Protocol Approval Date: 10/21/2016

ID: WIRB Protocol 20161880-1167645

Marijuana in Combination with Opioids in Palliative and Hospice Patients.

NCT#03233633

Clinical Procedures

The Connecticut Hospice, Inc.

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

TITLE:	Marijuana in combination with opioids for pain and symptom control in hospice patients.
PROTOCOL NO.:	None WIRB® Protocol #20161880
SPONSOR:	The Connecticut Hospice, Inc
INVESTIGATOR:	Theodore Zanker, MD 2969 Whitney Avenue Hamden, CT 06518 United States
STUDY-RELATED PHONE NUMBER(S):	Theodore Zanker, MD (203) 315-7556 (203) 980-0856 (24-hours)

1. _____ _____
Participant's Name Medical Record Number

You are being asked to take part in this clinical research study at The Connecticut Hospice, Inc. This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you have been prescribed opioid medication(s) for pain management. The Connecticut Hospice, Inc. is undertaking research to determine the pain-management benefits for its patients of combining marijuana and opioids.

DESCRIPTION OF RESEARCH

2. **PURPOSE OF STUDY:** To provide evidence about the use of marijuana in pain management in Hospice hospital inpatients. The primary goals are to reduce pain scores and to reduce required opioid dosages. Secondary goals include improvement in overall well-being, improvement in appetite, maintenance of weight, and reductions in depression and anxiety scores.

3. DESCRIPTION OF STUDY

Patients will be ≥18 years old, non-pregnant, and psychologically alert and oriented.

Subjects who have been prescribed opioids (i.e. morphine, fentanyl, or oxycodone) for pain will receive standardized marijuana (by mouth).

Patients must have pain as a primary symptom and meet the diagnosis requirements under the Connecticut Medical Marijuana Program. Patients that have cancer and non-cancer, with associated pain that have been diagnosed with a terminal illness will be eligible for the study.

Qualifying patients will receive a marijuana preparation in two different doses by mouth three times daily. This preparation contains two different cannabinoids, cannabidiol (CBD) and tetrahydrocannabinol (THC). The two different doses are 40mg CBD/1.5mgTHC and 80mgCBD/3mgTHC. These cannabinoids act in different ways in the body. It is hoped that they will decrease pain and inflammation without altering mental status.

Pain and other symptom assessments will be collected using a pain assessment scale and symptom assessment scale. Patients will undergo weighing and measurement of the blood oxygen levels. Patients will be taken out of the study if intolerable side effects occur. The patients will be followed and data collected only while in the inpatient Hospice setting.

Patients, through The Connecticut Hospice, Inc., will be registered with the Connecticut Department of Consumer Protection as a medical marijuana patient, as it pertains to the State of Connecticut Medical Marijuana Regulations.

This is an investigational study. No costs associated with the medication involved in the study will be the patient's responsibility. There is no cost or compensation to the patient for inclusion in the study.

4. REWARDS / POTENTIAL BENEFITS

While it can't be guaranteed it is hoped the benefits of the study will be:

1) Better pain control than with opioids alone.

2) Reduced side effects of opioid medications through reduction in required dosage.

3) Improvement in overall well-being, better control of nausea and vomiting, improved appetite, and reductions in anxiety and depression.

5. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

This study may involve unpredictable risks to the participants.

I. Potential risks of marijuana use: triggering or worsening of psychosis, temporary loss of motor coordination, paranoia, triggering or worsening of anxiety, loss of motivation.

II. Potential risks of opioid use: sedation, impaired breathing, opioid dependence, constipation, death. Please talk to your doctor about the risks of the particular opioid medication you are taking.

III. Pregnancy-Related Risks:

a. Taking part in this study can result in risks to an unborn or breastfeeding baby, you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications

Any FDA-approved forms of birth control, as prescribed by a physician, will be acceptable for patients participating in the study.

Females: If you are pregnant, you will not be enrolled into this study. If you become pregnant or suspect that you are pregnant, you must tell your Hospice doctor right away. Becoming pregnant will result in your removal from this study.

