

# **Ibogaine Therapy Information and Consent Form**

Name of Program: Iboga Therapy House

Program Director: Sandra Karpetas

Telephone: 604 785-0924

Email: Sandra@ibogatherapyhouse.net



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### Introduction

You are being asked to review this information because you have applied to the Iboga Therapy House to participate in an experimental ibogaine therapy because you have problem substance use and because it may help you to recover from a chemical dependence (or addiction) to a substance.

You should already have a diagnosis of chemical dependence from a physician, psychiatrist, or outpatient addiction counselor. Before having therapy at ITH, each person should have already submitted information and test results from a complete physical examination that includes a heart test (ECG), a blood test (CBC) and a liver enzyme test (AST/ALT) with your application to make sure that it is safe for you to participate in ibogaine therapy. You should have supplied information on any and all surgery you have had and the date when you had it. If these exams had found that it would not be safe for you to have ibogaine therapy, as might happen if you have a heart problem, then you cannot have ibogaine therapy and will not have been accepted into the Iboga Therapy House program.

If everything turned out alright and the ITH medical screener has confirmed these tests with your doctor, then if you do not meet any of the contraindicated conditions, and you meet all the requirements for ibogaine therapy at the Iboga Therapy House, then you will have been accepted into the program.

In this case, ibogaine therapy refers to receiving a dose of ibogaine, a compound derived from the root of a West African plant, at the Iboga Therapy House (ITH). This therapy occurs over 5 days in the ITH facility and includes preparation, a 24 to 36 hour experience under the influence of ibogaine (given in capsule form according to your body weight, what substance you are detoxifying from and how long you have been using it), rest, and working on bringing what you learned from your experience into your everyday life. Ibogaine is reported to have the ability to reduce or stop drug cravings and opiate withdrawal, and to help people think about their life by producing strong, dream-like experiences that may help people to make positive decisions about their recovery from drug use.

Ibogaine is not an approved therapy for problem alcohol or drug use in Canada. To date, it is not the subject of any regulation and is not illegal in Canada. Ibogaine is an experimental substance. The Iboga Therapy House is not a government licensed or approved therapy program.



Ibogaine is a naturally occurring psychoactive plant alkaloid. It is sourced from the roots of the plant *Tabernanthe Iboga* that grows in the forests of West Africa where it has a history of being used as a catalyst for rites of passage, spiritual exploration and healing by the African Bwiti culture.

In 1963, a man named **Howard Lotsof** discovered it to be effective in significantly reducing the symptoms of withdrawal from chemical dependence. Since then, other people, including some medical researchers, have found ibogaine potentially useful as a detoxification method for heroin, methadone, cocaine, crack and alcohol dependence, and also as a potential tool for people to use in psychotherapy ("talk therapy").

Ibogaine has a low abuse potential, meaning it is not likely to make people abuse it or be dependent on it, and studies in animals and collections of past reports in people have found it is useful as a detoxification method for addiction and chemical dependence in a single dose. To date, no one has yet done a research study of ibogaine in humans. Although there are many self-reports of people who have used it.

It works in two ways. The first process involves greatly reducing withdrawal symptoms, craving and increasing long periods of abstinence or reduced use. Some of these changes may be due to nor-ibogaine, a chemical the body makes when it metabolizes (breaks down) ibogaine in the liver. Studies in rodents found that noribogaine prevents cravings for several weeks or longer after a single dose. Some researchers think that noribogaine is also involved in a long-lasting anti-depressant effect after ibogaine therapy; however, it is not known how long the anti-depressant effect lasts, and it may happen in some people and not others.

The second process involves an experience that may be considered psychotherapeutic or emotionally, mentally and/or spiritually healing. People who have taken ibogaine have described the experience as creating 'a dream-like experience'. Ibogaine does not cause any loss of consciousness or changes in your sense of where you are or who you are. It does not create any illusions or inability to think properly. Some people report having dream-like visions. Not everybody experiences these visions or seeing images from ibogaine, which may be because of dose, how it works on the body or how your body processes it, and because everyone processes substances differently.

I have read the contents of this page. I have had the opportunity to ask questions about it and I understand what it says.

Ibogaine is of particular interest in the therapy of substance dependence because it appears to work differently than other approaches to treating addiction that rely on drugs (pharmacotherapies), such as methadone maintenance. Understanding how ibogaine works may tell us more about how we can help people with addictions.



Current Ibogaine therapists and researchers understand that while Ibogaine is an effective detoxification tool that can greatly reduce withdrawal and is useful in addiction treatment, it is not a "miracle cure" and works best along with well-defined therapeutic goals, adequate preparation, proper monitoring, compassionate care and support during the experience, taking the time to reflect on and learn from the experience, having a recovery plan to follow and possibly taking part in appropriate existing treatment options for aftercare.

Ibogaine is experimental, which means it is not an approved therapy for problem alcohol or drug use in Canada. To date, it is not the subject of any regulation and is not illegal in Canada.

### Therapeutic Procedures at the ITH

The Iboga Therapy House offers support and assistance to clients through the detoxification phase 24 hours a day throughout the 5-day program. There are ten facilitators on staff with a wide range of skills to support and monitor individuals in their therapy. Two staff members are professional substance use counselors, and there are also a host of community volunteers offering aftercare services such as bodywork/massage therapy, ecstatic dance, guided breathwork, reiki, light exercise such as yoga, and nutritional planning. One of two emergency medical technicians (EMTs), 1<sup>st</sup> Aid Level 3, is available on-site during each ibogaine session in case of an emergency.

