NYU Langone MEDICAL CENTER

# Main Study Informed Consent Form, Version D

**(Direct)**

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| **Title of Study:** | Preliminary Safety Study of Botulinum Toxin For Treatment of Myofascial TMJD Pain (S14-00946) |
| **Principal Investigator:** | Karen G. Raphael, Ph.D.<br>Department of Oral and Maxillofacial Pathology, Radiology, and Medicine<br>New York University College of Dentistry<br>380 Second Avenue, Suite 301<br>New York, NY 10010<br>(212) 992-7043 |
| **Emergency Contact:** | Dr. David Sirois<br>(908) 468-7560 |

## 1. About volunteering for this research study

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

People who agree to take part in research studies are called “subjects” or “research subjects.” These terms are used throughout this consent form. Before you make your decision whether or not to participate, you will need to know what the study is about, the possible risks and benefits of participating in this study, and what you will be expected to do. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, it will be necessary for you to sign this form. You may take part in the study after sending us a copy of this form by e-mail or fax, but it will also be necessary that you mail us this original form with your signature for our files. We will send you a copy of your original form to keep.

## 2. What is the purpose of this study?

The purpose of this study is to understand the risks that may be associated with treating facial pain (such as “TMJ pain”) with Botox injections. Botox is sometimes injected into chewing and surrounding muscles to reduce facial pain. Botox is a biological substance that causes partial muscle paralysis and, in the process, relaxes the injected muscles.

Botox is approved by the Food and Drug Administration (FDA) for a variety of pain conditions, but it has not been approved by the FDA for treatment of facial pain. It is sometimes used “off label,” to

treat patients with facial pain. We are interested in learning whether people who have received Botox treatment have experienced side effects, by comparing the frequency of symptoms in patients who have and who have not had Botox injections in their facial muscles to treat their pain. We also would like to find out whether the bones in and around the temporomandibular joint (TMJ) are affected by this treatment. The TMJ connects the top and bottom parts of your jaw and acts somewhat like a hinge when you open and close your mouth. We are the first investigators to do research regarding bone related impacts of Botox injections for facial pain in humans.

We are asking you to take part in this research study because you have been diagnosed with a TMJ/facial pain condition, have experienced TMJ/facial pain for at least the past six months, and have either (1) received two or more cycles of injections of Botox in your cheek and forehead areas to treat facial pain in the past 9 months or (2) have no history of Botox injections anywhere on your head and face but you have sought other facial pain treatments.

## 3. How long will I be in the study, and how many other people will be in the study?

This study will be an outpatient study.

Your *entire* participation in study procedures should take the equivalent of about a full day. Travel and scheduling will likely require *portions* of two or three days.

All study participants need to complete study procedures within 75 days after study enrollment.

With few exceptions, if you have been receiving Botox treatment for facial pain, we require CBCT imaging be completed between 6 and 10 weeks after your *most recent* Botox treatment.

The duration of the entire study is expected to be two to three years. About 100 study subjects over age 18 are expected to be recruited from the New York City and Los Angeles metropolitan areas. Approximately half will have had previous injections of Botox in their chewing muscles to treat their facial pain, and the other half will not have had Botox injections for any reason.

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

If you choose to take part in the study, the following will happen:

- If you choose to take part in the study, we will interview you by telephone about your facial pain, your overall health and well-being. If you prefer, you may complete an on-line survey covering the same topics. The interview or survey should take less than an hour.

- You will have special images taken of your jaw and upper neck at or near New York University College of Dentistry (NYUCD) or the University of California/Los Angeles (UCLA) depending on where you live. This procedure is a low-radiation scan known as Cone Beam Computed Tomography (CBCT). CBCT imaging is done as you are seated with your chin in a rest. It is painless.

If you have had Botox injections in your chewing muscles, we will let you know of a specific

range of dates within which you would need to be imaged. If you have not had Botox injections in your chewing muscles, we will specify an end date for imaging. This procedure should take about half an hour, not including any waiting room time. Facilities might ask that you arrive a half hour before your imaging appointment. If you were to accidentally move during CBCT imaging, causing the image to be unclear and not usable, the CBCT might need to be repeated.

There is a small chance that study radiologists will request a second image of your face be taken, after you have left your CBCT appointment. If that occurs, you will be requested to return for a second image, but that is entirely optional. Whether or not you return for a second CBCT would have no influence on compensation for study participation. (Please see section 9.)

Your CBCT images will be sent to University of Connecticut Health Center, School of Dental Medicine for analysis. Your images will not be sent with any information that identifies who you are.

- Unless you had bone density testing of the hip and lower back within the last year, and using particular machinery, you will have low radiation scans of your hip and spine called a DEXA scan. The imaging measures overall bone density. The DEXA scan will be performed at a location as close as possible to either your home, NYUCD, or UCLA.

  If you have undergone any other kind of medical imaging that involves swallowing or being injected with a contrast medium (dye), you will need to wait at least one week before you can undergo a DEXA scan.

  If you need a bone density scan, it should take less than an hour.

- We will also ask you to complete and sign a medical/dental health record release form and return it to us by ground mail or e-mail as an attachment. We will forward the form to the dentist or clinician(s) who treats your facial pain as indicated on the first page of the form, so that s/he can provide us with information about your history or facial pain treatment.

  It should also be noted that if your doctor provides treatment information inconsistent with your earlier self-reported treatment history and symptoms, the Principal Investigator may choose to terminate you from the study. Study compensation cannot be provided, if such a decision is made, even if study procedures are nearly finished.