Males: Tell the Hospice doctor right away if your partner becomes pregnant or suspects pregnancy.

6. ALTERNATIVE – ADJUVANT PROCEDURES OR TREATMENTS

You may choose not to take part in this study, in which case only traditional pain management strategies will be used.

ADDITIONAL INFORMATION

7. You may contact the study Chair with any questions, concerns, or complaints you have about this study or if you feel you have experienced a research-related injury. You may contact the study Chair, Theodore Zanker, M.D. at 203-315-7556 or 203-980-0856 (24-hours). You may also contact the WIRB (Western Institutional Review Board), which is the Review Board of The Connecticut Hospice, Inc. at 1-800-562-4789 or 360-252-2500 with any questions, concerns, or complaints that have to do with this study or your rights as a study participant.

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Email: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

8. Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits.

   If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your Hospice doctor. If you withdraw from this study, you will still be treated at The Connecticut Hospice, Inc.

9. This study or your participation in it may be changed or stopped at any time by the study Chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP - a regulatory agency that oversees research in humans), Western Institutional Review Board (WIRB) and the sponsor.

10. You will be informed of any new findings that might affect your willingness to continue taking part in the study.

11. The Connecticut Hospice, Inc. and its future patients may benefit from your participation and/or what is learned in this study.

    The Connecticut Hospice, Inc. has no financial relationship in this study.

STUDY COSTS AND COMPENSATION

There will be no direct costs to the patient to participate in this study.

If you suffer injury as a direct result of taking part in this study, The Connecticut Hospice, Inc. health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by The Connecticut Hospice, Inc. for this injury. By signing this consent form, you are not giving up any of your legal rights.

Your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs, including hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research. You will receive no compensation for participation in this study.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at The Connecticut Hospice, Inc. will be collecting and using your protected health information. This information may include personal identifying information about you (such as your name, race, date of birth, gender, city, and zip code), your medical history (including diagnoses, procedures, past drug use/abuse, and prescription history), study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your Hospice doctor and research team may share your study information with the parties named in Section D below.

B. Signing this consent and authorization form is optional. However, if you refuse to provide authorization to use and disclose your protected health information for this study, you will not be able to participate in this research study.

C. The Connecticut Hospice, Inc. will take appropriate steps to keep your protected health information private when possible, and it will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point. Federal agencies such as the FDA, OHRP, or WIRB (the IRB of The Connecticut Hospice, Inc.) might view or receive your record in order to collect data and/or meet legal, ethical, research, and safety-related obligations. In some situations, the FDA could be required to reveal the names of participants.

D. Your protected health information may be shared with the following parties:
- Federal agencies that require reporting of clinical study data (such as the FDA)
- WIRB, the IRB of The Connecticut Hospice, Inc.
- Officials of The Connecticut Hospice, Inc.
- Individuals with medical backgrounds who determine the effect that the study procedures may have on the disease
- Individuals who put all the study information together in report form

E. Normally you have a right to access your medical record. However, in order to preserve the integrity of this research study, you will not be permitted to have access to certain portions of your medical record while the study is ongoing.

F. There is no expiration date for the use of your protected health information. You may withdraw your authorization to share your protected health information at any time in writing. If you withdraw your authorization, you will be removed from the study and the study Chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study Chair or staff needs to use or disclose some of your research-related protected health information to preserve the scientific value of the study. Data collected about you up to the time you withdrew, will be used and included in the data analysis. The parties listed in Section D above may use and disclose any study data that were collected before you canceled your authorization.

G. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study Chair permission to enroll me into this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

WITNESS TO CONSENT
I was present during the explanation of the research to be performed under the Protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION DATE

PHYSICIAN OR STUDY CHAIR
A witness signature is only required for vulnerable adult participants.

PERSON OBTAINING CONSENT
I have discussed this clinical research study with the participant using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
SIGNATURE OF STUDY CHAIR OR PERSON AUTHORIZED TO OBTAIN CONSENT DATE