

Outside the Box Functional Medicine, PLLC
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INFORMED CONSENT for FUNCTIONAL MEDICINE

I, _____ [NAME OF PATIENT] (hereinafter “I”) seek the medical services of **Outside the Box Functional Medicine, PLLC** (“Practice”). I am executing this informed consent document (“**Informed Consent**”) to verify and confirm my discussion with Dr. LoriAnn Zettell, M.D. (“**Provider**”) regarding the risks, benefits, and alternatives to treatment through Practice. I am here for my own purposes and not on behalf of any third-party. I understand that I am a participant in the decision-making process and I am free to decline services or treatments at any time. I agree to bring to the attention of Practice’s clinical staff, if, at any time, I have any lack of understanding of such risks, benefits and alternatives, and inquire of clinical staff for further explanation until I have a full understanding before giving consent to any procedure or treatment.

1. Benefits of the functional medicine approach and scope of practice

I understand that Provider and his/her team use diagnostic and treatment methods that—in addition to conventional health care—are known as preventative, complementary, alternative, functional, naturopathic, or integrative medicine (collectively, “**Functional Medicine**”). In general, Functional Medicine may provide benefits that include relief of presenting symptoms and improved function that may lead to prevention, improvement, or elimination of the presenting symptoms, though no particular outcome can be warrantied or guaranteed. Functional Medicine focuses on nutritional and metabolic imbalances, diet, exercise, environmental influences, and psycho-social stressors based on the premise that they directly relate to the development and maintenance of illness. Functional Medicine evaluates these influences and then specifically tries to remedy them. It encourages patients to give up negative lifestyle patterns and establish more positive ones, regardless of the type of medical conditions for which they are seeking treatment.

2. Risks

I understand that, as with any health treatment, Functional Medicine is not without risk. Potential risks of treatment include, but are not limited to, allergic reactions, sensitivities, adverse effects from, or in response to, natural supplements or dietary measures, failure to improve or worsening of my condition, and difficulty adjusting to lifestyle modifications. Other side effects and risks may occur.

I agree to inform Practice's clinical staff of all known factors that might affect treatment, including, but not limited to, all medications, drugs, drug sensitivities and allergies, history of seizures, fits or fainting, presence of a pacemaker, bleeding disorder, use of anti-coagulants, damaged heart valves or occluded vessels, immune deficiencies, or other special risks of infection, as well as any other significant factors within my knowledge. I further agree to inform Practice's clinical staff of any disorder or state of mind that might affect my capacity to make informed health decisions, and should any such impairment exist, I will provide information regarding a surrogate decision maker.

I understand that Functional Medicine may be different than what some people consider "mainstream" medicine." I am aware that there is some controversy in the medical community as to integrative or functional medical practices. Some of the potential "risks" of Functional Medicine that are asserted by critics in this debate are:

- a. lack of sufficient testing to constitute "evidence-based" medicine;
- b. use of biologically active agents that can present risks when used in conjunction with conventional medical therapies;
- c. potentially negative biological or psychological effects that have received insufficient testing;
- d. delay in seeking mainstream treatment based on scientifically unsupported practices; and
- e. use of laboratory tests, the value of which other practitioners question.

I understand that, despite this debate, Provider and/or Practice only employs treatments Provider believes, based on his/her training, experience, evidence-backed studies, and current research, to be safe and effective, and Provider will alert me to the risks and benefits of any treatments before they are administered.

3. Off-Label Use of Devices or Medications

In addition, I understand that Provider may at times use FDA-approved devices or medications to treat a condition in a way that differs from the use specifically approved by the FDA for such device or medication. This is commonly known as "off-label use." Provider has informed me of this practice and will inform me and provide the opportunity for me to ask questions if Provider decides to use an FDA-approved device or medication off-label in conjunction with my treatment. I am requesting that Provider use his/her judgment in prescribing FDA devices or medications for me that are off-label but which he/she believes to be appropriate.

