DIRECTIONS TO USE THIS TEMPLATE:

- Do not use this form if there is an **optional** future storage of identifiable data/specimens. If not optional you may use this form.
- **Do not adjust the bottom margin or use the footer**; it has been reserved for use by the IRB.
- Follow the italicized guidelines in red print and complete as applicable for your project. Words in black print or Green are generally expected be used without modification; those in blue print are examples/optional. Please **delete the template guidelines and unwanted text** after the document is completed.
- The consent form should include all the section headings indicated in the template unless otherwise indicated.
- The headings of this consent form are generally phrased as questions from the participant; the content of each section is generally written as the response from the study team. The form should provide information that a reasonable person would want to have in order to make an informed decision about whether to participate or not.
- The consent form may **not** contain exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator or the Institution from liability for negligence. Phrases such as "I understand…" or "You understand…" are not appropriate as they can be interpreted as suggestive and can constitute coercive influence over a participant.
- The consent form should be written at an appropriate grade level for the group of participants, usually no higher than the 8th grade level based on an electronic grade level scoring system, which is available with most word processing systems. The IRB may consider higher reading grade levels based on the populations targeted in the study.
- The consent form must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the understanding of the prospective participant or LAR of the reasons why one might or might not want to participate.
- Informed consent is a process, not just a form. The written presentation of information can be used as a teaching tool to document the basis for consent and for the participants' future reference. Obtaining informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.
- The procedures used in obtaining informed consent should be designed to educate potential participants in language that they can understand. If a Principal Investigator proposes to use a participant population that does not speak or read English, a copy of the translated document, as well as the English version, needs to be forwarded to the IRB for approval.
- For projects involving VA employees as participants, Principal Investigators need to carefully review the template and not include any elements that may not pertain to these types of studies, such as statements involving usual care, alternate treatments, or current relationships with participant's health care providers.
- **Collection of full name and last 4 of SSN are needed for studies where the consent form will be filed in the medical record**

WRITING TIPS THAT MEETS READABILITY REQUIREMENTS:

- Use as few words with three or more syllables as possible
- Break all compound sentences into separate short sentences.
- Use simple, declarative statements where possible.
- Change all passive voice sentences to active voice.
- Proofread for spelling, typographical, and grammatical errors.
- Avoid imbedding list in phrases, instead breakdown into bullets or into a numbered list
- Use tables to present information such as visits, procedures and compensation
- Avoid using technical terms. If you must use them, explain what they mean in lay language.
- Restrict descriptions of procedures to those things the participants will actually experience.

Department of Veterans Affairs
VA Central California Health Care System
Fresno, California

VA RESEARCH CONSENT FORM

Version Date: September 27, 2019

Subject Name: _____ **Date:** _____

Title of Study: Comparison of Success Rate of Pharmacist Led and Multidisciplinary Benzodiazepine Tapering Clinic with CBT

Principal Investigator: Bruce Manzo, PharmD **VAMC:** Fresno

Study Sponsor: None

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study will review two forms of treatment to learn about how to best taper the dose and stop benzodiazepine treatment. It is unfunded. By doing this study, we hope to learn if having both a psychologist and a pharmacist involved in treatment can better help you to taper off your medication.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

You will be asked to attend up to ten therapy sessions with a psychologist. Additionally, you will also be asked to meet weekly with a pharmacist to review medication use. Your participation in this research may last up to twelve weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Benzodiazepines are not meant to be used long term. They can stay in your body for days and can have serious side effects. It is important that you do not suddenly stop taking your benzodiazepine. The dose should be slowly decreased by a medical professional. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The key reason you might choose not to volunteer is because you are not ready to start tapering your dose of benzodiazepine medicine. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary only. Read the information below closely and discuss it with your family and friends if you wish. If there is anything that is not clear, ask one of the study staff. Take your time to decide. If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

