Confidential

Physician Consent for NEED-PT (PI: Howard Kim) Study

The following is a study consent document.

After completing, you will be asked to complete a short survey on your demographic information.

NEED-PT Physician Consent Form

Title of Research Study: A Cluster-Randomized Trial of the Northwestern Embedded Emergency Department Physical Therapy (NEED-PT) Protocol for Acute Low Back Pain

Investigator: Howard S. Kim, MD MS

Supported By: Agency for Healthcare Research and Quality (R01HS027426)

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are an attending emergency physician at Northwestern Memorial Hospital.

What should I know about a research study?

Someone will explain this research study to you. Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you. You can ask all the questions you want before you decide.

Why is this research being done?

We are studying how patients respond to different treatments for low back pain. Low back pain is a major source of pain and disability for many people, and we don't know the best way to treat low back pain. Some have suggested that physical therapy can be helpful for low back pain, so we are studying patients who saw a physical therapist in the emergency room to see how they compare to people who did not see a physical therapist in the emergency room. By conducting this research, we hope to find a better way to treat low back pain in the future for other patients that might come in to the emergency room with similar problems. We are asking for your participation in this study because we will randomly assign a physical therapist to work with emergency physicians as a member of their team.

How long will the research last and what will I need to do?

We expect that you will be in this research study for up to one year. In this study, physicians will be randomized to have a physical therapist paired with them (or not have a physical therapist paired with them) during their emergency department (ED) shifts. This study uses a randomization method called "cluster randomization," whereby the intervention being studied (i.e., physical therapy) is randomized to physicians rather than individual patients themselves.

If you are randomized to have a physical therapist, you will be asked to allow a physical therapist to be positioned on your treatment team when you are working shifts during normal business hours (Monday-Friday, 8am-5pm). You will conduct your usual clinical duties as you normally would, however, we will ask you to allow this physical therapist to see and evaluate all your patients with low back pain automatically (ie, similar to how the ED pharmacist automatically performs a medication reconciliation for admitted patients).

If you are randomized to usual care (i.e., not have a physical therapist on your treatment team), you will conduct your usual clinical duties as you normally would. If you feel that a physical therapist consult is necessary for your patient, you may still consult the physical therapist.

More detailed information about the study procedures can be found under the section What happens if I say "Yes, I want to be in this research"?

Is there any way being in this study could be bad for me?

We do not foresee any risks to having a physical therapist work with you in the emergency room. We will collect basic demographic information about you for the study. We will not ask you for any personal health information. We will ask you some questions about your treatment decisions for patients with low back pain and your involvement of the physical therapist. There is a minimal risk of unintentional disclosure of this information to individuals outside of the research team.

More detailed information about the risks of this study can be found under Is there any way being in this study could be bad for me? (Detailed Risks)

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include increased efficiency and expertise in patient care by having a physical therapist work with half of the volunteer physicians. Future patients may also benefit from your research participation if findings from this research show that a physical therapist on the treatment team may influence and even improve care of patients with complaint of low back pain.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Howard S. Kim, MD MS
Principal Investigator
312-926-0591
howard.kim@northwestern.edu

Kayla Muschong
Research Coordinator
312-926-0591
kayla.muschong@northwestern.edu

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

Your questions, concerns, or complaints are not being answered by the research team. You cannot reach the research team. You want to talk to someone besides the research team. You have questions about your rights as a research participant. You want to get information or provide input about this research.

How many people will be studied?

We expect about 40 physicians will be in this research study.

What happens if I say “Yes, I want to be in this research”?

We will randomly assign you to either have a physical therapist work you or not have a physical therapist work with you (i.e., usual care). The group you are assigned to will be chosen by chance, like flipping a coin. Neither you nor the study investigator will choose your group assignment. You will have an equal chance of being assigned to either the physical therapist on your treatment team for up to one year or to usual care (i.e., no physical therapist on your treatment team) for the evaluation of patients with low back pain. We will collect basic background information about you at the beginning of the study, such as your gender, age, years in clinical practice, and average number of shifts worked per month. This data is used collectively to summarize the characteristics of physicians who participated in the study. You will answer these questions only once at the beginning of the study.

