



Project New Day Consent Form

1. Objectives

The services provided by Project New Day have been created with the intent to assist individuals in their path to healing. Project New Day exists to help people overcome addiction and actualize mental health through the responsible and legal use of psychedelics. The creation and administration of high-quality programs that help people overcome addiction and PTSD is our immediate focus. In combined support with psychedelic treatment, PND emphasizes the importance of support and guidance by ensuring open and positive relationships with highly qualified Project New Day coaches both before and after the psychedelic experience. Continued support through online communities created and facilitated by PND staff provides further support during your ongoing journey toward healing.

2. Program Procedures

What will happen if you join this program?

If you agree to be in this program, we will ask you to do the following things:

Screening: After signing this consent form you will have two or more screening sessions to find out if you are able to take part in the program. You will be asked to do the following:

- Complete questionnaires and interviews about your personal and family medical and psychiatric history.
- Complete questionnaires that assess your psychological and physiological functioning.
- Complete two zoom interviews with members of PND staff to further assess potential eligibility.

Preparation Sessions: Over a period of about 2 weeks following screening, you will have 6 sessions with a Project New Day coach. During this phase coach and participant will engage in conversation where preparation for the upcoming psilocybin session will begin. Goals and outcomes will be identified and meditative and mental imagery procedures that will arm you with strategies to make the most out of the psychedelic experience will be shared during this phase.

Treatment Workbook: As a part of the PND program each client will be given a treatment workbook. This book will contain activities that will further encourage the exploration of self, leading to a greater ability to heal and grow during the duration of the PND Healing Program.

Psilocybin Sessions: You will be asked to come to a facilitation center in Oregon for 2 day-long sessions. The two psilocybin sessions are scheduled approximately 2 weeks apart. On the morning of each day-long session you should eat only a light low-fat breakfast. Each session will last between 1 to 6 hours, depending on the dose of psilocybin received during session. This dosage will be decided between you and the facilitator. The dose of psilocybin received in the two sessions will not exceed the amount of 50 mg. When you come to the facilitation center, you will be given a final psychological and physiological screening. You will then be given a dose of psilocybin. One facilitator will be with you in this room throughout the session. You will be encouraged to focus your attention inward to your inner experience. You may use a nearby restroom when needed. For safety purposes, an audio/video recording will be made of the psilocybin sessions. For these sessions you must agree to remain at the facilitation center until the facilitation team says you are ready to leave. At the end of the session you will be driven home by a trusted friend or relative, planned previously by you and your facilitator. However, if the staff at the facilitation site believes it is necessary for safety reasons, you will stay overnight. It is the responsibility of the facilitator to record and retain the time and date that each administration session began and concluded as well as notifying the Authority if the administration session goes beyond 11:59 PM local time. Upon concluding the session the facilitator will require each client to sign a release document at the conclusion of the administration session which states that the client agrees to end their administration session and follow the terms of their transportation agreement. Within the 72 hours following the conclusion of the administration session, the facilitator will attempt to contact the participant to confirm the client's upcoming integration sessions.

Intermediate Coaching Session: Between your first and second psilocybin sessions, there will be a required life-coaching session with you and your designated PND life coach. During this session you will be asked to review your experience. During these meetings you will discuss thoughts and feelings about your session and discuss your treatment workbook and techniques to help in processing trauma and remaining abstinent. During some of these meetings you will be interviewed and asked to complete several questionnaires and tests to assess your mood and psychological state. Further preparation will be completed between you and your coach before engaging in the second, and final, psilocybin session.

Integrative Sessions: Psychedelic integration refers to the process in which the participant integrates the insights of their experience into their life. The PND Healing Program emphasizes the importance of providing the client with support via coaching integration sessions while arming clients with the tools and strategies that will allow them to continue integration outside of those settings. The psychedelic service centers may offer some form of integration but, in general, participants will partake in six coaching integration sessions with a PND coach.

Following psychedelic sessions with meaningful integration and support is a cornerstone of the PND model. Successful integration is reflected in the client’s ability to successfully process insights and adopt them into their day-to-day lives.

Continued Online PND Community Support: Following the final integration session it is important that you remain engaged in the process of healing. Project New Day understands this and has created an online community where continued peer support can be easily accessed. These digital spaces have been created with the belief that a safe and supportive space where one can express themselves freely without fear of judgement is crucial to the healing process.

Requirements for continued participation: Please understand that you are expected to report to the facility or to an office where preparatory, follow-up, or integration sessions may be held every time you are scheduled. You may be dropped from the PND Healing Program if you miss a scheduled session or appointment or if you are late. Your participation in the program may be stopped if one of the PND team members feels that it is in your best interest to stop. While you are receiving PND services you must follow PND regulations.

Program Timeline: We anticipate the following approximate timeline for program participation.