You may contact Dr. Bruce Manzo at (559) 225-6100 extension 5119 during the day or contact Dr. Cindy Duncan after hours at (559) 225-6100 extension 4883 if you have questions, concerns, complaints or wish to provide input about the research study (to include its validity and authorized contacts), or in the event of illness or injury that you believe to be related to the research study. If Dr. Bruce Manzo cannot be reached or if you wish to talk to someone other than Dr. Bruce Manzo, you may contact the Institutional Review Board by calling the VAPIHCS Research and Development Office at (808) 433-7785 (if you are in Oahu). If you are outside Oahu, you may call 1-800-214-1306, press 1 and ask to be transferred to extension 7785. If you have any questions about your rights as a research participant, you may contact the VAPIHCS Office of Regional Counsel at (808) 433-0136.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to test the effectiveness of providing mental health treatment by a psychologist when patients are following a pharmacist managed benzodiazepine medication taper. The psychologist will teach you how to cope with anxiety during the taper process. The experimental part of this study is combining both pharmacist and psychologist in your taper. You were referred to the pharmacist managed clinic because it has been determined by a medical provider that continued treatment with a benzodiazepine is not needed. Benzodiazepines are commonly used for anxiety or sleep problems. They should be used for short-term therapy. Use for more than two to four weeks increases side effects and can be habit forming. Side effects can occur with any dose, large or small. It is important to slowly taper off to minimize withdrawal symptoms.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take about six months. Your individual participation in the project will take up to twelve weeks.

Subject Name: _____ **Date:** _____

Title of Study: Comparison of Success Rate of Pharmacist Led and Multidisciplinary Benzodiazepine Tapering Clinic with CBT

Principal Investigator: Bruce Manzo, PharmD **VAMC:** Fresno

Study Sponsor: None

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, this is what will happen:

- You will discuss potential side effects and benefits of the study during the first visit with a pharmacist (30-60 minutes). Your pharmacist will be either Dr. Cindy Duncan or Dr. David Charlestham. The pharmacist will answer any questions you may have about the benzodiazepine tapering process. You will be asked for information relevant to this study such as your medical history, treatment goals, how you take your medications, and questions about your mood, anxiety or sleep. Next, you will be referred to the psychologist to schedule a meeting.
- During your first visit (30-60 minutes) with the psychologist, you will be introduced to cognitive behavior therapy (CBT). Cognitive behavioral therapy is a form of treatment which helps patients deal with distressing emotions by changing thoughts and behaviors through self awareness and skill building. Your psychologist will be Dr. Kathryn Connolly.
- After that, you will be meeting your psychologist and your pharmacist separately on a weekly basis or as directed. You can attend your follow up visits (30 minutes) via in person visits, telephone calls, or video chat. During your medication follow up, you will be asked questions to assess your benzodiazepine withdrawal symptoms by a pharmacist. However, you are free to skip any questions that you prefer not to answer. Your pharmacist will monitor your progress, including symptoms, counting pills, and monitoring your prescription refill history. During your CBT session, the psychologist will be teaching skills to help cope with anxiety, panic attacks, or potential mood changes. You will be scheduled to attend eight CBT sessions with a psychologist.
- During the study, you will be asked to:
    - Take your medication as directed.
    - Come for your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
    - Keep the medication in a safe place for your use only and away from children
    - Fill out your diaries as instructed.
    - Complete your questionnaires as instructed.
    - Ask questions as you think of them.
    - While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from

possible injury from things such as extra blood drawing or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur. To minimize these risks, the pharmacist will develop an individualized and gradual tapering plan for you. The pharmacist will monitor your symptoms at each follow up visit. For concerns about minor reactions or other questions about the tapering, please contact research staff at (559)225-6100 ext. 4883. Please seek immediate medical attention or call 911 for urgent/emergent care.

Risks associated with Cognitive Behavioral Therapy:

In general, there is little risk with getting cognitive behavioral therapy. You may feel emotionally uncomfortable at times. This is because CBT can cause you to explore painful feelings, emotions and experiences. You may cry, get upset or feel angry during a challenging session. You may also feel physically drained.

Risks associated with benzodiazepine tapering:

- Agitation
- Anxiety
- Irritability
- Increased sensitivity to light and sound
- Abnormal sensation (“pins and needles”)
- Muscle cramps/Jerks
- Fatigue
- Insomnia
- Headache
- Dizziness

- Difficulty concentrating
- Seizure
- Nausea
- Loss of appetite
- Weight loss
- Depression
- Ringing or buzzing in the ears
- "Electric shocks"
- Tremors
- Visual changes

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

Questionnaires

Some people become uncomfortable at being asked questions about mood, anxiety and sleep; if, for any reason, you wish not to answer specific questions or you wish to stop the session, you will be able to do so.