The Iboga Therapy House is not a government licensed drug therapy program.

Before beginning the ibogaine therapy, you should be prepared for a change in your life, have options or plans for your future and, perhaps most importantly, be connected with a number of healthy, caring and supportive friends or relatives. Ibogaine therapy should be considered as a 'catalyst' or 'tool' in your journey towards recovery and not necessarily as a 'quick fix or cure' in and of itself. We recommend and expect that you have tried other available therapy or detox options before trying Ibogaine.

I have read the contents of this page. I have had the opportunity to ask questions about it and I understand what it says.

Our therapeutic procedures are based on the Manual for Ibogaine Therapy: Screening, Safety, Monitoring & Aftercare, Second Revision by Howard S. Lotsof & Boaz Wachtel and are



modeled on the best practices of an ever-evolving body of knowledge. This manual is available online at: http://www.ibogaine.org/manual

### **Upon Arrival**

The therapy begins on a Monday and ends Friday. Upon arrival at the ITH facility, you will have an opportunity to become comfortable and familiar with the facility by going on a tour of the surroundings and amenities such as the lounge, kitchen, the room you will be staying in, bathroom, and outdoors areas. During this time you can get a better sense of the layout of the facility plus instruction in any procedures and other details of the use of the space. You will have an opportunity to meet the staff at this time, so that you may become more comfortable with them.

#### Voluntary Search

We will conduct a voluntary search of your belongings to make sure that you do not have any illicit substances or substances that are contraindicated (cannot be taken together) with ibogaine. You may refuse to be searched but if you do refuse you will not be allowed to take part in the Iboga Therapy House program. The search is conducted to ensure your safety while under our care. The search will be conducted in a dignified manner.

Procedures for the search are as follows:

- Your belongings will be taken to the room in which you will be staying.
- You will then be shown to the bathroom, given a robe and asked to change out of your clothes into the robe.
- The clothes are to be handed to the facilitator or staff person as you leave the bathroom.
- The facilitator or staff person conducting the search may take the clothes with them into the room and may search your clothes and belongings. You may watch the search take place.

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• Note: The facilitator/staff must be careful while performing the search in case there are any dangerous, harmful or sharp objects such as needles. If you have any of these in



your possession please let the staff person know beforehand, so that she or he does not <u>get hurt accidentally.</u> In case of a facilitator/staff being pricked by a used needle accidentally, they will be taken to the hospital immediately for care.

- If there are any substances found, the Iboga Therapy House retains the <u>right to refuse</u> therapy until the substance is discarded or destroyed by you and therapy may be postponed until a later time when the substance in question is deemed to no longer be in your system or in your possession. The person who is directing the program and/or giving the Ibogaine must decide on this period of time. She or he may get help in making this decision by talking with you and/or reaching a medical doctor or psychiatrist (if it is necessary, such as in the case of finding out how long a prescribed medicine may be in your body.)
- Note: In the case of illicit (or illegal) substances <u>the facilitator/staff person may not</u> <u>confiscate (take away) and/or dispose of the substance personally</u>, as possession of these may constitute a crime or felony. The facilitator/staff person may however watch (be a witness to) the disposal of the substance.

#### Intake Questionnaires

After the search, you will be asked to complete some questionnaires. These questionnaires will help us to get a better idea of your background and history with substance use, how you feel about yourself, the state of your quality of life and your mental, emotional and physical health.

#### **Before Ibogaine Therapy**

Ibogaine is known to greatly increase the effects of other drugs. For this reason ibogaine must not be taken until we can be sure that certain types of other psychoactive drugs (such as antidepressants, antipsychotics, benzodiazepines (Valium-like drugs), alcohol, amphetamines, stimulants, and other prescription medications or illicit drugs are cleared out of your system. It is possible that ibogaine can cause a potentially fatal or otherwise adverse (undesirable and/or dangerous) effect.

I have read the contents of this page. I have had the opportunity to ask questions about it and I understand what it says.

If you have been taking any of the drugs described above, before therapy then you should have <u>already</u> consulted with your doctor or psychiatrist and the Program Director about



whether it is safe to stop using these, how to taper down if so, and how long it would be before it is safe to take ibogaine.

If you have been taking any medications (prescribed or otherwise), illicit substances or other substances such as herbal remedies and supplements that you have not informed us about yet. <u>Please do so immediately</u>, as some medications may not be mixed with ibogaine and may be dangerous or harmful in combination with it, and this may affect your therapy session and our ability to administer any ibogaine to you.

We will monitor you for a long enough period of time to make sure that the substance/s you are dependent on and/or regularly use are no longer in your system. Monitoring period is 24 hours for methadone users, 12 hours for users of heroin, and other short acting opiates, cocaine or crack. You may begin to experience some of the first effects of withdrawal before you ingest the ibogaine, but if all goes well with the test dose (see below) we will be sure to give you the ibogaine before any moderate or extreme discomfort begins. If you are opiate dependent, you may start to have withdrawal symptoms such as runny nose and watery eyes, but you should not have to endure many withdrawal symptoms for very long.

#### Preparation

You will have the opportunity to ask questions about what you may expect from your lbogaine experience. You will have time to prepare yourself for the experience with activities such as selecting music, creating art, reading, journal writing, meditating, stretching or other activities that will help you to feel comfortable.

