Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name:

Title of Study: Care Outcomes for Chiropractic Outpatient Veterans (COCOV-Phase III)

Principal Investigator: Thad Abrams, MD, MS **VAMC:** Iowa City, Iowa

INFORMED CONSENT DOCUMENT

Project Title: Care Outcomes for Chiropractic Outpatient Veterans (COCOV Phase III)

Principal Investigator: Thad Abrams, MD, MS

Research Team Contact: Janice Hubbard, DC, MS Phone: 563-949-0676

This form provides important information about what you will be asked to do during the study. The form will also present information about the risks and benefits of study participation, and about your rights as a research subject.

- Use this document along with the discussion you have with our study team member to decide if you want to join this study.
- If you have any questions or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. You are invited to participate in this research study because you are a Veteran who has low back pain. You may or may not have additional symptoms affecting your mental health.

The purpose of this research study is to assess a model of caring for Veterans with low back pain using coordinated care. It will look at how providers in the Iowa City VA Health Care System refer patients and work together to care for patients like you.

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HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study. Of this number, 40 veterans will be enrolled in the study. An additional 5-10 Veterans Affairs clinicians will take part in an interview about their own participation in this research study.

HOW LONG WLL I BE IN THIS STUDY?

It may take up to 3 weeks to know if you qualify for this study. This includes time to schedule your first chiropractic visit. If you qualify and agree to take part in this study, your involvement will last for 10 weeks from this first chiropractic visit.

Your total time to complete study activities will be between 7 and 10 hours. This does not include the time for travel, chiropractic or other provider visits.

WHAT WILL HAPPEN DURING THIS STUDY?

You will complete some or all of the following activities if you join this study. The time you will spend on each activity varies.

- Baseline Visit (2 to 3 hours)
- Chiropractic visits (1 hour initial visit, 30 minute follow-up visits)
- Brief online questionnaires at week 3, 7, after the first chiropractic visit and before final chiropractic visit (10 minutes)
- Full online questionnaires at Week 5 and 10 (1 to 2 hours)
- Audio recorded exit interview completed in person or by phone (20 minutes)
- Researchers also will review and collect data from your VA electronic health record

Baseline Visit

The Baseline Visit includes this informed consent process, an interview, and questionnaires to determine if you are eligible for this study. Because this is a small pilot study, it is possible that we will go through the baseline visit and not have you complete the study if we have met our goal. You would still be able to see any provider, including the chiropractor, if this should happen and would not be denied any benefits you would have received.

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- **Interview:** You will answer some short questions about your current health and health care.
- **Questionnaires (research data collection forms):** Using a computer during your baseline visit, you will answer research questions about your:
  - Current health,
  - Back pain,
  - Mental health (including post-traumatic stress disorder (PTSD), anxiety, depression, and alcohol use),
  - Thoughts and expectations about your back pain care, and
  - Activities of daily living

If you choose to be in this study, you will complete some of these questionnaires today. You will then have the option to finish the rest online at home or elsewhere after your Baseline Visit. All Baseline Visit questionnaires must be completed before your first chiropractic visit. It is after that first chiropractic visit that, if eligible, you would be enrolled in the study if you agreed.

VA Electronic Health Record Review

If you consent to this study, a research team member will review your VA electronic health record (EHR) for your medical diagnosis, past, and current treatments. This will help the researchers know if you are eligible. A VA chiropractor will review your record to make sure you can receive chiropractic care. The project manager also will access your electronic record for study-related scheduling and messages with your providers. This will not affect your VA provider's use of your health records per standard procedure in your care. We will also be monitoring all health care you received during the study period.

Chiropractic visits

Chiropractic visits will use the VA standard of care. The chiropractic treatment in this study is not experimental. The experimental part of the study is your answers to questionnaires and how your doctors talk to each other about your care plan.

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Chiropractic Visit Schedule

- At the first chiropractic visit, we will determine if you can enroll in this study. If you are not eligible for the study, you still may be able to receive chiropractic care through the VA. That decision is made with your chiropractor.
- If you are eligible for the study, your chiropractor and you will schedule your chiropractic visits, as needed, for up to 10 weeks.
- Visits may occur 1 to 2 times per week. Some weeks you may have no chiropractic visit scheduled.
- Your first chiropractic visit is scheduled for 1 hour. The visit will include an exam and possibly treatment. Follow-up chiropractic visits are scheduled for 30 minutes each.