4. Alternatives and Responsibility to Maintain Separate Primary Care Physician

As alternatives, Provider encourages me to speak with and consider the advice of other Providers, including conventional or mainstream physicians and providers. Provider will consult with, but

does not replace, care currently provided to me by other physicians or providers, such as my internist, gynecologist, cardiologist, gastroenterologist, pediatrician (in the case of children), oncologist or other specialty care provider. In addition to discussing other modes of therapy that may be used for the treatment of my condition, Provider and I have discussed, and I understand, the possibility of a referral to a specialist for my condition(s) if I have not already consulted with an appropriate specialist. Provider has advised me that he/she does not admit patients to the hospital or treat hospitalized patients.

I understand that as a condition of my treatment by Practice, I must maintain a relationship with an outside physician to act as my primary care provider and to provide emergency and urgent care. If I encounter a medical emergency and am not able to obtain care from my primary care physician(s), I will contact 911 or report to a hospital emergency department as appropriate.

5. Medication and Responsibilities

I understand that Practice may make available medications, nutritional supplements and other products for sale to patients in its office and on its website. I understand that I am not obligated to purchase these products from Practice, and I can purchase medications, dietary supplements, and other products from any source of my choosing.

I understand that, as with any health treatment, there is no guarantee that I will obtain satisfactory results. If I am being treated for a medical condition, or have symptoms that suggest a medical condition may be present, I have been informed that it is in my best interest to discuss potential alternative methods of treatment for my condition with my primary care physician or an appropriate specialist before, as well as during, the course of treatments. I understand the services provided by Practice do not preclude me from using other treatments as well, though I recognize that I should inform any practitioners I am seeing about the various treatments I am using. I understand that my failure to comply with any treatment recommendations will have an impact on the results of treatment.

I understand that I must immediately inform Practice's clinical staff of any adverse effect of treatment noted, including any unanticipated pain or other negative sensation, unpleasant cognitive conditions, anxiety, depression or other negative emotions or any unpleasant taste or smell associated with the consumption of supplements or herbs.

I will immediately notify Practice's clinical staff in the event of pregnancy or breastfeeding, as some treatments may be contraindicated for pregnant or breastfeeding patients.

I understand that I am responsible for disclosing to Provider all medications, care, and assessments that I receive elsewhere and to provide medical records from other providers to ensure that care is coordinated and compatible. Likewise, I am responsible for informing any other health professionals of the treatments, supplements, and/or medications I undergo with Provider and/or Practice.

I understand that Provider's treatment may include the recommendation that I seek other types of treatment from other health professionals who are not affiliated with Practice. I understand that

while Provider may communicate with these professionals to explain why Provider made the recommendation, Provider does not supervise them and is not responsible for them.

I understand that Practice does not accept insurance and I agree that I am financially responsible for the services rendered. I understand that insurance companies are likely to consider Functional Medicine to be non-covered or to deny claims for Functional Medicine as non-standard care, preventative care, or as not medically necessary. I understand that Practice may provide me with a receipt for services called a “superbill.” I understand that I may submit this superbill to my insurance company or any third-party payors, **excluding Medicare**, for any services rendered by Practice. I understand that I may not receive full reimbursement or any reimbursement at all from these third-party payors. I also understand that if I am, or during the course of my relationship with Practice, become an eligible Medicare Beneficiary, then I will be given notice of Practice’s status with respect to Medicare and that I will be given separate notice about my financial responsibilities as they relate to Medicare.

NOTE: Do not sign this form unless you have read it and feel that you understand it. Ask any questions you might have before signing this form. Do not sign this form if you have taken medications which may impair your mental abilities or if you feel rushed or under pressure.

By signing below, I acknowledge and certify that I have had opportunities to ask questions and have had them answered to my satisfaction; I have read and fully understand the foregoing Informed Consent, and I have all of the knowledge I currently desire; I have discussed the issues noted above with Provider; and I agree and accept all of the terms above. I am legally competent and have sufficient knowledge to give voluntary and informed consent.

PATIENT

SIGNATURE: _____

PRINT NAME: _____

TITLE (if legal representative or guardian): _____

DATE: _____

I have explained this Informed Consent and answered all questions in layman’s terms, and informed the patient of the available alternatives and of the potential risks. To the best of my knowledge, the patient has been adequately informed, comprehends the information, and has consented.

PRACTICE

SIGNATURE: _____

PRINT NAME: Lori Zettell, MD, Manging Member, Outside the Box Functional Medicine, PLLC

DATE: _____