

**Institutional Review Board  
NYU School of Medicine**

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Principal Investigator: Karen Raphael, PhD

**INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH**

**TITLE OF RESEARCH:**

SLEEP BRUXISM AND CENTRAL SENSITIZATION IN MYOFASCIAL FACE PAIN

**A. PURPOSE OF THE STUDY:**

You are being asked to volunteer in a research study. The National Institutes of Health is the sponsor of the study, and has awarded a grant to New York University to conduct this study. Dr. Karen Raphael is the Principal Investigator and Dr. David Sirois is the Co-Investigator.

This consent/authorization form includes information about this study. The purpose of this study is to understand possible causes of a chronic facial pain condition called myofascial face pain.

One theory about the cause of this problem is that people with myofascial face pain engage in bruxism (grinding or clenching teeth) more often than other people, during either the day or night. To test this theory, we plan to study the movement of your facial muscles while you sleep to measure sleep bruxism (nighttime grinding or clenching teeth). We will also study the movement of your facial muscles while you are awake. You will be exposed to different kinds of mildly stressful tasks; such as loud noises, cold water, and other tasks you may be asked to do.

A second theory about the cause of myofascial face pain is that the central nervous system (brain and spinal cord) of people with myofascial face pain processes pain differently than other people. We plan to test how your central nervous system responds when you feel very hot surfaces.

The behavior and responses of people with myofascial face pain will be compared to people who do not have myofascial face pain. You are being asked to participate in this study because either (a) you are a woman who has a diagnosis of myofascial face pain or (b) you match certain descriptive characteristics (age, sex, etc.) of someone with facial pain participating in the study, but do not have facial pain.

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**B. SUBJECT PARTICIPATION:**

We estimate that the following number of subjects will enroll in this study:  
At this site: 180 Total at all sites: 180

SUBJECT PARTICIPATION:

- Inpatient
- Outpatient: 120 subjects with myofascial face pain
- other: 60 subjects without myofascial face

Your participation will involve three visits. The first visit will last approximately 6 hours. Visits 2 and 3 require you to stay overnight at the sleep center and will last approximately 12 hours.

**C. DESCRIPTION OF THE RESEARCH:**

You may have already had an examination of your facial muscles by a study doctor, to determine that you qualify for the study due to myofascial face pain or if you are control, absence of myofascial face pain. You must be able to fall asleep at night during the 2 required overnight stays at the sleep center for you to complete the entire study.

You will be asked to sign this consent form, after we know that you understand all of the details of this study and all your questions have been answered. After the consent is signed and you agree to participate in the study, we will begin the examination and testing.

For research study purposes, about one of every five participants will have a repeat examination. A study doctor who specializes in orofacial pain but who did not examine you before will do an examination. Like your previous examination, this one will include palpation (light pressing of your facial muscles) and will take about 20 minutes. All subjects will be scheduled for their next appointment at the Bluestone Center for Clinical Research and a two-night sleep study at the Sleep Disorders Center.

**Visit 1:**

- The study doctor will perform an examination to see whether you might have another painful condition called fibromyalgia, a condition involving muscle pain in many areas of the body. The examination will include palpation (light pressing) of your body muscles. About one of every five participants will have a repeat examination by a different doctor. Study participants without myofascial pain, will also be examined by the study doctor.



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- A sample of your DNA (the part of your cells that contains inherited information) will be obtained for purposes of testing whether people with myofascial face pain tend to have certain kinds of genetic characteristics more often than people without myofascial pain. This may help explain why some people are at higher risk than others for developing this type of pain. The DNA will be obtained from your saliva, by having you spit a couple of teaspoons of saliva into an empty container. The saliva sample will be linked to you by being labeled with your study ID number. Because these DNA tests are for research purposes only, you will not receive any test results. Furthermore, the test results will not be shared with any persons outside the research study.
- Before the start of the main activities for the day, your blood pressure will be measured.

**Heat Study**

- You will be asked to place a small pad on your skin that is connected to a machine that heats the pad. The pad is removable and you can remove it easily if you feel the need. Sometimes you will be asked to place the pad on part of your hand or arm and sometimes you will be asked to place the pad on your cheek. The temperature of the pad will go up and down. It will become hot but never burn your skin. This machine has been used in other studies, without anyone getting injured. The pad may get hot enough so that it feels painful for a short time. If it feels too hot, you can easily and quickly remove the pad from your skin. You will have full control over the heat pad and you can ask the study team to lower the temperature, if it feels too hot. At various points, a member of the study team will ask you to rate the amount of different kinds of sensations that you might have experienced when the pad heats up or when it cools down, on a 0-100 scale. You will be trained on how to record this on the 0-100 scale. You will also be asked to do another short series of ratings, when your foot is placed in a bucket of hot water (about 46°C) for about two minutes. The water cannot burn you, but is likely to feel very hot. You can remove your foot at any point, if you cannot tolerate it. This part of the study should take about an hour.