You should be prepared to have an experience that may move and even change you deeply on psychological, emotional and spiritual levels. The staff and facilitators will offer you support throughout the entirety of the therapy session. The role of the facilitators is to provide a safe atmosphere of receptivity (acceptance), caring and trust. If you have any questions or concerns, feel free to ask the staff at any time for assistance.

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You will be given the option of taking supplements of magnesium and calcium. These supplements are important to make sure your heart functions at its best. You will also be encouraged to drink plenty of water and electrolytes. You should refrain from eating any food for



7-8 hours before taking ibogaine. This is to reduce any nausea you might experience during ibogaine therapy. To learn more about this and other side effects of ibogaine, see "**Risks, Side Effects and Other Considerations**".

#### Therapy Procedures

After the required pre-ibogaine monitoring period, a medical technician and the ITH program director will perform a baseline check of your vital signs: we will record the results of your blood pressure, heart rate, and temperature.

If your vital signs are stable, we will then administer an anti-nausea medication (such as dimenhydrinate, sold in Canada as Gravol) to prevent the early onset of nausea. This will be followed shortly thereafter (usually about 30 minutes later) with a test dose, a capsule of 100 mg Ibogaine Hydrochloride (HCI) powder that you will take orally as a test for any allergic or bad reactions. Vital signs are then checked 10 minutes, 30 minutes, and one hour after the test dose. If there are no allergic or bad reactions to the initial dose of Ibogaine, then you will take the remainder of the full dose one hour later.

The full dose of ibogaine HCI will be in the 16-20 mg/kg range, but minus the amount of the 100 mg test dose, and is also given orally as a capsule. The exact size of the dose will depend on factors such as the severity of your dependence and the substance(s) from which you are detoxifying. For example, someone dependent on high doses of methadone may get a dose of Ibogaine in the 18-20 mg/kg range, with the possibility of a small supplemental or "booster" dose given 1-3 days after the initial dose, but someone dependent on low doses of heroin may get a dose of ibogaine in the 16-18 mg/kg range only once.

Effects of ibogaine may begin anywhere from 45 minutes up to 3 hours after administration. The entire experience may last between 24-36 hours. The withdrawal effects that you experienced before taking the ibogaine should then become significantly reduced or removed. During the session, you are continuously supported and monitored by experienced, supportive, and caring facilitators.



pressure are stable, and then every hour thereafter. An Emergency Medical Technician (EMT: 1st Aid Level 3) is present in case of an emergency, and he or she will observe the therapeutic procedures and provide care in case of a medical emergency. There is an Automated External Defibrillator at the ITH in case of a cardiac (heart related) emergency and we have also set up a protocol for emergencies with the local paramedics and hospital. Please see the section titled: **Emergency Protocol** for more information about how we plan to deal with any potential emergency situations.

As ibogaine may cause unsteadiness, light sensitivity, and sometimes nausea, you will probably spend most of the first part of the ibogaine experience lying down in a quiet, darkened room. You have the option of listening to music that you have chosen.

Facilitators provide support throughout the experience. The facilitators are available to talk, sit quietly, provide reassurance during the experience and/or simple bodywork such as massage or reiki (reiki is a non-contact form of energy work). Ibogaine may change memory recall processes and make people grow more thoughtful and introspective (inward looking). You may find that you want to talk very little with ITH staff. This is alright, so long as it does not stop them from doing routine monitoring and looking after your safety.

After these effects start to wind down or go away, you will enter into the final stage of ibogaine effects. In this stage, you will probably remain wakeful and introspective, thinking over whatever you experienced and learned so far. This may happen a day or so after ibogaine administration. At this point, ibogaine therapy returns to the more typical form of talk therapy, where you work to consider and bring together any insights or ideas from the ibogaine experience. The facilitators actively will work with you to help process the material. As Ibogaine can catalyze a powerful and sometimes profound effect on consciousness, the facilitators may also provide support by continuing discussions and talking with you, and through other types of healing if you request them and agree to doing them, such as Reiki, a non-contact form of body/energy-work, and massage. The facilitator's role is to provide a safe, attentive, therapeutic, and compassionate atmosphere for your experience.



The remainder of the stay at ITH is for rest and integration, working on bringing what you have learned into your life, life goals, and choices. You can have instruction in light stretching or yoga, as well as soothing baths, walks, and other therapeutic activities such as creating art relating to the experience. The staff will actively create and support discussion about the experience and about integrating healthy factors into one's life in various ways through lifestyle changes. We believe that taking the time to reflect on the Ibogaine experience is a necessary part of the healing process after Ibogaine.

#### Substance Counseling and Referral

There are 2 substance use counselors on staff who will work with you to look at your recovery plan and to start discussions about practical things that you can do to improve your quality of life. They may refer you to various kinds of aftercare options that may suit the needs that you describe, and they may offer some suggestions as to how you can inform yourself of other options, and how you can find information related to recovery and well being.

### Ibogaine Effects, Side Effects and Risks

#### Ibogaine's Subjective (personal) Effects

People who took ibogaine, either to help them overcome chemical dependencies, self-exploration or for spiritual reasons report some common elements to their experiences. These can be described as 3 'phases' of the ibogaine experience:

#### Phase 1: Acute

This first phase begins within 20 minutes to 3 hours after taking ibogaine, and lasts about 4 to 8 hours. During the beginning of this phase, nausea may occur possibly followed by vomiting, though this usually happens only once during the first several hours of therapy. For this reason you are encouraged to lie relatively still as movement may trigger the nausea. As noted above, you can take a medication such as Gravol to reduce nausea.

