Research Subject Informed Consent Form

Title of Study:	Interpersonal Violence in the Elderly s19-01097
Principal Investigator:	D'Andrea Joseph, MD, FACS Chief, Acute Care Surgery and Trauma Department of Surgery NYU School of Medicine 222 Station Plaza North, Suite 603 (516) 663-8702
Emergency Contact:	Patrizio Petrone, MD, PhD, MPH, MHSA, FACS (516) 663-9571

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called "subjects" or "research subjects". These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to implement screening and documentation of interpersonal violence (IPV) in the elderly trauma patient and to determine the predictive ability of electronic medical record variables to identify IPV. Our overall goal is to develop a tool to better predict high-risk IPV citims to tailor health care services and intervention.

3. How long will I be in the study? How many other people will be in the study?

The research study is expected to take approximately two years, but your participation may take an hour of a single day at most. The total expected number of subjects recruited for the study will be 200 per site. This study currently is conducted at several institutions through United States.

4. What will I be asked to do in the study?

In this study you will be asked to complete a series of questionnaires.

You are free to skip any questions that you prefer not to answer.

There will be no personal or private identifiable information and any information collected will not be used or distributed outside of this research study.

At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

5. What are the possible risks or discomforts?

Risk of Study

Known risks for this study include the discomfort and inconvenience of questions that may relate to privacy and/or confidentiality concerns to IPV. The research may involve risks that are currently unforeseeable, but are minimal.

Other Risks

There is a risk of loss of confidentiality of collected information, but all efforts will be made to secure all study related information collected and will only be accessable by the current research team.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

The information gained from this study will be used to help understand and improve the development of a tool that will assist in reconizing future patients that experience IPV. .

8. What other choices do I have if I do not participate?

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

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

If you withdraw from participating in this study, you may also want to withdraw your authorization for us to use your personal identifiable health information. Any identifiable health information that has already been used and disclosed to Dr. D'Andrea Joseph cannot be withdrawn. If you do decide to withdraw, we ask that you contact Dr. D'Andrea Joseph to let us know that you are withdrawing your authorization for the use and disclosure of your identifiable health information. Dr. Joseph's mailing address is 259 1st Street, Mineola, NY 11501.

However, even after you have requested that we no longer use your personal identifiable health information, we may have to continue to use the information that has been collected prior to your withdrawal in order to ensure the research study can be completed as necessary. We are unable to take back anything we have already done or any information we have already shared with your permission.

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

9. Will I be paid for being in this study?

There will be no payment related to this study. Participation is voluntary.

10. Will I have to pay for anything?

There are no additional costs for participating in this study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the studyGovernmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- The study sponsor: American Association for the Surgery of Trauma (AAST)

- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date