

**SHANTI COUNSELING SERVICES, LLC**  
**Theresa Callard-Moore, ACSW, LMSW**  
**6199 Miller Rd., Suite A, Swartz Creek, MI 48473**  
**810-630-0904 x2**

## **Informed Consent form for PATIENTS**

Name the group of individuals for whom this informed consent form is for adult men and women who participate in traditional and /or complementary and alternative medicine CAM (sometimes referred to as Holistic) and who we have invited to gather health data for one year.

**Sponsored by: Theresa Callard-Moore, ACSW**

**Research Assistance by: Holly Nolan-Forry, Kelly Dues, Robin Mikkola**

### **THE INTEGRITY PROJECT**

**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 a Holistic Psychotherapist conducting research on what individuals are doing to stay healthy, outside of visiting your doctor's office. I am looking at 25 individuals who do not participate in holistic methods and 25 who do. Holistic methods may include visiting a chiropractor, a massage therapist, an acupuncturist, going to yoga class, etc. I would like to invite you to do a health survey (Health Risk Assessment or HRA) when you begin, which you will have access to the results. Then for 12 months I will send you a survey to complete, where you will self-report your health habits for the month. At the end of the year, you will get another chance to do a health survey (HRA) and see if your health has improved, stayed the same, or declined. The research will allow me to gather data to see if holistic methods improve your overall health.

Your participation is free and all your data will be confidential. I am going to give you information on this research project. You do not have to decide today whether you will participate in the research. If there are any words or terms that you do not understand, I would be happy to explain them to you. If you have any questions later, you can ask me at any time.

### **Purpose of the research**

Currently there are 325 million people in the United States, which would estimate the 38% of people using CAM at 12 million people. The number of holistic providers is more difficult to estimate since it could include massage therapists, acupuncturists, chiropractors, holistic dentists, holistic psychotherapists, reiki practitioners, etc. Many of these methods are not included in our traditional healthcare coverage, so they are paid for privately. Many of my patients reported feeling better when they added holistic or CAM to their traditional healthcare. I have developed a business plan that could bridge the gap between traditional healthcare insurance and CAM and make it more affordable for the consumers.

### **Type of Research Intervention**

The goal of this research is to gather a base line health survey at the start of one year, collect your wellness habits every month, and do another health survey at the end of one year.

### **Participant selection**

You can participate in one of two groups. The first group of 25 adults will be using traditional health care and self-determine that they don't typically use CAM. The second group of 25 adults will be selected if they self-determine they regularly use CAM. Your name and email will be collected to send you the link to the health surveys and to be able to send you monthly surveys. Your demographics will be collected (i.e.: male/female, age, and weight) but your name will remain anonymous. You will not be getting "junk emails" from the study, only one email per month with a survey of your current health practices.

**Example of question:** "how many vegetables do you eat per day?" or "how many days this month did you walk at least 30 minutes?".

### **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at Shanti Counseling Services will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic. You may change your mind later and stop participating even if you agreed earlier.)

- **Examples of understanding:** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

### **Duration**

The research takes place over 10 minutes per survey, once every 12 months in total. During that time, it will be necessary for you to open your email, click on the link provided, and complete the survey. You will complete 2 health surveys (HRA) total and 10 follow up surveys each month using Survey Monkey,

In summary, you will be asked to complete 12 surveys total.

- **Examples of understanding:** *Can you tell me if you remember the number of times that we are asking you to come to complete the surveys? Do you have any other questions? Do you want me to go through the procedures again?*

### **Risks**

There are no known physical risks for participating in this survey process, other than any risk involved by using your personal computer. Your name and email address will only be used by Theresa Callard-Moore, ACSW for the Integrity Project. It is possible that you may be contacted for follow up or asked to participate again in the future. Your information will not be sold or used for spam marketing. You can have your email removed from the survey any time.

- **Examples of understanding:** *Do you understand that your name and email will be kept confidential?*

### **Benefits**

If you participate in this research, you will have the following benefits: Your participation is free and the 2 health surveys (HRA) normally cost \$30.00 each, therefore you receive information about your health valued at \$60.00. There may not be any direct benefit for you but your participation is likely to help us find the build a bridge between Complementary and Alternative Medicine and Traditional Medicine. The awareness brought by this research may help us build Integrity: A Community Health Plan, which can benefit consumers, Holistic Providers, Holistic Organizations, and the health of your community.

### **Reimbursements**

Your participation is sponsored by Theresa Callard-Moore, ACSW for the cost of the health surveys and monthly surveys. You will not be reimbursed for your participation.

- **Examples of understanding:** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay you? Do you have any other questions?*

### **Confidentiality**

The information that we collect from this research project will be kept confidential. 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. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

**Example of understanding:** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

### **Sharing the Results**

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

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

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

### **Alternatives to Participating**

If you do not want to participate in the study, but would like to share your success or failure story about your medical or holistic care, we are collecting qualitative data and will be using that to support our research as well. You may send your story to *integrityresearchproject@gmail.com*. Your name, email, and demographics will remain confidential. We will send you a separate email with the consent form to collect qualitative data for you to sign.

### **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: ***Theresa Callard-Moore, ACSW 6199 Miller Rd., Suite A, Swartz Creek, MI 48473***

- ***Example of understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study?*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

**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 to 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**

**If illiterate**

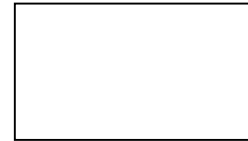
**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness** \_\_\_\_\_  
**participant**

**AND Thumb print of**

**Signature of witness** \_\_\_\_\_

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



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

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:**

- 1. Sign up for research project by email**
- 2. Send links for health survey and monthly surveys**
- 3. Share outcome data with participants before publishing data.**

**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.**

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

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

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