

# **Chronic Pain Diagnosis and Treatment in Torture Survivors**

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## WEILL CORNELL MEDICAL COLLEGE

### Informed Consent and HIPAA Authorization for Clinical Investigation

**Project Title:** Chronic pain diagnosis and treatment in torture survivors

**Research Project #:** 20-10022730

**Principal Investigator:** Gunisha Kaur, M.D., M.A.

**INSTITUTION:** Weill Cornell Medicine

### INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you are over the age of 18 and have experienced torture. This project evaluates whether a screening tool may improve the ability of your healthcare evaluator to make more accurate medical diagnoses. It requires you to attend a research appointment to complete a brief screening form and non-invasive medical evaluations.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

- (a) Taking part in the study is entirely voluntary.
- (b) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others;
- (c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You should take whatever time you need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The National Institute of Health is funding the research study. Dr. Gunisha Kaur is the primary investigator.

The study will take place at Weill Cornell Medicine, the Weill Cornell Clinical and Translational Science Center (CTSC), and the Weill Cornell Medicine Pain Centers.

### **WHY IS THE STUDY BEING DONE?**

The purpose of this study is to determine if standard protocols for the assessment of survivors of torture result in the under or missed diagnosis of medical conditions and illnesses identifiable by physicians. Additionally, this study will determine if a validated screening tool can supplement current standard protocols and indicate when patients should be referred for further evaluation.

### **HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

Participants in the study are referred to as subjects. About 100 subjects will take part in this study.

### **WHAT IS INVOLVED IN THE STUDY?**

If you agree to participate in this study, you will receive a non-invasive evaluation by a physician. You may also receive a medical evaluation of trauma as guided by the United Nations Istanbul Protocol. You will complete the Brief Pain Inventory (BPI) – a brief screening tool. The whole study will be conducted in your native language and will take approximately 60 to 90 minutes. If you are also receiving a UNIP evaluation, your study appointment may take from three to three and a half hours.

It is important to understand that this study is not providing treatment for any medical conditions or illnesses detected by our evaluation. **Participation in this study will have no influence on the decision regarding your asylum status.**

### **HOW LONG WILL I BE IN THE STUDY?**

You will be in the study for approximately one to three and a half hours. This includes the consenting process, evaluations, and completion of the BPI. After this appointment, you are finished with the study. There are no long-term follow-ups.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher first. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Weill Cornell Medicine. In addition, you will not lose any of the benefits to which you are entitled.

### **WHAT ARE THE RISKS OF THE STUDY?**

The risks of participation in this study include possible reemergence of psychological symptoms during physical evaluation and questionnaire. However, this risk is minimal; data show that it is unlikely to happen with brief, non-invasive encounters. You may also feel inconvenienced or distressed by having to completing the questionnaire.

For more information about risks and side effects, ask the researcher or contact Gunisha Kaur, M.D. at (212) 746-2461 or gus2004@med.cornell.edu.

### **ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

We cannot and do not guarantee that you will receive any benefits from this study. However, a possible benefit to you is the potential diagnosis of medical conditions. We hope the information learned from this study will benefit refugee torture survivors in the future.

### **WHAT OTHER OPTIONS ARE THERE?**

Instead of being in this study, you may choose not to participate in this study.

### **WHAT ABOUT CONFIDENTIALITY?**

Efforts will be made to protect your personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. If you choose to participate in this study, your written asylum affidavit, either from the Weill Cornell Center for Human Rights or an external site, including but not limited to the Columbia Human Rights Initiative Asylum Clinic (CHRIA), the Mount Sinai Human Rights Program, and the NYU Grossman School of Medicine Asylum Clinic, will be made visible to a trained member of the WCM study team. No personal or identifiable information in the affidavit will be included in any reports or publications resulting from this study. Records of study participants are stored and kept according to legal requirements. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- The WCMC Institutional Review Board (IRB)
- Biomedical Research Alliance of New York (BRANY)
- The Office of Human Research Protection (OHRP)
- National Institutes of Health

By signing this consent form, you authorize access to this confidential information.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. All data will be entered by the research coordinator into a secure REDcap database provided by the WCM CTSC. All paper forms will be scanned into REDcap and original copies retained in a locked cabinet in a secure office, only accessible to appropriate study staff. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

### **AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results

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- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- Department of Health and Human Services agencies
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

**Notice Concerning HIV-Related Information:** HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

**Collection of Identifiable Private Information:**

Identifiers might be removed from your identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

**CERTIFICATE OF CONFIDENTIALITY**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

**WHAT ARE THE COSTS?**

There are no costs associated with your participation in this study.

**EFFECT ON APPLICATION FOR ASYLUM STATUS**

Participating in this study will have absolutely zero effect on your application for asylum status. The information collected in this study will not be released to agencies involved with determining your asylum status.

**POLICY/PROCEDURES FOR RESEARCH RELATED INJURY**

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**The Policy and Procedure for Weill Cornell Medical College are as follows:**

We are obligated to inform you about WCMC's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCMC or NewYork-Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

**COMPENSATION FOR PARTICIPATION**

You will receive compensation for participating in this study at the conclusion of your visit. Compensation will include a \$100 gift card for time and travel if you participated in a medical evaluation and survey, or \$200 if you also participated in the United Nations Istanbul Protocol evaluation.

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

We will tell you about new information that may affect your health, welfare, or participation in this study.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, contact Dr. Gunisha Kaur at (212) 746-2461 or [gus2004@med.cornell.edu](mailto:gus2004@med.cornell.edu) or the on-call research staff (after 5 pm weekdays and weekends) at (212) 746-6700, Pager #16662 or [irb@med.cornell.edu](mailto:irb@med.cornell.edu). Be sure to inform the physician of your participation in this study.

If you have any questions about your rights as a research subject, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:  
(646) 962-8200  
1300 York Avenue  
Box 89  
New York, New York 10065

For complaints regarding this research study, or if you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns, or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at [www.branyirb.com/concerns-about-research](http://www.branyirb.com/concerns-about-research).

## Consent for Research Study

**Project Title:** Chronic pain diagnosis and treatment in torture survivors

**Principal Investigator:** Dr. Gunisha Kaur, M.D., M.A.

### **RESEARCHER'S STATEMENT**

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

\_\_\_\_\_  
Signature of person obtaining consent  
(Principal Investigator or Co-investigator)

\_\_\_\_\_  
Print name of person obtaining consent

\_\_\_\_\_  
Date

### **SUBJECT'S STATEMENT**

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with *Dr. Gunisha Kaur* and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Print Name of Subject

\_\_\_\_\_  
Date

### **WITNESS'S STATEMENT (Complete when using short form consent)**

I confirm that the research study was thoroughly explained to the participant. The researcher reviewed the consent form and answered all questions. The participant appeared to have understood the information.

staff and to inform them immediately if I experience any unexpected or unusual symptoms.

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Print Name of Witness

\_\_\_\_\_  
Date