**Stress Study**

- The study staff will record how your body responds to mildly stressful tasks by attaching electrodes (small sticky pads) to your face and chest. Your blood pressure, the activity of your heart, and movement of your facial muscles will be measured during a number of different tasks.
  - 1) For the first half-hour of this session, you will be given something relaxing to do, like reading a magazine or watching a video, while you are being monitored.
  - 2) Then you will participate in 4 different tasks. Each task will be recorded on videotape. The study staff will monitor the activity of your heart, your blood pressure, temperature and the movement of your facial muscles.



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1. You will be asked to place your foot in very cold water for 2 minutes. If the water feels too cold, you can easily and quickly take your foot out of the very cold water.
2. You will be asked to do a mental math test for 5 minutes
3. You will be asked to give a speech about your views on a controversial topic. You will have about 4 minutes to prepare and 3 minutes to give the speech. The speech you give will be recorded on videotape.
4. You will be asked to perform a 3 minute game in which you look for certain target words on a computer screen and press a button as quickly as possible, in order to avoid a blasting "white noise".

Just before each of the tasks, you will be given detailed instructions about what to do for each task and you will be given a couple of minutes break between each task. This entire session, including relaxation time, should take less than an hour.

Some people will do the heat study first, and others will do the stress study first. You will be given a break between the heat study and the stress study.

- You will be asked to complete a number of questionnaires about such things as your history of painful symptoms, your treatment history and response to treatments, your current medication use, your use of coffee and cigarettes, and your belief about your sleep quality and habits of grinding or clenching your teeth. You will also be asked to complete several questionnaires about your emotions, including how you cope with stress and any feelings of depression or anxiety. You can refuse to answer any of the questions that you do not feel comfortable answering.
- Within the next 2 days you will be scheduled for the sleep portion of the study (visits 2 and 3) which requires you to stay overnight for two consecutive nights. This will be arranged with you in advance.

**Visits 2 and 3:**

At your scheduled appointment time and date, you will arrive at the New York Sleep Institute located at 724 Second Avenue.

- On the first night, a sleep study will be performed to determine the presence of facial and body movement during sleep. Electrodes (sticky skin pads) will be attached to your skin on various parts of your body and your face in order to monitor brain waves, breathing and movement. The oxygen level in your blood will be monitored by a finger



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clip. You will also be monitored throughout the night(s) by audio and video. After this first night, it is possible that we may discover that you have a sleep disorder. If we discover that you have a sleep disorder we will tell you all the information we find out about you. A sleep disorder may make it impossible for you to continue in the study.

- If you are eligible for the second sleep study night, you will be instructed to try to make your daytime activities (during the day between the first and second sleep study nights) as normal as possible, including your usual amounts of caffeine consumption (drinking beverages such as coffee, energy drinks, sodas and tea); and tobacco use, if any, physical activity, medication and work.
- On the second night, you will report to the New York Sleep Institute in anticipation of the sleep study. You will undergo the same monitoring procedure described for the first night.

After this visit, you will have completed the study.

**D. COSTS/REIMBURSEMENTS:**

This is not a treatment study and no routine care will be provided as part of this study. There will be no costs to you for participating.

This study is being sponsored by a grant from the National Institutes of Health.

Reimbursement for your time and associated costs will happen according to the following plan:

- If you participate in the full study (half-day study of stress and pain, and the two-night sleep study), you will be reimbursed \$450 for your time, travel and inconvenience.
- If you do not participate in the sleep portion of the study, you will be reimbursed \$35 for your time, travel, and inconvenience.
- If you complete the first night of the sleep study, but cannot continue to the second night (for example, if you can not fall asleep in a laboratory setting), you will be reimbursed \$200 for your time and associated costs.

Payment for your participation will be processed by New York University. You will receive a check for your participation by mail.



**E. POTENTIAL RISKS AND DISCOMFORTS:**

The following are risks and discomforts that you may experience during your participation in this research study.

