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CONSENT FOR RESEARCH

Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Pain with trigger finger injection: A comparison of steroid alone versus steroid/lidocaine mixture

Principal Investigator: Kenneth Taylor, M.D.

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Telephone Numbers: Weekdays: 8:00 a.m. to 4:30 p.m. (717) 531-5638; After hours and weekends: (717) 531-8521 (ask for the orthopaedic resident on 24-hour call)

Subject's Printed Name: _____

We are asking you to be in a research study.

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.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

We are asking you to be in this research study because you have a condition in your finger called trigger finger. Trigger finger is a condition that affects the tendons in your fingers or thumb.

This research is being done to compare pain relief and efficacy of trigger finger injection using a combination of lidocaine/corticosteroid versus corticosteroid injection alone or corticosteroid/saline combination.

Approximately 221 people will take part in this research study at Hershey Medical Center.

2. What will happen in this research study?

After you have read through this consent form, all of your questions have been answered to your satisfaction, and you have agreed to participate by signing this form, it will be determined by reviewing your medical history if you meet all of the criteria to participate in the study.

If you are eligible to be in the study, you will be randomized (assigned at random, like flipping a coin) to one of three study groups:

- CS - corticosteroid alone
- CSL – corticosteroid/lidocaine combination
- CSS – corticosteroid/saline combination

All treatment drugs are FDA approved and considered standard of care.

Randomization means that neither you nor your study doctor will choose what group you will be in. You will have an equal (1 out of 3) chance of being placed in any one of the three groups. You will not know which treatment group you have been randomized to (this is called blinding). This is used to decrease the amount of bias in a study.

The study investigator will perform a single injection under your skin into the joint surrounding your finger. One minute after the injection, you will complete a Patient Survey to assess your pain level and whether and how often you trigger (snap). Ten minutes after that, you will complete another Patient Survey. Objective hand exam will be performed including range of motion at MP, PIP and DIP joints, presence of clicking or locking, triggering score, pain with range of motion and grip strength as part of your routine standard of care.

You will receive a telephone call from the study doctor or member of his team six weeks following your injection. The telephone call should take about 10 minutes. The purpose of this call is to see how your hand is doing as well as have you complete the Patient Survey.

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

If you take part in this research, your major responsibilities will include:

- Completing the Patient Survey during your visit.
- Allowing a member of the research team to contact you via phone six weeks post-injection visit. During that phone call, you will be asked questions about how your hand is doing and you will need to complete a Patient Survey verbally on the phone.
- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

3. What are the risks and possible discomforts from being in this research study?

There is a risk of loss of confidentiality if your medical information or your identity are obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments.

There is a risk of allergic reaction to lidocaine or the preservative used in lidocaine.

There is risk of some pain and discomfort with the injection as well as the possibility of nerve damage (numb finger) for a period of time after the injection.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

You likely will not benefit from this particular research study; however, the treatment group that you are assigned to could be more beneficial than another in providing you pain relief.

4b. What are the possible benefits to others?

The results of this study may guide future treatment decisions.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive standard of care treatment only.
- Be part of a different research study, if one is available.

Before you decide if you want to be in this research, we will discuss the choices that are available to you. We will tell you about the possible benefits and risks of these choices.

6. How long will I take part in this research study?

If you agree, you will be in the research study for six weeks. You will not need to return to the research site again but will need to allow a member of the research team to contact you via phone six weeks following your injection.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers: your name, medical record number, phone number, and a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Taylor's research office.
- Your research records will be labeled with your code number and kept in a safe area in Dr. Taylor's research office.
- A copy of this signed consent form will be included in your HMC medical record. This means that other HMC healthcare providers will know you are in this study.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- The HMC/PSU pharmacy
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?
8a. What will I have to pay for if I take part in this research study?

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.

- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies will not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and he/she will arrange for medical treatment.

HMC/PSU compensation for injury

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?

The institution and investigators are not receiving any funds to support this research study.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from

the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

Your research doctor may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful, your condition has become worse, you become pregnant, you did not follow the instructions of the study doctor, you experience serious side effects
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

If you will be in another clinical research study at Hershey Medical Center or elsewhere while in this research, you should discuss the procedures and/or treatments with your physician or the study doctors. This precaution is to protect you from possible side effects from interactions of research drugs, treatments or testing.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study, Dr. Kenneth Taylor at 717-531-8521 or the orthopedic surgery doctor on 24-hour call if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to talk to someone else about any concerns related to the research.

You may visit the HSPO's web site at http://pennstatehershey.org/irb under subject information for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

A description of this clinical trial will be available at 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.

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INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Witness to Consent of Subjects Who Cannot Read or Write

Witness Statement: Your signature indicates that you were present during the informed consent discussion of this research for the above named subject, that the information in the consent form and any other written information was presented orally to the subject or subject representative, that he/she was given the opportunity to ask questions, that the informed consent decision was freely made by the subject or subject representative who indicated his/her consent and authorization for participation by (check the box as applicable):

☐ Making his/her mark
☐ Other means: _____
(fill in above)

_____	_____	_____	_____
Witness Signature	Date	Time	Printed Name