If you are assigned to the physical therapy group, we will ask you about your work schedule and find suitable days to assign the physical therapist to work with you. The physical therapist will only be assigned to your ED shifts that occur during normal business hours (Monday-Friday, 8am-5pm) due to limited staffing. While the physical therapist is on your treatment team, you will conduct clnical care as per your usual practice, which includes incorporating input from multiple team members (e.g., nurses, technicians, pharmacists, and specialists) in the management of any given patient. In this case, the physical therapist will evaluate all your patients who present with a chief complaint of low back pain without you specifically consulting the physical therapist to do so. You may choose to incorporate or disregard the physical therapist’s assessment at your own discretion. However, the physical therapist consultation note will appear in the patient’s medical record and the patient will be billed for the evaluation, just as it is in current clinical practice.

A research assistant with also work with you and the physical therapist to determine whether the patient would be eligible for longitudinal data collection as part of the research study. If the patient is deemed not eligible (ie, due to chronic low back pain), or does not want to participate in the study, the physical therapist would still evaluate the patient and provide you with their treatment recommendations. If you believe the patient has red-flag symptoms (eg, bowel or bladder incontinence) that necessitate timely diagnosis and intervention, you will retain the ability to have the physical therapist not evaluate the patient such that you can pursue these emergent diagnoses. If the physical therapist becomes aware of any red-flag symptoms during the course of their assessment, they will stop their assessment and inform you immediately. Finally, patients would retain the ability to refuse the physical therapy assessment, just as they have the ability to refuse any individual clinical service provided in the ED (eg, electrocardiogram, urine pregnancy test, blood tests, x-rays, pharmacist evaluation, medical student evaluation).

If you are assigned to the usual care group, you will not have a physical therapist assigned to work with you. You will conduct clinical care as per your usual practice, which may include consulting physical therapy at your own discretion

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

Accept your assignment to either the physical therapy or usual care group. If assigned to physical therapy, allow the physical therapist to be present on your treatment team and evaluate patients with low back pain. What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can ensure that you do not receive any further e-mails or other notifications. If you were assigned to the physical therapy group, we will make sure that the physical therapist no longer joins your treatment team.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment or your present or future employment (for employees at NU or its affiliates).

Detailed Risks: Is there any way being in this study could be bad for me?

We do not foresee any risks to having a physical therapist work with you in the emergency room.

Although we will collect basic background information about you (e.g., age, gender, years in practice) we will de-identify this information by giving you a unique study number (e.g. Physician 1, Physician 2). If this background data is included in any publication, it will be presented collectively for all study participants rather than for individual participants (i.e., “The average years in clinical practice for physician participants was 8.6 years.”). This background information helps readers to understand whether a study population might be applicable to their own practice setting. During the conduct of this research study, there is a chance that a loss of confidentiality of this information could occur, however, we expect this risk to be a minimal risk. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: What happens to the information collected for the research?.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. There is a minimal risk that the physical therapist assigned to your treatment team impacts your clinical efficiency. However in a recent evaluation of Northwestern ED visits for low back pain, we found that the overall length of stay between patients receiving physical therapy and usual care were similar (223 vs 225 minutes, respectively).

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: increased efficiency and expertise in patient care by having a physical therapist work with you. Your patients may also benefit from your research participation by having a physical therapist work with them to improve their care.

Data Collection, Sharing, and Additional Details

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including study records and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Your data relating to this study will be stored on a password-protected, access-limited drive on the Northwestern University Feinberg School of Medicine server. Only the research team will have access to this securely stored data. The data will be stored for a period of three years following the completion of the study.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to the medical records of your patients to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

You will not receive any direct compensation for your participation in this study.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on 08/31/25. You may revoke consent to participation in this research at any time and in any format.

Confidential

Consent Authorization

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Participant Name: _____

Date: _____

Participant Signature: _____

Confidential

Research Study Consent

Please review and complete the study consent below.