Purpose of visit	Approximate Timing and Description
Initial Screening Survey	The initial screening survey takes approximately 30 minutes to complete and is the first phase of screening. Responses will be collected online and reviewed by PND staff for eligibility.
Zoom Interview 1	Approximately 1-2 weeks following the completion of the initial screening survey a zoom interview will be scheduled, given your responses meet inclusionary criteria. During the first Zoom interview, participants will review responses provided and initial screening survey and provide additional details where necessary.
Zoom Interview 2	To ensure that the history of each participant is thoroughly considered before finalizing a decision regarding eligibility, a second Zoom interview will take place 1-2 weeks following the primary interview. Responses will be reviewed to ensure accuracy and a final decision will be made following this conversation.
Final PND contact	Upon the completion of the PND screening procedures, a final decision will be made. Participants will receive an email stating whether they have been approved to move forward with PND services approximately 1-2 weeks following the final Zoom interview.

Psychological and Physiological Evaluation	PND will work with facilities to ensure that psychological and physiological evaluations are done preceding the psilocybin sessions. This will help to ensure the participants safety before engaging in the psychedelic experience.
Preparatory Coaching Sessions	For six weeks leading up to the first psilocybin session, participants will meet with a designated PND coach once a week for preparatory sessions. Client and provider will review goals and desired outcomes for PND experience and techniques to help get the most from the upcoming psilocybin sessions.
Psilocybin Session I	Client will meet with psilocybin session facilitator at the facilitation center within two weeks following the final preparatory life-coaching session and engage in the first of two psilocybin sessions.
Intermediate Coaching Session	Following the initial psilocybin session, a follow-up coaching session will be required. During this session you will be asked to review your experience and will be prepared for the final psilocybin session.
Psilocybin Session II	Client will meet with psilocybin session facilitator within one week following the follow-up life coaching session and engage in the second of two psilocybin sessions.
Integrative Coaching Sessions	One week after the second psilocybin session the participant will begin integration sessions. Integration sessions will take place once a week over the course of six weeks. Integration sessions are meant to help the client integrate the realizations experienced during the psychedelic experience into their daily routines.
Ongoing support through PND online communities	Following the last integration session, the participant will have immediate an on-going access to online support communities, designed and facilitated by Project New Day.

3. Inclusion/Exclusion Criteria

The table below outlines the inclusion and exclusion criteria the PND model follows. Each participant will be individually screened for potential exclusionary criteria. The safety of every participant is of the utmost importance, and exclusionary criteria exists to ensure that those who engage in PND services can do so safely.

Inclusion-Exclusion Criteria

Area of Concern	Inclusion Criteria	Exclusion Criteria
Need for Treatment	Meets Moderate to Severe Substance Abuse or PTSD criteria.	Meets Mild substance Abuse or PTSD criteria. Or Client is not currently struggling with addiction or PTSD
Psychological Screening	Has no background of Bipolar 1, Bipolar 2, schizophrenia, or severe personality disorders	Has a diagnosis of Bipolar 1, Bipolar 2, schizophrenia, or severe personality disorder
Physiological Screening	Is not currently diagnosed with or being treated for any condition that a licensed medical professional deems unsuitable for participation in psilocybin services.	Is currently diagnosed with or being treated for: high blood pressure, heart condition, epilepsy, or any condition a licensed medical professional deems unsuitable for participation in psilocybin services.
Drug Screening	Is not currently prescribed and taking any drug that may negatively impact the beneficially therapeutic effects of psilocybin. Or Is currently prescribed a potentially exclusionary medication but is able to refrain from taking prescription medication for at least 48 hours prior to psilocybin session.	Is currently prescribed and taking any drug that might interfere with the effects of psilocybin.
Client Interview	Staff member assesses that the client meets criteria for a general level of functioning that can be improved through PND services.	Staff member assesses that the client does not meet general criteria to receive PND services. (History of violent crime, homelessness, etc.)

Consent	Consents to receive a therapeutic dose of psilocybin under the supervision of facilitator.	Does not consent to receive a therapeutic dose of psilocybin under the supervision of facilitator.
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4. Leaving the Program

- You can agree to be in the program now and change your mind later.
- If you wish to stop, please tell us right away.
- If you decide you do not want to participate in the second psilocybin session, you may choose to continue to participate by completing integration sessions and participating in online support communities.

5. Drug Motivation

High doses of psilocybin have been shown in clinical studies to be an effective treatment for a myriad of mental health disorders including anxiety, addiction and PTSD. Traditional treatments that rely on the prescription and administration of antidepressants come with a list of side effects and often long-term use that Project New Day is passionate about leading mainstream treatment models away from. Project New Day intends to build on the success found in controlled investigations to bring a style of treatment that allows for healing that goes far beyond masking symptoms and rather aims at healing the root cause of addiction and PTSD.