I have read the contents of this page. I have had the opportunity to ask questions about it and I understand what it says.

During the first phase, usually most people have visual imagery or phenomena generally consisting of rapid and chaotic imagery lasting usually between 4-6 hours after taking ibogaine. These visions may be quite intense, though people report that these visions will generally



subside (stop or slow down) temporarily if the eyes are opened. Some people who have taken ibogaine have reported that they did not have any visions.

Some people have reported experiencing images of their life appearing as if on a screen or in a "waking dream". Ibogaine has been termed an 'oneirophrenic', which essentially means a substance that causes a dream-like experience.

People have also observed mild tremors (shaking) and ataxia (loss of muscle coordination) during the first phase, with a tendency for the tremors to be stronger in women with amphetamine or stimulant (for instance, methamphetamine or speed) dependencies.

Most people are sensitive to light and sound. For this reason, the room where you will stay during ibogaine therapy is kept darkened and sound disturbance is limited, although as noted above, you can listen to music of your choice if you wish to do so.

#### Phase 2: Evaluative

People describe the second phase as sort of life review whereby the images they see become more personally related, and more connected to the process of life change. People frequently describe a visionary sequence in which they take up a re-evaluation of their life. Some meet family members or review a childhood experience. Some have reported experiencing visions related to the addiction and life events contributing to it. These experiences can include recall of memories one has forgotten or repressed, and may help the individual to understand the underlying reasons for his/her addictive behavior. This phase may last between 5-20 hours.

The second phase is often a very personal experience and during this phase, people often stop talking with others and remain silent and thoughtful. People often reported that the ibogaine itself was the true facilitator and guide, inducing visions that relate symbolic and archetypal information or insight. (According to Carl Jung, archetypes are characters, images, plot patterns, rituals, and settings that are shared by diverse cultures; people sometimes experience archetypes in dreams or in subconscious thoughts. Jung believed that archetypes are part of humanity's "collective unconscious".)

Some have described a feeling that this introspection process creates or supports a sense of self-discovery and/or reconnection to spiritual ideals and values.

I have read the contents of this page. I have had the opportunity to ask questions about it and I understand what it says.

The frequency and pace of the visions or personal process often slow down during this phase. People often use this time for reflection on the inner self and re-evaluation of their path in life. During this time, some integration, or bringing together, of what was learned from the first phase of the experience, may occur.



#### Phase 3: Residual Stimulation

This phase may last 10-24 hours or longer. It is a period of time where the visual effects start to subside (fade, stop), and people remain awake, often reviewing the experience. A return to normal consciousness occurs over time with some remaining stimulation.

Some may experience muscle soreness, perhaps due to remaining still and lying down for such a long period of time. However this can be resolved with stretching, light yoga, massage and movement such as walking.

Some individuals may remain awake for long periods of time afterwards or get only short periods of light sleep during the third phase. Some may have difficulty getting long periods of sleep for a time following therapy. This is quite normal. Supplements such as melatonin or herbs such as valerian root, hops and passionflower may help people get more sleep or return to normal sleeping patterns.

#### **Risks of ibogaine**

Though there are many reports of people's experience with ibogaine, there are no completed research studies of ibogaine in humans that determine or prove what the risks are.

There are risks to taking ibogaine. These risks can be substantially minimized through careful and thorough screening, searching people prior to therapy, proper monitoring and care of people having ibogaine therapy, and appropriate emergency personnel and response (see section titled: **Emergency Protocol** for more information about our emergency procedures). Risks associated with doses of ibogaine used to treat chemical dependencies include changes in blood pressure or pulse, dehydration due to vomiting, heart arrhythmias and possibly death.

#### **Possible Discomforts or Side Effects**

Some possible discomforts or side effects typically associated with doses of Ibogaine used to treat dependencies include: ataxia (temporary loss of muscle coordination), tremors (shaking), photosensitivity (sensitivity to light), nausea, vomiting, slight changes in blood pressure and sometimes slight back pain. Any side effects experienced subside (fade away, stop) 24-48 hours after the onset of therapy and are not considered withdrawal symptoms, which should be greatly reduced or removed through the action of the ibogaine.

I have read the contents of this page. I have had the opportunity to ask questions about it and I understand what it says.

### **Potential Drug Interactions**



Ibogaine may increase the potency of opiates and stimulants and possible interaction with drugs or medications that are known to slow down the heart see section titled: **Potential Drug Interactions** below).

The liver breaks ibogaine down to Noribogaine through an enzyme known as Cytochrome P450- 2D6. The CYP 4502D6 enzyme is a chemical in the body that breaks down food, liquids, drugs, or anything else people ingest, through a process called metabolism. There are many different types of enzymes, but there is only one enzyme, CYP2D6, that primarily makes it possible to break down more than a quarter of all prescription drugs, including virtually all anti-depressants and ADHD ("attention deficit disorder") treatments.

Anyone who is taking medications (prescribed or otherwise) will not be treated with ibogaine until we are sure the substance in question is no longer in the system. We will not treat anyone on necessary long-term medication if there is no information available on possible interactions with ibogaine or psychoactive compounds.

If you are taking a substance or medication, please inform us immediately. If you are on a substance that you wish to stop taking or taper down and stop taking, you must do so safely and with the assistance and recommendation of your physician or psychiatrist. You will not be given ibogaine until you can attest that the substance in question is no longer in your system. We will request to speak to your doctor or psychiatrist to verify that this has been done according to their advice or recommendation.