What to Expect During a Chiropractic Visit

- Chiropractic visits may include a health history, exams and treatment to your lower back, neck, upper back, arms or legs.
- Recommended treatments will be explained to you. You may ask the chiropractor any questions you have about possible treatments.
- During your chiropractic visits, you may sit or lie in different positions on a treatment table. The chiropractor may move (lift or lower) the table during treatment. Some treatments include a quick, downward motion or "drop" of the table that sometimes comes with a loud sound.
- Your body will be moved by the chiropractor. The chiropractor may touch, support or move your back, head, neck, hips, arms or legs with their hands or other part of their body during treatment or exams.
- The type of chiropractic treatment you receive may vary. The chiropractor may make a quick and controlled motion with the hands to move some of your joints. Other treatments might involve slower, stretching type movements. Handheld devices that make a clicking sound might be used for treatment. The chiropractor may also use a technique called *Gua sha*, which is a type of massage to a specific area using a handheld device.
- The chiropractor may suggest exercises, such as back exercises. You also may get advice on actions you can take at home to care for your back.

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Other Considerations for Chiropractic Visits

- If enrolled, we ask you to avoid acupuncture treatments while you are in the study.
- As part of the research model, the chiropractor will monitor your health during the study. You may have a change in your health that needs assessment or treatment. If needed, the chiropractor will refer you to other VA health care providers. This may include your primary care provider, mental health provider, or emergency services.

Online Questionnaires

Completion of some online questionnaires may take a few minutes and others may take up to 2 hours. You may skip any questions you prefer not to answer. The day you receive your first chiropractic treatment starts the online questionnaire schedule (6 times total):

- After your first chiropractic treatment – 10 minutes
- 3 Weeks after your first chiropractic treatment (Week 3) – 10 minutes
- 5 Weeks after your first chiropractic treatment (Week 5) – 1-2 hours
- 7 Weeks after your first chiropractic treatment (Week 7) – 10 minutes
- Before your last scheduled chiropractic treatment* - 10 minutes
- 10 Weeks after your first chiropractic treatment (Week 10) – 1-2hours

*Note: You may not receive 10 weeks of chiropractic treatment, so your last scheduled chiropractic treatment will be decided by you and the chiropractor. Regardless of your last scheduled treatment, we will still ask you to complete research forms at weeks 3, 5, 7, and 10.

If you do not have access to a computer with internet and are unable to complete the questionnaires online, you have the option of completing them over the phone. If you will need to complete the questionnaires over the phone, the project manager will call you at the beginning of the week they are to be completed.

Audio Recorded Exit Interview

You will be asked to complete a one-time exit interview in person at weeks 8-10 , or up to two months after your completion in the study. This exit interview can be completed by phone if you are no longer seeing the

chiropractor or if you cannot complete it in person. The interview will ask about your experience in the study. We will ask about changes you noticed in your symptoms and about your relationship with the chiropractor. We also will ask how we might improve this study to make it better for other Veterans. The interview will take about 20 minutes to complete.

The interview will be recorded on a digital audio-recorder. We will not use your name or other information that might identify you to others on the recording. Instead, we will use your study number to save the recording. Study team members will review written transcripts from the recordings to assure that no personal data was included. If any personal data is noted, study team members will remove this detail and include a statement in its place: [personal data removed].

The digital recording will be placed on a secure server at Palmer College of Chiropractic for long-term storage. The de-identified recording will be uploaded to a secure server to be typed up by a service (Way With Words). This written transcript will be saved as a computer file at Way With Words that is labelled with your study number only. Study team members at Palmer College will download the transcript from the Way With Words secure server for long-term storage on the Palmer secure server. Once this occurs, Way With Words staff will delete the recording and transcripts from their server. The recording then will be erased from the audio-recorder. The audio-recorder will be kept in a locked briefcase held by the project manager, Dr. Stacie Salsbury (Co-Investigator), or assistant study coordinator, or in a locked file cabinet, when not in use.

The recording will be kept on the secure server at Palmer College of Chiropractic for 3 years to allow for data analysis. The de-identified transcript will be kept on the secure server at Palmer College of Chiropractic as a permanent record from this study. Study team members, including the project manager, data core manager, and investigators will have access to both the recording and transcripts.

