

# **Biolife Advance NF Informed Consent**

# Biolife Health Center, LLC

16175 Golf Club Road Suite 108, Weston, FL 33326

## Informed Consent form for Participant

This Informed Consent Form is for adult men and women who we are inviting to participate in research on a health app trial called Biolife Advance NF - Remotely Guided Integrated Behavioral Health.

The title of our research project is: Testing of Biolife Advance NF to evaluate the performance, effectiveness and usability of the app. The app is designed to help in conditions such as anxiety, stress, ADHD, depression, mood, peak performance, drug addiction, PTSD, and other conditions.

Name of Principal Investigator David Priede, PhD.

Name of Organization: Biolife Health Center, LLC.

This Informed Consent Form has two parts:

- 1. Information Sheet
- 2. Certificate of Consent

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

## PART I: Information Sheet

#### Introduction

Biolife Health Center, LLC is conducting research on a health app designed by NewroFlow and to be implemented in a proprietary health system called Biolife Advance NF. This system uses a multitude of modalities and this test is part of one of such.

There may be some areas of this document that you do not understand. Please ask us any question you may have by calling the Principal Investigator at 954-655-9539 or via email at admin@biolifeHCresearch.com.

#### Purpose of the research

The purpose of this research is to obtain your feedback on the following areas of the app:

- 1. Ease of use and design (qualitative data).
- 2. Content (questionnaires, multimedia, exercises, and reading material).
- 3. Get data on your results (quantitative data).



# Type of Research

This research is an evaluation of the Biolife Advance with the Neuroflow modality only. Biolife Advance NF consists of multiple modules and this research is only a part of the program. We are interested in your observations and what you like and dislike. and effectiveness of the health improvement programs.

#### **Participant selection**

We are inviting adults that are willing to participate as a user of the health program.

## **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you agreed earlier.

#### **Procedures and Protocol**

This research will involve filling out an online health questionnaire, downloading the app to your phone or tablet (Apple or Android) and complete the app sessions 3-5 days per week. The app will send you a notification when it's time to do a session. Each session takes 10-15 minutes and can be done at any time of the day.

The app includes a journal section. After every session we would like to write down your observations. We will have access to your valuable comments after every session and include them in the research documentation.

## Duration

The research takes place over a 1-month period.

#### Risks

We do not foresee any risks since this is an evaluation research of an app.

#### **Benefits**

If you participate in this research, you will have the following benefits: the Biolife Advance NF is a health improvement program. During the process, you may benefit from the health improvement features it provides. Your participation will help improve Biolife Advance NF to help improve overall health of future participants.

## Reimbursements



Your participation is free. You will not be given any other money or gifts to take part in this research. All equipment, training sessions, evaluations, etc., are provided at no cost to you.

# Confidentiality

It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

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 encrypted and saved in our servers following Information Security Management System (ISMS) standard ISO/IEC 27001 and 27002. No-one but the researchers will be able to have access to it. Any information about you will have a number instead of your name. Only the researchers will know what your number is and we will keep that information secured. Your information will not be shared with or given to anyone except Biolife Health Center Research division researchers.

## Sharing the Results

The knowledge that we get from doing this research will be shared with you through the app, and personal or online sessions via video conferencing. Confidential information will not be shared after analyzing and tabulating the results. After the research is completed, the results will be used to improve the app, intake, evaluations and other procedures.

## **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.

## 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, you may contact David Priede, PhD, at (954) 655-9539 or via email at admin@biolifeHCresearch.com.

# 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