Also, if you are taking any herbs or herbal supplements, please inform us immediately.

#### Heart Problems (QT Interval)

Ibogaine, like many other drugs that are metabolized by CYP 4502D6, may produce a lengthening of the QT interval of the heart rate. The QT interval is the section on an electrocardiogram (ECG, heart test) that indicates the time it takes for the heart's electrical system to fire an impulse through the ventricles and then recharge itself. A prolonged QT interval may lead to a potentially fatal disorder known as Torsades de Pointes. Having an EKG before ibogaine therapy may indicate whether there is a preexisting prolonged QT interval, and this information indicates whether you should be treated with ibogaine or not.



If you have already been screened for therapy with ibogaine, then you should have already submitted a copy of your ECG to the Iboga Therapy House screener. If the results of your ECG were normal and all your other test results were normal, then it may potentially be safe for you to have ibogaine therapy.

Many prescription and over the counter medications and well as foods and other substances can prolong the QT interval by interfering with CYP2D6. Thus, all QT prolonging substances should be discontinued for at least four half-lives of that substance, prior to therapy with ibogaine. A half-life is the time it takes for one-half of the original dose of a medication to leave the body.

Substances and medications known to potentially prolong the QT interval include: anti-arrhythmics, antibiotics, anti-cancer medications, anti-convulsants, antidepressants, anti-hypertensives, anti-fungals, anti-infectives, anti-malarials, anti-mania medications, anti-nauseants, anti-psychotics, appetite suppressants, bronchodilators, catecholamines, cholinesterase inhibitors, decongestants, diuretics, immunosupressants, muscle relaxants, opiates, sedatives, stimulants, sympathomimetics, and vasoconstrictors.

Grapefruit and Quinine (often used as flavor in tonic water) are also strong QT prolonging substances and <u>should not be taken with or before ibogaine</u>.

#### Fatalities

To date, there have been eight reported fatalities after ibogaine therapy. Some of these deaths were caused by or associated with cardiac (heart) problems. These deaths seem largely to be due to surreptitious (hidden) use of contraindicated substances during therapy, improper screening or poor supervision. Estimating from the available information on past and current underground and medical treatment centers, ibogaine has been given to thousands of people without incident. It has also been reported that cardiac incidents are not seen in any greater numbers in ibogaine treated patients than in the non-ibogaine treated population. Thorough screening, careful monitoring for hidden substance use, and supervision during ibogaine therapy should prevent the occurrence of cardiac problems or deaths. Contraindicated conditions are described below in the section titled "**Contraindicated Medical Conditions**".

You have the right to see more detailed information about what is known about these fatalities. If you wish to know more you may ask the program director for more information.



### **Psychological Distress, Anxiety and Panic**

As lbogaine is a strong and powerful psychoactive, meaning it strongly alters consciousness and how we see, think and feel, we recommend that if you have had any serious reaction such as deep anxiety or paranoia as a result of ingesting any hallucinogens, entheogens, psychedelics, psychiatric medications or other mind-altering substances, you should seriously consider your choice to try ibogaine, possibly thinking of ibogaine only as a last resort. While there is no data regarding this, it remains possible that a psychological reaction may occur. There is a risk that ibogaine could trigger or exacerbate any psychiatric problems or issues.

#### Other Risks

Other risks of ibogaine include psychological distress and risks related to discussing sensitive information, including potentially illegal activities, with ITH staff. The Iboga Therapy House will take precautions to keep your personal information confidential by keeping all your records in a locked filing cabinet after your therapy. During the therapy, your file will be available to staff of the Iboga Therapy House and will only be shared in the case of a medical emergency with medical personnel such as paramedics and emergency providers at the hospital. You may be asked to sign a consent form to release your medical information to emergency personnel before your therapy. See sections titled: "Confidentiality" and "Emergency Protocol" for more information about this.

#### **Contraindicated Medical Conditions**

It is not safe for people with certain diseases or medical problems to have ibogaine therapy. For this reason the Iboga Therapy House will not give ibogaine to anyone with the following conditions:

Asthma, Bleeding problems, Cancer, Cerebellar dysfunction (Meneire's disease, balance problems), Chronic blood clots, Chronic fainting, Diabetes, Emphysema, Epilepsy, Gastrointestinal tract diseases (Crohn's, Inflammatory Bowel Disease), Gynecological problems, Heart attack, Heart failure, Heart murmur, Heart surgery, Heart irregularities, HIV, AIDS, Hepatitis C (if active and with liver enzymes 200% above normal), Hypertension (high blood pressure), Kidney problems/Renal Disease, Liver problems, Lung problems or Respiratory Disease, Obesity (extreme), Palsy, Pregnancy, Psychiatric problems, Seizures, Stroke, Thyroid problems, Tremors, Tuberculosis, Ulcers.



You will be asked to list all prior surgeries and dates as part of your application for therapy. If you have omitted anything, or have a medical condition that is not listed here, <u>please</u> let us know immediately.

#### Information for Females

Women may metabolize certain drugs (including ibogaine) more extensively (thoroughly) or rapidly than others. This may be particularly true for women who are within one week (before, during and after) of menstruating. These factors are important in determining the dose of ibogaine that you will receive. If you are close to your menstruation date or are menstruating at the time you are scheduled to take ibogaine, please let us know.