- These study procedures can be completed in any order, as convenient. The amount of time between these procedures does not matter, as long as all are performed within 75 days after study enrollment.

## 5. What are the possible risks or discomforts?

During this study, you will have exposure to radiation from a CBCT scan and DEXA bone density scans (if needed). This radiation exposure is not necessary for your medical care and is for research purposes only. One CBCT scan has a radiation exposure of 0.215 mSv and the DEXA scans have a radiation exposure of 0.024 mSv. If both a CBCT and DEXA scanning are required, study related radiation would be a total of 0.239 mSv beyond usual conditions of daily living. Such a level of radiation is less than 8% of the yearly natural background radiation in the US (3 mSv). The use of radiation may involve a low risk of cancer and is required to obtain the desired research information.

The need for a repeated CBCT is highly unlikely, occurring in far less than 1% of clinical imaging. In the rare event that you would need a repeat image, your CBCT radiation would increase to approximately

0.454 mSv for the study as a whole (about 15% of the yearly natural background of radiation on earth at sea level).

Pregnant women cannot be exposed to radiation. Women known to be pregnant, or who suspect they are pregnant, cannot have CBCT or DEXA scans.

In order to be eligible for this study, we require that you are not pregnant and, unless you have permanently stopped menstruating, are willing to continue to use a highly reliable form of contraception (abstinence from intercourse, birth control pills, IUD, etc.) during your participation in the study. **Pregnant women or women at risk of becoming pregnant are not eligible to participate in the study, because it involves radiological imaging**.

The research may also involve other risks that are not currently foreseeable.

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 of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal government agency sponsoring the project, needed for auditing or program evaluation by *the National Institute of Dental and Craniofacial Research* which is funding this project. 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.

## 6. What if new information becomes available?

During the course of this study, we may discover new information that could be important to you, including information that might cause you to change your mind about participating in the study. We will notify you as soon as possible if such information becomes available.

## 7. What are the possible benefits of the study?

You are not expected to receive any direct benefit from participating in this research study. The study may result in benefits to society by adding to our knowledge regarding the safety of Botox injections in the chewing muscles. A possible benefit to you is that CBCT imaging or the DEXA scan may potentially reveal previously undetected clinical problem that would merit additional medical testing. All participants will receive copies of their clinical radiology reports and a brief letter indicating whether clinical follow-up is recommended.

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

You are free to choose not to participate. Your choice will have no effect on any treatments that you are currently receiving.

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

Yes, you will be paid $400 after all study procedures are completed, to compensate you for your time, travel, and any loss of wages due to your participation. If you do not complete all the required study procedures or are terminated from the study by the Principal Investigator, you will not receive payment.

In order for you to receive a payment check, we will need to ask for either your Social Security number or your Alien Registration number. If you do not have either of these numbers, you may participate in the study but we will not be able to provide you with payment.

## 10. Will I have to pay for anything?

No, you will not have to pay for any procedures or tests that are part of the study. These are covered by research funds.

If an imaging facility accidently sends a bill or bills your insurance, let us know immediately and it will be taken care of. Contact the lead study coordinator, Jane Bradshaw, at (212)998-9208 or jmb39@nyu.edu. You may also contact the Principal Investigator, Dr. Karen Raphael, at (212)992-7043 or kgr234@nyu.edu.

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

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

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

There are no plans by the NYU School of Medicine, Medical Center, or College of Dentistry to pay you or provide you other compensation for any injury. Please know, however, that you do not give up any of your legal rights by signing this form.

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

Your participation in the study will end after you have returned the medical/dental record release form to us, completed the interview, undergone CBCT imaging and (if necessary) a bone density scan. We will review your personal CBCT imaging and bone density scan and send a clinical summary to you within one month of completion of the study. If you are scheduled but miss more than two CBCT or bone density appointments, we may decide to discontinue your participation in the study before all procedures have been completed.

If you decide to participate, you are free to discontinue your participation in the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

## 13. How will my information be protected?

The NYU College of Dentistry (NYUCD) and NYU Langone Medical Center (NYULMC) are committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You

have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

**What information about me may be used or shared with others?**

The following information may be used or shared in connection with this research:

- Information in your medical and dental records for which you have authorized release, and
- Information in your research records (interview/on-line survey results, results from CBCT and bone density imaging).

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

**Why is my information being used?**

Your health information will be used by the research team and others involved in conducting and overseeing the study.

**Who may use and share information about me?**

The following individuals may use, share or receive your information for purposes of this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study,
- The study sponsor: National Institutes of Health,
- Health care providers who provide imaging or other clinical services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

**How long may my information be used or shared?**

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

**Can I change my mind and withdraw permission to use or share my information?**

Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, please send a written notice to the Principal Investigator of the study whose contact information appears at the top of page 1 of this form. If you were to withdraw your permission, you would not be able to remain in the study.

**How will my privacy be protected?**

Any electronic or paper forms and documents will have multiple layers of protection. If you would like specific details about protection methods, study personnel will discuss procedures to protect your privacy and confidentiality. We have also provided you with a separate document which details the steps taken to protect your privacy.

## 14. Optional permission for future use

NYUCD and NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYUCD, NYULMC or its research partners. To give us this additional permission, please check the box on this page and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYUCD and NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYUCD, NYULMC or its research partners. _____ Subject Initials

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

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

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

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

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

| Name of Study Subject (Print) | Signature of Subject | Date Signed |
|---|---|---|
| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent | Date Signed |
| Name of Principal Investigator (Print) | Signature of Principal Investigator | Date Signed |