VA Electronic Health Record Data Collection

We will collect information about your care that is routinely stored in your VA electronic health record, such as health care visits and medication usage.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate.

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Risks from Research Data Collection

- You may feel fatigued or tired after completing questionnaires.
- You may feel uncomfortable answering personal questions about yourself or your health.
- You may experience emotional distress after reading or answering some questions. You may skip any questions you do not feel comfortable answering. We encourage you to talk with your mental health provider if any distress continues.
- There is a very small risk of the confidentiality of your personal health records, personal data or social security number to be compromised. However, the research team has a number of measures in place to prevent this from occurring.

Risks from Chiropractic Visits

Participating in chiropractic care has risks associated with the specific treatments which can vary depending on your level of pain, condition, and prior treatment history. Participating in this research is not anticipated to alter that risk. Some possible side effects from chiropractic treatment include light-headedness or dizziness, sweating and a flushed feeling. These symptoms may occur right after a treatment and usually last only a few minutes. Sometimes, you might feel muscle or joint pain, fatigue, muscle stiffness or soreness, mild to moderate surface bruising under the skin of the area treated, or headache for a short time after a treatment. These symptoms often last less than 24 hours. They may last up to 48 hours. While rare, some chiropractic patients may experience bone fractures or muscle and ligament strains or sprains. If the chiropractor believes you are at a high risk for these rare but more serious side-effects and he/she is unable to treat you in a manner that reduces your risk, you will not be included in our study.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may not benefit from being in this study. However, you may experience a change in your back pain as a result of receiving care from your chiropractor per usual practice. In either case, the research community and the general public may benefit from the knowledge gained from this study.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, feel free to contact and consult with a trusted healthcare provider or other person, such as a family member. You may consider seeking care for your low back pain from

another health care provider. If you do not join the study, you may still receive chiropractic care at the VA or at other locations

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study. However, we do know there is travel and time involved in your participation.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study with up to $100 in gift cards to Wal-Mart. You will need to complete the following assessments within the designated time frame to receive this benefit.

- A $25 Wal-Mart gift card will be given after completion of Baseline Visit questionnaires.
- A $25 Wal-Mart gift card will be given after completion of Week 5 questionnaires.
- A $25 Wal-Mart gift card will be given after completion of Week 10 questionnaires.

If all 3 of the above questionnaires are completed within the designated time frame, an extra $25 Wal-Mart gift card will be given after completion of Week 10 questionnaires.

When you complete the online questionnaires at each of the above times we will mail you the gift card. For example, when you finish your Week 5 questionnaires online, you will see a screen that says "You have completed this set of study questionnaires". We will get a message saying it was completed and send your gift card through the US mail. If you complete the information over the phone, we will let you know you finished that week's questionnaires and that we will be mailing your card.

The research team will try to arrange your Baseline Visit and Exit Interview when you will already be at the VA for another appointment. If this is not possible, we will pay you $0.56/mile for distances over 20 miles for either or both visits. This will be paid directly to you in the form of a check mailed to your preferred address. We will need your social security number and preferred address on file to process this check. Any travel over 20 miles for regular visits such as chiropractic visits or regularly scheduled visits would be paid through the regular process at the VA.

Purpose and use of your Social Security number:

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We will ask you to enter your full Social Security number into a secure database that will be used to access your health care records and to ensure you are appropriately reimbursed for eligible travel. Only the study team data manager and the Office of Financial Affairs at Palmer College of Chiropractic will access your social security number. Your number will be deleted from the research related database once the study team data manager has confirmed receipt of your VA health care records and travel reimbursement requests have been paid. This process will be approximately 1-2 months after you've completed this research study.

We may also give you, free of charge, pens and/or keychains during your participation in the study.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health - National Center for Complementary and Integrative Health (NCCIH) is funding this research study. This means that the Iowa City Veterans Administration, the University of Iowa, and Palmer College of Chiropractic are receiving payments from NCCIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NCCIH for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. The VA electronic health record will contain a record that you are part of this study. However, research records will not be stored in the VA electronic health record.