#### Information for Women who are able to have children:

We do not know how safe it is to take ibogaine during pregnancy; therefore, if you wish to take ibogaine, you are advised to take a pregnancy test within 14 days prior to your therapy. In addition, you and your sexual partner/s should be using an acceptable method of birth control: for example, condoms or female condoms before your ibogaine therapy.

Oral contraceptive use can interfere with the metabolism of many drugs and certain drugs can impair contraceptive efficacy. We do not know if oral contraceptives change ibogaine metabolism in any way or vice versa.

We do not know if ibogaine can cause harm to an unborn baby. If you should become pregnant before your therapy, you must inform the Program Director immediately. In respect of your health and that of your unborn child you will be excluded from therapy with ibogaine.

#### Information for Males

#### Sexually active males:

No one knows for certain whether ibogaine can change your sperm; therefore, you and your sexual partner/s should consider using an acceptable form of birth control such as condoms or female condoms for 70 days after ibogaine therapy (sperm in the testes live for 70 days before being regenerated).



#### Pain Management

For those with pain management issues (whether you are prescribed medication for pain or otherwise), we will determine readiness (find out if you are ready) for the program only if you can demonstrate your options for dealing with pain have been examined in full detail and that you have taken steps to seek out professional help for pain management. If you have pain management issues, we require a written statement from you demonstrating that you have seriously considered what pain and pain management means to you, to your recovery from substance use and to your health, including an outline of the potential options that you may have in seeking help for pain management.

If you have been taking opiates to help deal with physical pain, there is a risk that physical pain will return once the opiates have been detoxified from your system through the action of the ibogaine. If you have physical pain requiring medication after your, we recommend that you seek out help for this from your medical doctor or other pain management specialist and that you strongly consider putting a pain management plan into action before you have ibogaine therapy.

### **Emergency Protocol**

In the case of any medical emergency, we will immediately call for emergency services by phoning 911. The local hospital has been advised about our ibogaine therapy program and about the potential need for their response with emergency services.

There are 2 Emergency Medical Technicians (EMTs) on staff at the Iboga Therapy House. One of the 2 EMTs will be present to observe your therapy and to act immediately in case of any medical emergency before the paramedics arrive.

There is an Automated External Defibrillator (AED) onsite in case of a cardiac emergency. An AED is a portable electronic device that diagnoses and treats cardiac arrest by reestablishing an effective heart rhythm. This treatment is called defibrillation, which applies an electric shock to the entire heart muscle, uniformly clearing the electrical activity of the heart, hopefully allowing it to resynchronize. The EMTs are trained in its use and will employ it if needed.

Ambulance Service BC, the Provincial emergency medical ground transport service has a unit in Gibsons. In case of an emergency, they will be called and can arrive at the Iboga Therapy House facility within 5 minutes. Transportation to the hospital may take 15-20 minutes.



The Poison Control Center of BC has also been informed about our program and about ibogaine.

### Alternative Sources of Therapy

A number of different kinds of treatment programs are available for detoxification and recovery from chemical dependence in Canada. Ibogaine therapy is only one option. Ibogaine therapy is an experimental procedure in Canada and is not government licensed or approved.

You should take your time to familiarize yourself with all the options available to you for detoxification from chemical dependence, recovery and/or therapy before you freely choose to participate in this program. Not participating in this or any other form of therapy is also an option. This is your choice.

# **Potential Benefits**

The use if ibogaine for addiction therapy and psychotherapy is experimental. This means that there is no guarantee that this therapy with ibogaine will benefit or help you, although some people have reported beneficial experiences from taking ibogaine.

Other people seeking information and/or therapy with ibogaine may benefit from the information gathered from your participation in this program in the future. Please see the sections titled: "**Data Collection, Publication and Communication of Results**", for more information about how others may benefit from your participation in this program.

# Quitting or Withdrawing from Participation in the Program

You have the right to leave the program at any time. If you do decide to leave, then you should be aware that you will not be able to return into the program until you have reapplied and gone through the application and screening process a second time, and it has been deemed by the program director that a second try is recommended and safe for you. If you do decide to reapply, you will be asked to pay for the therapy costs again.



You will not be reimbursed for any costs that you had paid to the Iboga Therapy House for your therapy once you have begun the therapy process at the facility except in the case of the therapy needing to be postponed for medical reasons or for other unforeseen circumstances where the Iboga Therapy House had to postpone your therapy after you had arrived at the facility. In this case, you will be informed by the Program Director of your options to reschedule the therapy or get a refund for a portion of the fee you paid minus any costs that were incurred during your stay and possibly any portion of the initial deposit.

You should be aware that once you have taken the ibogaine, and are under its effects, it is highly advised that you remain in our care at least until the effects have subsided. This is so that we may ensure that you will remain safe and can respond in case of any emergency or adverse (negative) effects that put you in danger. You will also be significantly affected by ibogaine's effects and may not be able to perform simple tasks alone or remain conscious of your actions. Under no circumstances should you attempt to drive under the effects of ibogaine.

You should be aware that ibogaine will significantly reduce your tolerance for other substances such as opiates, stimulants or amphetamines and that if you do decide to leave the Iboga Therapy House and use either of these after you have ingested a therapeutic dose of ibogaine, that you should only use an amount that would be equal to trying it for your first time and as if you have very little or no tolerance. This precaution may prevent a potentially fatal overdose.