- For participants with facial pain, the palpation (light pressing) of your facial muscles might make your facial pain feel a little bit worse. This is expected to happen for less than 10% of facial pain participants. If your face pain does increase at all, it will go back to its usual levels within the next 48 hours.
- The stressful tasks during the stress testing may make you anxious and you may feel uncomfortable. These kinds of tasks have been used safely in similar kinds of studies. We will be available to speak with you and assist you if you become uncomfortable and we expect that you will feel fine within minutes after the tasks are completed.
- During the stress tasks some participants will find that keeping their skin in cold water is painful. At any time, you can remove your foot from the very cold water if you find it too uncomfortable.
- During the heat testing, most participants will feel brief painful sensations, although the maximum temperature to which you could be exposed has been shown in earlier studies to be safe. At any time you can remove the pad easily from your skin, if you find it to be too uncomfortable. If you do experience any local tenderness at the location where the heat pad had been resting, it is expected to disappear within a day.
- The equipment for the sleep study consists of wires attached to your skin. People who have been in sleep studies report that between the time they are ready to fall asleep, they adjust to this equipment, and are able to sleep.
- During both the stress testing and sleep studies, you may experience minor discomfort when the surface sensors are placed or removed from your skin. A small number of subjects may experience skin irritation that continues even after removing the sensors, due to an allergic reaction.
- As a result of participating in the sleep study, you may feel fatigued during the next day, if you don't experience a normal night's sleep in the lab.
- We will be performing tests of your DNA to determine whether you may have inherited genetic variations that could be related to how painful sensations are

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processed and your susceptibility to myofascial and other forms of pain. The genetic information that will be gathered in this study is only being obtained for conducting research. Your name will be removed from your samples and a numeric identification number will be assigned and include the date the sample was obtained. A copy of this information will be stored electronically at NYU College of Dentistry in an electronic file. The electronic information stored in computers will be protected with passwords and encrypted (coded) to protect it.

- The information that links your name and PHI to the ID number will be kept in a separate database and will not be entered into the study database. The database containing your name and PHI will be accessed during the study only by staff that interacts directly with you. The database will be password protected.
- Original hard copy information from the study will be stored in a limited access locked area that that can be accessed only by study staff.
- While we have no intention of releasing your genetic information to anyone outside of the research team, no data files are absolutely secure, and there is always a small risk of unintentional disclosure of your DNA results to others who are not part of the research study. We will do everything possible to keep the information in a way that cannot be linked to you.

**F. POTENTIAL BENEFITS:**

There is no direct benefit to you expected from your participation in this study, other than the possible value of knowing whether you have a specific pain related diagnosis and/or specific sleep disorder. It is hoped the knowledge gained will be of benefit to others in the future.

**G. ALTERNATIVES TO PARTICIPATING IN THE STUDY**

This is not a study related to treatment of a disease or condition in eligible subjects. You are free to choose not to participate in the study.

**H. CONFIDENTIALITY:**

Private information about you that identifies you may be used or shared for the purposes of this research project. This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which NYU School of Medicine and College of Dentistry will safeguard your privacy and confidentiality.

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If you agree to be in this research program, Dr. Raphael and her study team will be asking you to have certain tests involving how you react to stressful tasks, how you move your body and jaw muscles at night, and how your central nervous system (brain and spinal cord) processes painful sensations. None of these tests would have been done as part of your regular care. However, if it is determined from the sleep studies that you have sleep bruxism (grinding or clenching teeth), Drs. Raphael and Sirois may use these test results both to treat you and to complete this research. The results of these tests will be kept in your research chart and will be reported to the National Institutes of Health. Results of tests and studies done just for this research study and not as part of your regular care will not be included in your medical record.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of New York University School of Medicine (NYUSM) will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

When your study information will be disclosed outside of NYUSM as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. NYUSM will not disclose the code key, except as required by law.

Confidentiality of Your Research Record

Your research records will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. If your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The confidentiality of your research record is also protected by federal privacy regulations, as described below.

Confidentiality of Your Study Information

Your study records include information that identifies you and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. If data from this study are to be published or presented, we will first take out the information that identifies you.

Retention of Your Study Information

The study results will be kept in your research record for at least six years or until after the study is completed, whichever is longer. At that time, either the research information not already in your medical record will be destroyed or information identifying you will be removed



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from such study results at NYU. Any research information in your medical record will be kept indefinitely.

Your HIPAA Authorization

A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, in most cases we must seek your written permission to use or disclose identifiable health information about you that we use or create [your "protected health information"] in connection with research involving your treatment or medical records. This permission is called an Authorization.

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not be in the research program, but refusing to sign will not affect your health care (or payment for your health care) outside the study.