Let the study team know if you have any questions.

Title of Research Study: A Cluster-Randomized Trial of the Northwestern Embedded Emergency Department Physical Therapy (NEED-PT) Protocol for Acute Low Back Pain (also known as "the Northwestern back pain study").

Investigator: Howard S. Kim, MD MS

Supported By: Agency for Healthcare Research and Quality (R01HS027426)

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you came to the emergency room for low back pain.

What should I know about a research study?

Someone will explain this research study to you. Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you. You can ask all the questions you want before you decide.

Why is this research being done?

We are studying how patients respond to different treatments for low back pain. Low back pain is a major source of pain and disability for many people, and we don't know the best way to treat low back pain. Some have suggested that physical therapy can be helpful for low back pain, so we are studying patients who saw a physical therapist in the emergency room to see how they compare to people who did not see a physical therapist in the emergency room. By conducting this research, we hope to find out if this study will show a difference in patients with low back pain who see a physical therapist in the emergency room compared to those patients who do not see a physical therapist in the emergency room. This research may lead to improvements in future emergency care for patients with low back pain.

How long will the research last and what will I need to do?

If you agree to participate, we expect that you will be in this research study for up to one year. In this study, the emergency room doctors have already been assigned (by random chance) to either have a physical therapist paired with them or not have a physical therapist paired with them. This assignment happened before your emergency room visit today and is part of a common research design called "cluster randomization." As a result, you may or may not see a physical therapist in the emergency room today.

As part of the research study, you will receive seven electronic surveys over the next year asking about your low back pain symptoms and whether you have used any medications for pain. These surveys will be sent to you by secure email link or secure text message (or over the phone, if you do not have email or text messaging) at one week, one month, two months, three months, six months, and one year after your emergency room visit.

If you saw a physical therapist in the emergency room today, you will be asked to perform three home exercises that have been personally selected for you by the physical therapist (eg, supine lower trunk rotation). You will also be referred to follow-up with an outpatient physical therapist. If you did not see a physical therapist in the emergency room today, we will refer you to see an outpatient physical therapist.

More detailed information about the study procedures can be found under the section. What happens if I say "Yes, I want to be in this research"?

Is there any way being in this study could be bad for me?

There is a small risk of accidental disclosure of your private information to others that are not involved in research. Additionally, we will ask you to perform some home exercises after you leave the emergency room today. These

exercises will involve movement, so there is a small risk that these activities may temporarily make your pain worse.

More detailed information about the risks of this study can be found under “Is there any way being in this study could be bad for me? (Detailed Risks)”

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, performing home exercises may ultimately improve your low back pain and allow you to recover from an injury more quickly. We also hope that your participation in this research study will allow us to learn more about physical therapy for low back pain and help other patients in the future.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate. If you choose not to participate in this study, you will still receive all of the usual components of medical care determined to be necessary by the emergency room physician. This could include advice from the physician, medications, laboratory or imaging tests, or an evaluation by a physical therapist.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Howard S. Kim, MD MS
Principal Investigator
312-926-0591
howard.kim@northwestern.edu

Kayla Muschong
Research Coordinator
312-926-8117
kayla.muschong@northwestern.edu

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

Your questions, concerns, or complaints are not being answered by the research team. You cannot reach the research team. You want to talk to someone besides the research team. You have questions about your rights as a research participant. You want to get information or provide input about this research.
How many people will be studied?

We expect about 360 people will be in this research study.

What happens if I say “Yes, I want to be in this research”?

If you saw a physical therapist in the emergency room today, they will have provided you with some recommended exercises to perform at home. As part of the research study, we will ask you to tell us how frequently you performed these exercises. We would also like to know how your symptoms are doing at home in the year following your emergency room visit. You will receive an e-mail or text message survey containing several questions about your low back pain symptoms and medications you have taken for low back pain at one week, one month, two months, three months, six months, and year following your emergency room visit (see below for full list of surveys). These surveys can be completed at home and should take about 15 minutes to complete. Finally, we will collect some basic information about your emergency room visit from the medical record, such as the total time spent in the emergency room, any medications received or prescribed, any imaging studies obtained, and your visit diagnosis.

