES
The procedure involves (describe in lay terms the procedures to be performed on subject, including all lab tests, amount of blood to be taken in teaspoon amount, x-rays, randomization procedure, use of placebo, etc.).

In your description of procedures, please clearly distinguish among two categories of procedures:

ROUTINE CLINICAL PROCEDURES WHICH WOULD BE DONE EVEN IF THE SUBJECT WERE NOT INVOLVED IN THE STUDY:
•
•

ROUTINE CLINICAL PROCEDURES WHICH ARE ADDED TO THE SUBJECT'S CARE SPECIFICALLY BECAUSE OF HIS/HER RESEARCH INVOLVEMENT (e.g., extra blood draws, clinic visit(s), an experimental drug, or an innovative surgical intervention).
•
•

The study continues for (give number of procedures and overall time involvement of subject).

When the study is ended, you may not be able to continue with treatment that was part of the study.

RISKS/DISCOMFORTS
You may experience (list toxic and side effects, discomforts and inconveniences, possibility of unforeseen risks).

Also, include, if applicable, either:

1. Although none are reported, there may be risks to an embryo or fetus associated with the study procedure. If you are a woman, you should be either post-menopausal, surgically sterile (tubal ligation), or use an acceptable method of birth control, such as oral contraceptives, a barrier method of contraception, an intrauterine device (IUD), or Norplant. You should also not participate in this study if you are nursing an infant.

   or

2. The risks to an unborn child or fetus are not known at this time. If you are sexually active, you and your partner should be using oral contraceptives, a barrier method of contraception, an intrauterine device (IUD), or Norplant. Also, you should not participate in this study if you are nursing an infant.
COSTS FOR STUDY PROCEDURES:  (SAMPLE STATEMENTS – Select the applicable statement and modify to fit your study)

1. There will be no cost to you if you participate in this research.

2. Aspects of this research which would occur during routine clinical care (i.e., if you were not participating in research), will be billed to your insurance and any portion of these bills which are not covered by your insurance will be your responsibility. However, any portions of this research study which would not normally occur during routine clinical care, will be paid by the study sponsor and/or Albert Einstein Healthcare Network. [Explain the type and extent]

NOTE: The IRB strongly discourages the submission of research protocols in which any costs directly related to research participation are borne by the study subjects, since this may result in inequitable access to the research based on income. If you submit a study for which one of the following paragraphs applies, you are required to provide a detailed ethical justification of this (i.e., not merely a statement that you or the sponsor lacks the funds to cover these expenses) on a separate sheet of paper.

3. The drug(s) or device(s) used in this research (name(s) of drug(s) or device(s) will be supplied at no cost to you. All other costs, if not covered by your insurance, will be your responsibility. The type and extent of such costs will be discussed with you by the person in charge of the research or by someone he/she designates. [NOTE TO INVESTIGATOR: You must clearly define and discuss at the IRB meeting when presenting the protocol.]

4. All costs of this research, if not covered by your insurance, will be your responsibility. The type and extent of such costs will be discussed with you by the person in charge of the research or by someone he/she designates. [NOTE TO INVESTIGATOR: You must clearly define and discuss at the IRB meeting when presenting the protocol.]

REIMBURSEMENT FOR STUDY PARTICIPATION:
If there is reimbursement for study participation, include statement pertaining to the reimbursement, e.g., “You will receive up to $ ___ total for completion of this study. This is for your time and travel costs related to the study.”

BENEFITS
1. Benefits that may occur from this study are said to include (state realistic benefits)

2. There may be no personal benefit to you but the knowledge received may be of value to humanity.

If you are to be a control subject in the study, that means that you will receive a placebo, a non-effective substance or procedure, or a currently standard drug or procedure. [Use this statement]
only if a placebo is part of the protocol.]

**ALTERNATIVES**
Alternative procedures or treatments for your condition are (state what alternatives there are or that alternatives do not exist). **[NOTE: Omit if not a treatment study]**

[If no therapy is an option, indicate so or state consequences.]

**RIGHTS**
Your participation is voluntary. You can choose to take part or not to take part in the study. If you choose to take part, you can change your mind at anytime and stop taking part in the study. Whatever decision you make, it will not affect your care or the relationship you have with your doctors or the Albert Einstein Healthcare Network.

You will be told of any new information learned during the course of the study which might affect the your understanding of the information in this consent and your willingness to continue to participate.

Your participation in this study may be ended by the principal investigator or the sponsor if they feel it is in your best interests.

[Also, include a statement (if applicable) that says] You may be financially responsible for the continued use of this drug/medication if it becomes approved by the Food and Drug Administration (FDA).

No guarantees have been made as to the results of your participation in the study.

**COMPENSATION FOR INJURY:**
In the event of an injury resulting from your participation in this project, you will be provided with clinically appropriate medical care for that injury within the capabilities of the Network. However, Albert Einstein Healthcare Network cannot assure that the medical care and treatment will be provided without charge, and the costs incurred may, ultimately, be your responsibility.