This Authorization will not expire unless you withdraw it in writing. You have the right to withdraw your authorization at any time, except to the extent that NYU has already relied upon it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K.

By signing this form you authorize the use and disclosure of the following information for this research:

- Your research record
- Results of laboratory and clinical tests
- Clinical and research observations made during your participation in the research

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research:

- Every research site for this study, including this hospital
- Every health care provider who provides services to you in connection with this study
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- The following research sponsors and the people and companies they use to oversee, administer, or conduct the research: National Institutes of Health
- The United States research regulatory agencies and other foreign regulatory agencies
- The members and staff of the hospital's affiliated Institutional Review Board
- The members and staff of the hospital's affiliated Privacy Board
- Principal Investigator: Karen Raphael, Ph.D.
- Study Coordinator(s)
- Members of the Research Team
- Bluestone Center for Clinical Research and its staff and affiliates
- The New York Sleep Institute and its staff and affiliates

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- The Patient Advocate or Research Ombudsman
- Members of the NYU/NYUMC Clinical Trials Office/Office of Research and Sponsored Programs

If any of the companies or institutions listed above merges or is sold during the course of this research, your Authorization will cover uses and disclosures of your protected health information to the new company or institution that assumes responsibility for the research.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

**I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:**

All forms of medical (or dental or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study.

If you sustain any injury during the course of the research or experience any side effect to a study drug or procedure, please contact the Principal Investigator Dr. Raphael at the following telephone number: 212-992-7043. If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. You do not give up any rights to seek payment for personal injury by signing this form.

**J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:**

Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.



**K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:**

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your Authorization for us to use or disclose your protected health information for the study. If you do decide to withdraw your consent, we ask that you contact Dr. Raphael and let her know that you are withdrawing from the study. Her mailing address is New York University College of Dentistry, Veterans Administration 16 North, 423 E. 23<sup>rd</sup> Street, New York, NY 10010. If you wish to withdraw your Authorization as well, you must contact Dr. Raphael in writing.

Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study and may be asked to return for a final check-up.

The study doctor may also decide to withdraw you from the study for certain reasons. Some possible reasons for withdrawing a subject from the study would be worsening health or other conditions that might make it harmful for you. Other reasons that could lead to withdrawing a patient from the study include failure to keep study appointments or follow directions or the need for treatment that is not allowed in the study.

For withdrawal of samples:

If you agree to allow your genetic information (cells from your saliva) to be kept for research, you are free to change your mind at any time. We ask that you contact Dr. Raphael in writing and let her know you are withdrawing your permission for your cells to be used for research. Her mailing address is New York University College of Dentistry, Veterans Administration 16 North, 423 E. 23<sup>rd</sup> Street, New York, NY 10010. You may ask us to destroy any unused cells or have all identifying information removed that would link the sample to you.

**L. PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH:**

I can authorize the principal investigator at NYU (Dr. Raphael) to contact me about future research on chronic pain. If I agree to be contacted about future chronic pain research within the NYU College of Dentistry, Bluestone Center for Clinical Research, this future research will be



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approved by NYU Institutional Review Board (IRB), and Dr. Raphael or her co-investigators will be affiliated with the research protocol.

If I agree, then someone from Dr. Raphael’s research staff might contact me in the future and she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

[check one]

I agree to be contacted by the NYU Principal Investigator or Co-Investigators of the research study titled: “Sleep Bruxism and Central Sensitization in Myofascial Face Pain”.

I **do not** want to be contacted by the NYU Principal Investigator or Co-Investigator of the research study titled: “Sleep Bruxism and Central Sensitization in Myofascial Face Pain”.

\_\_\_\_\_  
Signature of participant or legal representative Date

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the NYUSM or NYUCD facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

**M. CONTACT PERSON(S):**

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-263-4110.

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Dr. Karen Raphael at the following telephone number 212-992-7043.

12 of 13 Subject’s Initials: \_\_\_\_\_ Date: \_\_\_\_\_

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AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

- I have read this consent form or it was read to me by: \_\_\_\_\_.

Any questions I had were answered by: \_\_\_\_\_.

I am am not participating in another research project at this time. (If yes, you should discuss this with your study doctor.)

I voluntarily agree to participate in this research program at:

- NYU College of Dentistry; Bluestone Center for Clinical Research
New York Sleep Institute

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form.

By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures of my protected health information as described above.

WHEN THE SUBJECT IS AN ADULT:

Print Name of Participant Signature of Participant Date

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

13 of 13 Subject's Initials: Date:

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