If you saw a physical therapist in the emergency room today, the physical therapist evaluation is part of your standard medical care and you and your insurance company will be billed as you would for any clinical care received, such as blood or urine tests, x-rays, medications received, or procedures such as stitches. The follow-up surveys are part of the research study.

The follow-up surveys will be sent to you seven times over the course of the next year. The surveys will contain questions from the following questionnaires:

PROMIS-Pain Interference Oswestry Disability Index Pain Medication Use Survey Numeric Pain Rating Scale Global Rating of Change Scale Pain Self-Efficacy Questionnaire Pain Catastrophizing Scale Keele STarT Back Screening Tool
What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

Answer seven surveys about your symptoms and medication use over the next year.
If you saw a physical therapist today in the emergency room, tell us how frequently you performed the home exercises shown to you. You would tell us this information during the seven surveys mentioned above.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can remove you from any future e-mails or phone calls about further study participation.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you ask to withdraw from the study, we will ask you what you would like us to do with the data already collected in the past. You can either choose to allow us to use the previously collected data or you can ask us to delete it.

Detailed Risks: Is there any way being in this study could be bad for me?

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. Although the researchers have procedures in place to lessen the possibility of this happening, we cannot guarantee against unintentional disclosure of your information. This may result in loss of privacy or reputational harm.

If you saw a physical therapist today, they will have recommended that you perform some exercises at home. Performing recommended exercises will involve movement, so there is a risk that these activities may temporarily make your pain worse. We will not ask you to go through any movements that are unsafe or contraindicated, so we expect the risk for worse pain to be low and that care is taken to minimize such risk.

At each of the seven follow-up surveys, there will be an option to let us know about any worsening symptoms. We will monitor your comments weekly and contact you if needed. If you experience severe or debilitating pain, please contact the study staff sooner using the telephone or email address on the previous page. If you experience any of the following symptoms, please go directly to the nearest emergency room: loss of sensation to your legs or buttocks, weakness in your legs, or loss of control of your bladder or bowels. These could be signs of a more serious cause of your low back pain than what was originally diagnosed in the emergency room.

See the section below titled: “What happens to the information collected for the research?”.

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay (i.e., costs associated with your emergency room visit), such as the doctor’s evaluation, physical therapist evaluation, bloodwork, X-rays, or medications given. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: improvement in low back pain as a result of participating in physical therapy after your emergency room visit.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or elder] abuse or neglect.

Your data relating to this study will be stored on a password-protected, access-limited drive on the Northwestern University Feinberg School of Medicine server. Only the research team will have access to this securely stored data. The data will be stored for a period of three years following the completion of the study.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop

reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Data Sharing and Final Details

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you agree to take part in this research study, we will pay you up to $70 for your time and effort. This breaks down as follows: You would receive a $10 Visa gift card after completing each follow-up survey (at the original emergency room visit, then at one week, one month, two months, three months, six months, and one year following your emergency room visit). These gift cards will have an expiration date but will not have any fees for use and will not have restrictions on use. These gift cards will be provided in electronic format and delivered to you by e-mail.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

Results of physical examinations in the emergency room Medical history Lab tests or radiology tests obtained in the emergency room Records about study medication or drugs Billing information The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

Authorized members of the Northwestern University and the Shirley Ryan AbilityLab" workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board. Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers. Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities. Other University research centers and University contractors who are also working on the study, Study monitors and auditors who make sure that the study is being done properly, Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate

permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on 08/31/25.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Howard S. Kim, MD MS
Institution: Northwestern University Feinberg School of Medicine
Department: Department of Emergency Medicine
Address: 211 E. Ontario St, Ste 200, Chicago IL 60611.

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Consent Authorization

◯ I consent to participate in this study
◯ I do NOT consent to participate in this study

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Patient first name: _____

Patient last name: _____

Today's Date: _____

Patient Signature: _____