If you do decide to leave, you will be asked to sign a release form stating that you have decided to leave against the advice of the program director and staff, that you are aware of the potential negative consequences and that you are willing to assume responsibility for any negative events that may occur as a result of your leaving. This release form will also serve to release the Iboga Therapy House and any of its staff for any liability for dangerous or negative events occurring from your withdrawal (quitting or leaving from) from our program and our care.

You will be discharged from the Iboga Therapy House program at any time should a situation arise where you verbally or physically assault another participant in the program or any staff member. Also, you will be discharged from the program if any misconduct on your behalf puts any individual in the program and/or any staff member in physical danger.

Should you consider that a negative event or misconduct occurs on the part of the Iboga Therapy House and/or its staff while you are in our care, you have the right to fill out an Incident and Grievance Report with the Dora Weiner Foundation. See the section titled: "**Incident and Grievance Reports**" for more information.



### Data Collection, Publication and Communication of Results

At the Iboga Therapy House we understand the need for an innovative, multidisciplinary approach to evaluating the potential benefits of Ibogaine-assisted detoxification. Through your participation in our program we intend to examine ibogaine's potential contribution to the reduction of harms associated with problematic substance use and chemical dependence.

To help improve the delivery of ibogaine therapy in Canada and elsewhere in the world. We will be collecting ibogaine therapy-related data through your participation in this program.

Our goals for the collection of this data are:

- To provide preliminary incentive towards further initiatives supporting and evaluating the development of Ibogaine-assisted detoxification therapy,
- To provide access to up-to-date and accurate information about Ibogaine to the drug consumer population seeking alternative recovery options as well as to the medical community, and the community at large,
- To gather preliminary evidence about whether ibogaine-assisted therapy can facilitate improvements in quality of life for drug users and for others seeking personal therapeutic exploration and healing through the use of ibogaine,
- To find out what the benefits are compared to the risks for those seeking therapy with Ibogaine,
- To determine (find out about) its therapeutic potentials and develop a therapeutic model for Ibogaine use in Canada by generating and evaluating best practices for an Ibogaine-assisted therapy and drug treatment model.

We intend to collect this information in hopes of gaining a better understanding of the benefits and risks of ibogaine therapy and therapy and may seek to communicate this information to interested parties. We may seek to share the results of the data without divulging or sharing any of your personal information. For more information about how we will keep your personal information confidential (kept secret) and private, please see the section titled: "Confidentiality" below.



## Confidentiality

You will be discussing sensitive information concerning your substance use behavior, including personal information about work and family relationships and potential discussion of potentially illegal activities. Discussing and recording sensitive information is an unavoidable aspect of participating in this program. We understand the necessity of confidentiality and privacy, and will not share your personal information with anybody else. All personal and identifying information about you collected during the course of your participation in this program will be kept confidential and secret. Only the staff of the Iboga Therapy House will have access to your personal information. The only people who will have access to your personal therapy file will be people on staff at the ITH. This includes the Program Director, the facilitators, the 2 EMT's (Emergency Medical Technicians) and the 2 substance counselors. The staff of the Iboga Therapy House have signed a confidentiality agreement that states that they will not share any identifying personal information. This agreement states the following:

"Client's health records and personal information are confidential.

I understand that I may become aware of patient or customer information in the course of performing my duties at The Iboga Therapy House and I am prohibited from divulging or communicating this information both during and after my employment. I agree to respect the client's right to confidentiality and privacy.

I agree to access client's personal health information only as permitted in the performance of my duties or as otherwise directed by the Program Director. I agree to preserve the confidentiality of all clinical or client information and to not divulge this information in any form, except where authorized by the client or required by law or in the case of a medical emergency where the information will be shared with the appropriate medical emergency service personnel. Any breach, on or off duty, of this agreement will be taken seriously. Any violation can or may result in legal or disciplinary action including dismissal."

Your medical records and sections of your therapy information file will be shared with medical personnel for the provision of emergency medical services in the case of an emergency.

Copies of relevant data which identify you only by code number and which contain no personal identifying information may be used or shared for the purposes of the Iboga Therapy House but you will not be identified by name, initials, date of birth, address, email, phone numbers, health insurance policy number or care card number.



By signing this form, you are agreeing to make your records available for use, analysis, interpretation and publication by the Iboga Therapy House under the condition and agreement that your above mentioned and other identifying personal information will not be shared.

### Incentives

The Program Director, the EMTs and other ITH staff will be paid for their work in this program. The costs of the therapy are based on a non-profit business model and will go towards covering the costs of your therapy and related costs. No profit will be made from what you pay for your therapy. A small contingency fee has been added to the costs of your therapy to cover any potential unexpected costs. If at the termination of the program, there is a surplus of funds from the contingency fee, it will be designated towards the purposes of the Iboga Therapy Society and/or may be donated to another non-profit organization with similar purposes and goals.

# Your Rights and Responsibilities as a Participant

### **Ibogaine Patients' Bill of Rights**

The Dora Weiner Foundation (http://www.doraweiner.org) has developed the following bill of rights.

- 1. You have the right to understand and use these rights. If for any reason you do not understand your rights or you need help in understanding your rights, the Ibogaine provider must make assistance available, including an interpreter.
- 2. You have the right to receive therapy with Ibogaine and to be informed of the dose and form of ibogaine you will receive.
- 3. You have the right to receive complete information about your diagnosis, therapy and prognosis.
- 4. You have the right to participate in all decisions about your therapy.