Photographs, audiotaping, or videotaping

There will be no photographs, audio tapes, or video tapes made of you as part of this study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

- Avoiding serious side effects from benzodiazepine withdrawal.

- Avoiding serious side effects from long-term benzodiazepine use.
- Learning how psychotherapy can help you cope better with anxiety.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

Your privacy is very important to us, and the research staff will make every effort to protect it. However, some of your medical information may be given out if required by law. If this should happen, the research staff will do their best to make sure that any information that goes out to others will not identify who you are. Some of your health information, such as your response to benzodiazepine tapering treatment, results of study tests, and medicines you took, will be kept in the VA database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Taking part in this study will involve collecting private information about you. This information is used for research purposes. This information will be protected in the following ways:

- Any patient protected information will be locked in filing cabinets or on computers protected with passwords inside of the locked pharmacy department.
- The primary investigators or designated pharmacist or psychologist will have access to this information for therapy purposes only.
- The Institutional Review Board (IRB) is a group of people who review the research with the goal of protecting the people who take part in the study.
- Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered.
- Records will be destroyed in accordance with Records Schedule DAA-0015-2015-0004, item 0032 following VA Directive 6300 and Part two, chapter 8, code 8300.6 of VA Records Control Schedule 10.1, cut off at the end of the fiscal year after closure of the research project. Files and data will be destroyed six years after cutoff, or may retained longer if required by other Federal regulations. Paper data will be destroyed by placement into locked shredding bins located at VA Central California HCS campus. Electronic data will be destroyed following VA and Federal guidelines.

- If there are theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls, an incident report will be reported according to VHA Handbook (VHA Handbook 1200.05, 10j; VHA Handbook 1058.01, 11.a; VA Handbook 6500, Appendix D, AC-19, PL-4, IR-1, IR-6 and VHA Handbook 6500.2)
- While this study is being conducted, you will have access to your research related health records.
- This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Identifiers might be removed from the identifiable private information or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, drug, alcohol or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the VA Cooperative Studies Program (CSPCC), CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC), CSP Site Monitoring Auditing and Review Team (SMART), CSPCC's Human Research Committee (HRC), Institutional Review Board, Food and Drug Administration Office (FDA), Office of Human

Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Bruce Manzo and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study. There is no payment offered for participation.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study in accordance with applicable federal regulations (38 CFR 17.85). You will be treated for the injury at no cost to you. This care may be provided by the VACCHCS or arrangements may be made for contracted care at another facility. You have not released this institution from liability for

negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you may contact the VACCHCS Office General Council Pacific District North 707-437-1906.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY and AFTER HOURS:
Dr. Cindy Duncan at (559) 225-6500 extension 4883
Emergency and ongoing medical treatment will be provided as needed. If you need immediate treatment in an emergency, please call 911 or visit your nearest Emergency Department.

DO I HAVE TO TAKE PART IN THE STUDY?

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study.

If you decide to take part in this study, can you stop later?

Yes. You can decide to stop at any time. There will be no penalty to you, and you will not lose any benefits. If you decide to stop for any reason, it is important to let the research staff know as soon as possible so you can stop safely. If you stop, you can decide whether or not to complete follow-up study questionnaires.

If data was already collected prior to your withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

If you are a VA employee or student, your refusal to take part in this study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. Also, you may discontinue taking part at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received.

Subject Name: _____ **Date:** _____

Title of Study: Comparison of Success Rate of Pharmacist Led and Multidisciplinary Benzodiazepine Tapering Clinic with CBT

Principal Investigator: Bruce Manzo, PharmD **VAMC:** Fresno

Study Sponsor: None

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigators reserve the right to terminate the participation of any participant in the study due to missing four or more follow-up appointments, if any participant chooses to stop participating, or if any participant is unable to complete the taper process. If you stop participating in the study, you may be at risk for side effects associated with continuing long-term benzodiazepine medication. We request that you follow up with your regular provider(s).

FUTURE USE OF DATA AND RE-CONTACT

If any of your data is going to be retained after the study for future research:

- The data will be stored securely in the VA computer database.
- The principal and co-principal investigator(s) will have access to the data.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Cindy Duncan has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent form, or it has been read to me. I will receive a copy of this consent form after I sign it. A copy of this signed consent form will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

PARTICIPANT'S IDENTIFICATION (last, first, middle)

NAME:
SSN: (LAST FOUR)
FACILITY ID: 570