There is the possibility that others may inspect research records. Some of these records could contain information that personally identifies you. Members of the groups listed below could potentially view identifiable information:

- Study team members at Palmer Center for Chiropractic Research
- Palmer College of Chiropractic Institutional Review Board (a committee that reviews and approves research studies)
- University of Iowa
    - Auditing departments of the University of Iowa
    - University of Iowa Institutional Review Board
- Iowa City VA Health Care System
    - Human subjects auditing personnel

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- Personnel with approved access to your electronic health record

Yale University - Yale Center for Medical Informatics

To help protect your confidentiality

Your protected health information and personal data that is protected by the Health Insurance Portability and Accountability Act (HIPAA) will be made confidential in the following ways.

- Only authorized members of the research team will have access to your protected health data. Research team members are trained in confidentiality procedures and have received VA data security training.
- Research team members who have access to your electronic health record will only review records related to the aims of this study.
- Whenever possible, we will **not** use your name or other information that might identify you to others on study-related documents. Instead, we will use your study code number. Your study code number linked to your name will **only** be saved on secure computer networks accessible only to researchers at Palmer College of Chiropractic. Study-related documents falling under this category include all research questionnaires completed on the study survey site (called RedCAP), as well as the audio-recording from the exit interview.
- Your name, birthdate and/or partial Social Security Number **will** be included two paper forms: this informed consent document and the VA Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research Form. Copies of these forms will be maintained at the ICVAHCS and Palmer College of Chiropractic.
- A scanned copy of this Informed Consent Document will be placed in your VA electronic medical record.
- Paper documents, such as this one, will be transported by the PM in a locked bag from Iowa City to the Palmer College of Chiropractic. Once there, these documents will be kept in a locked filing cabinet located behind locked doors.
- Your responses to the online questionnaires will be transferred electronically to Palmer College of Chiropractic using encryption, a process to maintain confidentiality.
- Computer files and networks at Palmer College of Chiropractic will be password protected, and are accessed only by authorized researchers.
- Audio-recordings will be saved as electronic files on a secure computer network at Palmer College of Chiropractic using a code number. The audio-recordings will be uploaded to a transcription service (Way With Words) on the internet; no personal information will be included in this upload.

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- If we write a report or article about this study or share the study data with others, we will not use your name and only share data in such a way that you cannot be directly identified.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WILL I RECEIVE NEW INFORMATION ABOUT THE STUDY WHILE PARTICIPATING?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, such as new treatment for low back pain, we will promptly provide you with that information.

CAN SOMEONE ELSE END MY PARTICIPATION IN THIS STUDY?

Under certain circumstances, such as if you experience a serious or life-threatening change in your health, researchers might decide to end your participation in this study earlier than planned.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact:

- **Janice Hubbard, DC, MS (Project Manager) at 563-949-0676,**
- **Christine Goertz, DC, PhD (Study Co-Principal Investigator) at 800-531-0987,**
- **Cynthia Long, PhD (Study Co-Principal Investigator) at 563-8845150, or**
- **Thad Abrams, MD, MS (VA Principal Investigator) at 319-338-0581x7700.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. You also may contact Ronnie Firth, DC, Chair of the Palmer College of Chiropractic Institutional Review Board, at 563-884-5843. To offer input about your experience as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/.

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

CHANGE IN HEALTH STATUS

If you have a change in your health or a significant increase in pain, please contact: **Janice Hubbard, DC, MS (Project Manager) at 563-949-0676.**

RESEARCH-RELATED INJURIES

If you experience a research-related injury, please contact: **Thad Abrams, MD, MS (Principal Investigator) at 319-338-0581x7700.**

RESEARCH SUBJECT'S RIGHTS

I have read or have had read to me all of the above. The study was explained to me and my questions were answered. 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. **Initial _____**

I have been told that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. Initial _____

The Iowa City VA Health Care System is available to provide necessary medical treatment for any injury resulting from participation in this research study. I have been told that I will not be required to pay for care received as a subject in this study except in accordance with federal law (Title 38 United States Code 1710(f) and 1710(g)) and that certain veterans are required to pay co-payments for medical care and services provided by the VA. **Initial _____**

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I received a VA brochure "*Volunteering in Research"* before signing this informed consent document. (http://www.research.va.gov/programs/pride/veterans/Volunteering-in-Research.pdf)

Initial _____

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 06/22/19.

_____ _____

(Signature of Subject) (Date)

STATEMENT OF PERSON WHO OBTAINED CONSENT

I have discussed the above points with the subject. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

Signature of Person who Obtained Consent Date

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