**CONFIDENTIALITY / AUTHORIZATION:**
*The following statement must be included for all clinical trials and the wording in the statement must be verbatim.*

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

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an Authorization.

By signing this form, you authorize the use and sharing of the following information for this research:
(delete those that do not apply; add information that is not listed)

- Information from your medical records that is necessary for this study
- Information we collect from you about your medical history
- Results of laboratory tests that are necessary for this study (list specific tests)
- Clinical and research observations made during your participation in the research.
- Survey forms
- Questionnaires

Any health information that is used or shared under this Authorization will **NOT** include any special health information related to genetic testing, treatment for AIDS/HIV, psychiatric care and treatment, or treatment for drug and alcohol abuse unless specified above.

By signing this form, you authorize the following persons and organizations to receive your protected health information for purposes related to this research **(list the ones that are appropriate)**: members of the research team, other research sites (insert names), the research sponsor (insert name), and any laboratories or other individuals who provides services or analyze health information in connection with this study.

In addition, regulatory agencies that provide research oversight such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP) or the appropriate offices of Albert Einstein Healthcare Network and its Institutional Review Board (IRB), which is the committee responsible for ensuring your welfare and rights as a research participant, may review and/or photocopy study records which may, if they feel it necessary, identify you as a subject.

If information obtained in the study is published, it will not be identifiable as your results unless you give specific permission.

The Albert Einstein Healthcare Network complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. A copy of the Notice will be provided to you.

The information collected during your participation in this study will be kept indefinitely **(or give expiration date if applicable)**. Your Authorization for this study will not expire unless you cancel it. You can cancel this Authorization at any time by writing to the study investigator at:

Insert Principal Investigator Name and Address

If you cancel your Authorization, you will not be able to continue to participate in this research. The principal investigator and the research team may continue to use information about you that was collected before you cancelled the Authorization. However, no new information will be collected about you after you cancel the Authorization.
You have a right to refuse to sign this form. If you do not sign the form, you may not be in the research study, but refusing to sign will not affect your health care outside the study.

**WITHDRAWAL FROM STUDY:**
In the event that you withdraw from the study, the study physician will ask your permission to continue study follow-up, and all clinical data, as it relates to the study, will continue to be collected from your medical records.

**CONTACT INFORMATION:**
If you feel that you have not been adequately informed of your rights with respect to the privacy of your health information or if you feel the privacy of your health information has not been adequately protected, you can contact the Network’s Privacy Office at: Gratz Building, 1000 West Tabor Rd, Philadelphia, PA 19141, (215) 456-0485 or privacy@einstein.edu.

All questions regarding your participation in this study, or in the event of injury, all questions pertaining to that injury will be answered by (state name of person(s) and place professional degree behind name) or his/her designate who can be reached at area code and phone number).

For any questions pertaining to your rights as a research subject, you may contact Robert Wimmer, MD, chair of the Institutional Review Board, Albert Einstein Healthcare Network, Paley Bldg., First Floor, (215) 456-6243.

**UNDERSTANDING OF PARTICIPATION:**
The information in this consent form has been explained to me and all of my current questions have been answered. I have been encouraged to ask questions about any aspect of this research study at any time. Whenever I ask questions, the questions will be answered by a qualified member of the research staff or by the investigator(s) listed on the first page of this consent form.

By signing this form, I agree to participate in this research study and give authorization to use the information collected for this research as explained in this consent form. A copy of this consent form will be given to me.

________________________________________
Printed Name of Subject

________________________________________
Subject Signature (relationship, if kin or guardian signs for subject) Date:

________________________________________
Printed Name of Person Holding Consent Discussion

________________________________________
Signature of Person Holding Consent Discussion Date:

Einstein Date:
Witness to consent when applicable:

**Witness Statement:** Your signature indicates that you were present during the informed consent discussion of this research for the above named participant, that the information in the consent form and any other written information was verbally discussed with the participant (or legally authorized representative) in a language that he/she could understand, that he/she was given the chance to ask and receive answers to his/her questions, that the decision to take part in the research was freely made by the participant (or legally authorized representative) who indicated his/her consent and authorization to take part in this research by:

- [ ] Signing his/her name
- [ ] By making his/her mark
- [ ] Other means: __________________________  
  explain

Printed Name of Witness: __________________________

WITNESS SIGNATURE: __________________________ DATE: _____ TIME:____

**INVESTIGATOR’S STATEMENT**

I, the undersigned, certify that to the best of my knowledge, the subject signing this consent form has had the study fully and carefully explained by me or a member of the study staff and has been given an opportunity to ask any questions regarding the nature, risks, and benefits of participation in this research study.

INVESTIGATOR OR DESIGNEE*: __________________ Date: ________________  
SIGNATURE

*DESIGNEE REFERS TO CO-INVESTIGATOR OR SUB-INVESTIGATOR ONLY.