- 5. You have the right to receive therapy without discrimination as to race, color, religion, sex, national origin, disability, or sexual orientation.
- 6. You have the right to receive considerate and respectful care in a clean and safe environment free of unnecessary restraint.
- 7. You have the right to be informed of the name and position of the provider who will be in charge of your Ibogaine therapy
- 8. You have the right to receive all the information that you need to give informed consent for any proposed procedure or therapy you will receive and the possible risks and benefits of the proposed procedure or therapy.
- 9. You have the right to refuse to take part in research, including a full explanation sufficient to help you to decide whether or not to participate.
- 10. You have the right to refuse therapy and be told what effect this may have on your health.
- 11. You have the right to be informed of alternate therapies.
- 12. You have the right to privacy while undergoing lbogaine therapy and confidentiality (kept secret / privacy) of all information and records regarding your care.
- 13. You have the right to review your therapy record without charge and obtain a copy of your therapy record for which your provider can charge a reasonable fee, with the understanding that you cannot be denied a copy solely because you cannot afford to pay.
- 14. You have has the right to complain without fear of reprisals about the care and services you are receiving, and to have the provider respond to you.
- **15.** You have the right to file a Grievance Form and have a patient advocate intervene on your behalf. (Please see the section titled: "**Incident and Grievance Reports**" below)



### **Ibogaine Patients' Responsibilities**

- 1. You are responsible for providing information about past illnesses, hospitalizations, medications, and other health-related matters.
- 2. You are responsible for informing your therapy providers and other caregivers if you anticipate problems in following prescribed therapy.
- 3. You must take responsibility for requesting additional information or clarification about your health status or therapy when you do not fully understand the current information or instructions.

### About the Dora Weiner Foundation

The Dora Weiner Foundation, Inc. (DWF) was established as a 501(c)3 not-for-profit Corporation in 1983. The activities of the Foundation are exclusively charitable, educational and scientific with the intent to encourage and promote public knowledge of research in the study of chemical dependence and substance-related disorders and to advocate for the rights of patients being treated for dependence to drugs.

### **Incident and Grievance Reports**

The Ibogaine Report Form Project is being implemented by the Dora Weiner Foundation (<u>http://www.doraweiner.org</u>) to improve ibogaine therapy by providing a process for reporting information of adverse (bad, dangerous or otherwise negative) medical events, safety issues and other incidents that may impact on ibogaine therapy and care. The form enables patients and providers alike to report any incident whether negligible or life threatening. Data of a medical nature will be shared with all ibogaine providers to help assure the safety of persons treated with ibogaine. Information that is shared will not include the identity of patients or providers. An incident report may be filed by a provider, a patient or any therapy team member.



This form may also be used to file a grievance. However, grievance reports may only be filed by patients. Discussion of grievance reports will only take place between the Dora Weiner Foundation and the parties involved. Should you wish us to contact the ibogaine provider on your behalf we will require you to sign a medical information release form. Patients have the right to file a grievance report in accordance with the <u>Ibogaine Patients' Bill of Rights</u>. In order to validate an incident or grievance report you will have to identity yourself and provide other contact information.

#### **Confidentiality**

All information that you provide will be held strictly confidential in the same manner as the patient protections described in the US Federal Confidentiality Regulations 42 CFR and the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) as established by the Department of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). However, data from reports that does not identify you may be used in research or publication.

#### Validation

All reports must be validated. All persons submitting reports will be contacted as part of the validation process. If you do not receive a response to your report within ten business days please call us at 1 718 442-2754 or email us at the address below. If you call please indicate you are calling to discuss a Report issue.

The report may filled out online at: http://www.doraweiner.org/incident.html

Should you have any questions or need assistance in filling out this form, contact the **Dora** <u>Weiner Foundation</u> by email at: <u>dwf123@earthlink.net</u>



# Whom do I call if I Have Questions or Problems?

For questions about the program contact:

Sandra Karpetas Program Director Iboga Therapy House

604-785-0924

Sandra@ibogatherapyhouse.net

In case of a therapy-related emergency, please contact Sandra Karpetas, or go to the nearest hospital emergency department.



# **Consent Form for Participation in the Iboga Therapy House Program**

**†**I have read and understood the informed consent form and have indicated this by initialing each page of the form.

**\***I have had sufficient time to consider the information provided and to ask for advice if necessary.

**†**I confirm that the medical vocabulary, language and techniques mentioned were explained to my satisfaction and that I received satisfactory responses to my questions.

\*I understand that all the information collected will be treated as confidential.

\*I consent to the publication of the results of my participation in the Iboga Therapy House program as long as the information remains anonymous and/or disguised and that no identification could be made.

\*I was informed that my participation in this program is voluntary and that I am completely free to refuse to participate or to withdraw from this program at any time.

\*I was informed that by signing this consent form, I am not waiving any of my legal rights but that I am releasing the Iboga Therapy House and its staff from any liability associated with any negative event that may happen as a result of my participation in this program.

\*I understand that the Iboga Therapy House will act in my best interests in case of an emergency and that they may call and ask emergency services to respond and/or provide care to me.

**†**I understand that there is no guarantee that this program will provide any benefits to me.

**\***I understand that ibogaine is an experimental substance and that there are potential risks associated with taking it.

\*I have read this form and I freely consent to participate in this program.

\*I have been told that at my request I will be given my own copy of this signed and dated form.

Name of participant	Signature of participant	Date
Name of consent witness	Signature of witness	Date

