

Consent Form for Participation in the Research Study Entitled
Voice Damage and College Athletes

Funding Source: None.

IRB approval #

Principal investigator
Marcus Anthony, M.D.
3301 College Avenue
Fort Lauderdale, FL 33314
(954) XXX-XXXX

Co-investigator
Roberto Calvo, Ph.D.
3301 College Avenue
Fort Lauderdale, FL 33314
(954) XXX-XXXX

Institutional Review Board
Nova Southeastern University
Office of Grants and Contracts
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information
Nova Southeastern University
Speech-Language Pathology Clinic
3301 College Avenue
Fort Lauderdale, FL 33314

Description of the Study

This project involves research. The goal of this study is to see if a voice therapy program can help college athletes who have problems with their voice reduce the damage to their vocal chords. You are invited to participate because you are a patient at the clinic who has vocal problems and you are a college athlete. If you agree to be involved, Dr. Marcus will look at your vocal chords before you start voice therapy. We will do this via a stroboscopic test which is a regular part of a voice evaluation. This is a test where a small tube that has a camera on the end goes down your throat. This lets us look at your vocal chords and record a video picture of them. This should not take more than 15 minutes. Dr. Calvo or one of his master's students will then work with you one hour per week for 14 weeks (a total of 14 hours) on voice therapy exercises. These exercises will include making different noises at different pitches. We'll also working on how to project your voice without hurting your vocal chords. All of the therapy will be standard treatment. The untried portion of this study is to see if the therapy works with college athletes. At the end of the 14 weeks, we will take a video picture of your vocal chords again using the same test as the first time, which will take another 15 minutes.

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Video Recording:

This research project includes video recording of your vocal chords while we ask you to make different sounds. This video tape will be available to be seen and heard by the researchers, master's students working on the project, and personnel from the university's human research oversight board (the Institutional Review Board or IRB). Screen pictures of your vocal folds may be used in publication of the research results or for use in conference presentations. Your agreement allows us to use this video tape for an indefinite period of time. Because your voice will be potentially identifiable by anyone who sees or hears the tape, your confidentiality for things you say on the tape cannot be promised. We will not ask you to say personal things while you are videotaped: you will make sounds and say common words and phrases.

Risks/Benefits to the Participant:

There are minimal risks to you. You may be uncomfortable or feel like you are gagging during the two stroboscopic tests. We will try to make you comfortable. Dr. Anthony will try to help you with any problems you have with the tests. There is a small risk of damaging the vocal cords during the stroboscopic tests. You might need to see other medical professionals if you have any problems. You will have to pay for these services.

Because we are recording your voice and image of your vocal chords it is possible someone might find out you are in the study. We will be using your name on the recordings and on notes taken during therapy. If someone found these notes or tapes the person would know you are in the study. We will keep all data in a locked cabinet. We will not use your name when presenting or publishing the findings of this research study.

A benefit to being in this study is that you'll get 14 weeks of free treatment.

If you have any concerns about the risks or benefits of participating in this study, you may contact Dr. Anthony or Dr. Calvo or the university's human research oversight board (the Institutional Review Board or IRB) IRB office at the numbers indicated above.

Costs and Payments to the Participant

There are no costs for your participation. You will be paid \$100 for being in the study. Twenty-five dollars will be paid after the first test. You will get \$50 dollars at the end of the 14 weeks of therapy. You will get the last \$25 after the last test.

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Confidentiality and Privacy:

We will keep your information confidential. We will keep records and tapes in a locked cabinet at the speech clinic for 36 months. Study records with your name on it will be shredded 36 months after the end of the study. As noted above in the video recording section, if we use your video recording it may be kept longer than 36 months. If we choose not to use your video recording in presentations or publications, it will be destroyed 36 months after the end of the study. All information obtained in this study is strictly confidential unless we are required to share it by law. The university's human research oversight board (the Institutional Review Board or IRB) IRB and other government agencies may review research records.

Use of Protected Health Information (PHI):

As part of this study, you are asked to allow Drs. Anthony and Calvo access to your speech records at the NSU Speech-Language Pathology clinic. The purpose of this authorization is to allow the researchers to obtain the following specific information to be used as part of this research study. (1) Pictures of your vocal chords from previous visits and vocal intake information. (2) Record of any past therapy received at this clinic. You may change your mind and revoke (take back) this authorization at any time, except to the extent that the researchers have already acted based on this authorization. To revoke this authorization you must write to: Marcus Anthony, MD, 3301 College Avenue, Fort Lauderdale, FL 33314.

Your treatment at NSU will not be affected in any way by your refusal to give this authorization or to later decide to revoke authorization. You will not be able to participate in the study procedures if you decide that you will not give authorization. If you allow this transfer of information from your medical file, this information will no longer be protected by federal or state law and, thus, it is possible that this information could be re-disclosed. However, we will protect the confidentiality of this information as discussed in the Confidentiality section. You have the right to refuse to sign this authorization and informed consent. This will not affect your treatment in any manner.

You have the right to inspect or copy your Protected Health Information to be used or disclosed as permitted under federal and state law (whichever gives you greater access rights). You also can refuse to sign this agreement. Participating in this study does not affect your rights to inspect or copy your Protected Health Information.

Initials: _____ **Date:** _____

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Participant's Right to Withdraw from the Study:

You can refuse to join or leave this study at any time. In either case there is no penalty or loss of services to you. If you choose to leave, you may ask that any of your data which we collected be destroyed unless this is not allowed by state or federal law. If you do not take part in this study, you can pay to receive the standard voice therapy (including the stroboscopic test), but your data will not be used in any research studies.

Other Considerations:

If the researchers learn information that might change your mind about being involved, you will be told of this information.

Voluntary Consent by Participant:

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate in the research study entitled "Voice Damage and College Athletes". All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study they will be answered by Drs. Anthony or Calvo. I also voluntarily agree to the release of my PHI as described in this document. A copy of this form has been given to me. This consent ends at the conclusion of this study.

Participant's Signature: _____ Date: _____

Witness's Signature: _____ Date: _____