



**Best Life Pharmacy and Restaurant - Christopher Sylvain**

**This Informed Consent Form is for men and women who are current residents of the New Orleans, Louisiana, and surrounding areas, and who we are inviting to participate in research on a waist reduction diet program. The title of our research project is “Quit Switch Sweat: Reducing Belly Fat and Preventing Diabetes.”**

**Christopher Sylvain**

**Best Life Pharmacy and Restaurant**

**Xavier University**

**Quit Switch Sweat Research Proposal**

**PART I: Information Sheet**

**Introduction**

I am Christopher Sylvain, working for Best Life Pharmacy and Restaurant. We are doing research on diet and the reduction of waistline to prevent chronic diseases and to improve quality of life. 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.

**Purpose of the research**

Having a larger than normal waistline is very common in adults living in America. Those who have disproportionate waistlines are likely to develop weight-related diseases such as diabetes or heart disease, and many also struggle with low self-esteem and low quality of life. Having an enlarged waistline is very preventable with healthy eating habits and exercise. The reason we are doing this research is to find out if the Quit Switch Sweat diet plan is better than other weight loss programs that are currently being used.

**Type of Research Intervention**

This research will involve three lifestyle and diet changes for 40 days. The three components include:

1. Quit – Quit drinking soft drinks, juices, diet drinks and smoothies
2. Switch – Switch to brown from white. Brown Rice, Whole Grain Pasta and Dreads
3. Sweat – Sweat Daily

**Participant selection**

We are inviting all adults who live in America to participate in this research on the new diet program.

**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 Best Life Pharmacy and Restaurant will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment this is routinely offered at Best Life Pharmacy and Restaurant for waist reduction and weight loss, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

**Procedures and Protocol**

**A. Description of the Process**

During the research you will follow these dietary guidelines.

1. Quit – Quit drinking soft drinks, juices, and smoothies
2. Switch – Switch from white grains/bread to whole wheat grains/bread
3. Sweat – Sweat/Exercise

In total, you will be asked to track your waist size, weight, and height 2 times in 40 days. Once on day 1 and once on day 40. You will be asked to track the number of times you did not follow the Quit Switch Sweat diet plan as the misses occur.

**Duration**

The research takes place over 40 days. During that time, it will be necessary to track your waist size, weight, height, and number of times you did not follow the Quit Switch Sweat diet plan.

In total, you will be asked to track your waist size, weight, and height 2 times in 40 days. Once on day 1 and once on day 40. You will be asked to track the number of times you did not follow the Quit Switch Sweat diet plan as the misses occur.

**Side Effects**

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

**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 except

**Sharing the Results**

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meeting in the community, and these will be announced. After these meetings, 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 of your rights will still be respected.

**Alternatives to Participating**

If you do not wish to take part in the research, you will be provided with the established standard treatment available at Best Life Pharmacy and Restaurant.

**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.

Christopher Sylvain

2657 Tulane Ave

New Orleans, LA 70119

504-621-6048

Csylvain@bestlifepharmacy.com

**This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.**

* ***Example of question to elucidate 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? Etc.*

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**

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

**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**

**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.**

**2.**

**3.**

**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**