



## **Informed Consent form for Case Reports Utilizing Tension and Trauma Release Exercises (TRE®)**

**Principal Investigator:** [Name]  
**Organization:** TRE® Research Team  
**Research project:** Case Reports Utilizing TRE®

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form.**

### **PART I: Information Sheet**

#### **Introduction**

I am [Name] working for TRE® Research Team. We are doing research on the effects of TRE®. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me.

#### **Purpose of the research**

This research is to observe and document the effects of TRE® in individuals.

#### **Type of Research Intervention**

This research will involve TRE® instruction and practice. TRE® is designed to reduce stress by releasing deep tension patterns created by immediate exposure to extreme stress and/or from prolonged chronic emotional or physical pressure and strain. Through seven simple exercises, TRE® turns on a self-controlled muscular shaking that is the body's natural re-balancing process. These tremors spread from the legs, up the spine, releasing tension throughout the body.

Designed as a self-help modality, the TRE® technique is easily learned, reproduced, and practiced with immediate results being the norm. In 2011, the US Department of Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury recognized TRE® as a promising modality for regulating stress and promoting resiliency, especially due to its “simplicity, brevity, and immediate effects.”



## **Participant selection**

We are inviting individual adults to participate in this research on TRE®.

## **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate in this research project, you will still be able to receive TRE® instruction. You may change your mind later and stop participating even if you agreed earlier.

## **Procedures and Protocol**

In addition to the standard treatment you may already be receiving by your primary medical providers, you will be instructed in TRE®. You will practice TRE once each week for [number] minutes with a TRE® instructor. You will be asked to practice TRE® independently [number of times] each week for [number] minutes for [number] weeks and keep a diary of your experiences. You will also be asked to fill out several questionnaires before, during, at the end of the [number] week research period, and once more [number] weeks later.

## **Risks**

By participating in this research, there is a possibility that you may experience some mild fatigue, muscle soreness, and/or emotional distress. While the possibility of this happening is very low, you should still be aware of the possibility. I will try to decrease the chances of this happening, but if something unexpected does happen, I will provide you with corrective instruction and emotional support.

## **Benefits**

If you participate in this research, you will have the following benefits: TRE® instruction. Your participation is likely to help us answer the research question, which will likely benefit others.

## **Reimbursements**

There is no compensation for participating in this research.

## **Confidentiality**

The information that I collect from this research project will be kept confidential. Any information about you will have a number on it instead of your name. Only I will know what your number is and we will lock that information up with a lock and key. De-identified information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. It will not be shared with or given to anyone except TRE® research team and the research affiliates involved in the



processing of the statistical data.

### **Sharing the Results**

The knowledge that we get from doing this research will be shared with you before it is made widely available to the public. We will publish the results in order that other interested people may learn from our research. Confidential information will not be shared.

### **Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment in any way. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

### **Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

[Name, physical address, email address, phone number]

## **PART II: Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

**Print Name of Participant** \_\_\_\_\_

**Signature of Participant** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**



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**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Print Name of Researcher/person taking the consent** \_\_\_\_\_

**Signature of Researcher /person taking the consent** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**