6. Risks

Possible psilocybin effects and side effects: Psilocybin is a hallucinogenic drug with effects similar to other hallucinogens such as LSD and mescaline. Psilocybin is thought not to be organically toxic (not believed to be physically harmful to the body). However, psilocybin has not been put through the standard range of animal and human tests that are used to assess the toxicity of therapeutic drugs. This means there is no scientific data to prove either toxicity or safety. There is a chance, which we believe to be small, of physical toxicity not yet found in historical religious use, contemporary illicit use, or in the past 40 years of experimental and clinical use of this drug. The main effects of psilocybin are psychological. A high dose of psilocybin can bring about a very broad range of profound changes in perception and consciousness during the hours of drug action. About one-third of people in previous studies reported moderate to strong feelings of fear or anxiety after receiving psilocybin. Changes in normal perception can include visual or hearing changes (pseudo-hallucinations), and unusual smells, tastes, or other bodily sensations. You may experience anxiety, panic, or paranoia (suspiciousness) during the period of drug action. You may behave in ways such as intense crying, laughing, or panic that you might later find embarrassing. You may experience powerful

emotions, both pleasant and unpleasant. Your sense of time may be altered, such that time seems to pass more quickly or slowly than usual. You may have a sense that your body and mind have separated. The effects of psilocybin usually last about 5-7 hours. As with other experiences of a strongly positive or negative nature, you may have dreams and/or lasting memories of psilocybin session experiences. After the psilocybin sessions, there may be short-term to permanent changes in personality, attitude, or creativity. During the period of drug action, psilocybin may also cause dizziness, nausea, vomiting, incontinence, increased pulse and blood pressure, dilated pupils, increased reflexes, tremors, and muscle twitching. A few people in a study at John Hopkins, had blood pressure increases during psilocybin sessions. Taking any drug also involves a possibility of allergic reactions such as itching, rash, or hives. Some people have reported headache starting about 7 hours after taking psilocybin and sometimes lasting into the following day. In addition, there are risks, which appear to be uncommon, of adverse effects that last for hours to days after the psilocybin sessions. These include mood disorders (such as depression), psychotic disorder, and anxiety disorder. There are rare reports where hallucinogen exposure appears to cause, speed up, or precipitate the onset of significant or lasting psychiatric illnesses such as psychoses and occasional or lasting visual perceptual disorders (“flashbacks”, visual disturbances). There are no large well controlled studies of psilocybin to prove or disprove that such long-term effects occur. However, we believe the chance of such lasting effects is very small. The risks of adverse effects due to psilocybin will be minimized through the volunteer selection and screening procedures, the hours of preparation you will have with a trained and experienced guide before the psilocybin sessions, and the supportive environment and care that will be given during the psilocybin sessions. You will be carefully monitored throughout each session, and appropriate care will be given as needed. Appropriate care will be discussed with your facilitator prior to engaging in psilocybin session.

7. Injury

What treatment costs will be paid if you are injured during this program?

Project New Day does not have a program to pay you if you are hurt or have other bad results from taking part in Project New Day Healing Program.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.
- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a program-related injury.

8. Benefits

It is the aim, that taking part in psilocybin assisted life coaching services will help you to overcome addiction and/or symptoms of PTSD, but this cannot be guaranteed. The combination of compassionate coaching, responsible use of psychedelics, and a source of

connection and support have been shown to effectively address the underlying problems of addiction and symptoms of PTSD. If you do overcome addiction or see an improvement in symptoms of PTSD the resulting improvements in quality of life may be directly correlated to your participation in these services.

The scientific knowledge gained through your participation will contribute to a better understanding of the nature of effects of psilocybin in the treatment of addiction. By taking part in this program, you may help others in the future.

9. Privacy

Project New Day has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this program and who might see or use it. Generally, only people on the Project New Day team will know that you are participating in our program. However, there are a few exceptions that are listed later in this section of the consent form. The people working as part of your support team will collect information about you. This includes things learned from the procedures described in this consent form. They may collect other information including your name, address, date of birth, and other details. The Project New Day team will need to see your information. Individuals outside of PND such as facilitation center staff may also be provided with certain details collected by PND. We cannot provide PND services without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not receive services offered by PND. We will use and disclose your information only as described in this form. However, people outside of the Project New Day organization who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

10. Costs

All Project New Day services will be given to you at no cost.

11. What does your signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form.
- You accept the provisions in the form.
- You agree to participate in PND services.

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM.

This consent form is approved from XX/XX/XXXX to XX/XX/XXXX.

Do not sign after the expiration date of: XX/XX/XXXX

Signature of Participant

Date

Signature of Person Obtaining Consent

Date

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY PND; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.