Department of Veterans Affairs	VA RESEARCH CONSENT FORM Consent by Legally Authorized Representative/Surrogate Version Date: October 24, 2019

Title of Study: **ID#:**	**Drug Reduction in Older Patients: The DROP Trial**		
Principal Investigator:	Amanda Mixon, MD Sandra Simmons, PhD	**VAMC:**	Tennessee Valley Healthcare System
Participant Name:		**Date:**	

You are being asked to consent on behalf of the study participant. The following document is an exact copy of what the study participant receives/signs in order to participate in this research project. Please read the document in its entirety and ask all questions necessary to determine interests in participation. Please note that references to "you" throughout the document are referring to the participant and not yourself.

PURPOSE OF THE STUDY

You are being asked to take part in a research study at the VA Tennessee Valley Healthcare System Medical Center because you are aged 50 or older and have been recommended to go to a Skilled Nursing Facility (SNF) when you leave the hospital. You also currently take 5 or more medicines to treat your health conditions. This study is sponsored by the Department of Veterans Affairs.

The purpose of this study is to reduce the number of medicines you are prescribed, if appropriate, and determine how this affects your health. We know that taking too many medicines can increase your risk for making mistakes, such as taking the wrong dose of a medicine. We also know that many medicines commonly prescribed to older adults can have side effects that cause you to feel dizzy or unsteady, which can result in a fall, make you feel more confused, less hungry, have feelings of sadness, or more of an urgency to go to the bathroom. However, we do not know if stopping or reducing medicines will improve your health or any of these symptoms. We also do not know for the majority of prescribed medications, whether symptoms or conditions return when a medicine is stopped or reduced. However, we will monitor changes in your symptoms and conditions closely during your hospital stay as part of this study.

Your participation in this study would require approximately 45-60 minutes of your time while you are hospitalized at the Nashville VA Medical Center to answer some questions. In the weeks and months following your hospitalization, you will be contacted twice to answer additional questions by phone which should last no more than 45 minutes.

Our goal is to enroll 540 patients at the Nashville VA Medical Center.

DESCRIPTION OF THE PROCEDURES AND APPROXIMATE DURATION OF THE STUDY

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If you agree (or consent) to participate in this research study, someone from our research team will interview you while you are in the hospital. They will ask you questions about your memory, mood, appetite and weight, pain, whether or not you have difficulty getting to the bathroom and if you've fallen recently. We are asking these questions because some medicines can cause you to lose your appetite, have bladder accidents or increase your risk of falling due to dizziness, for example. We also will ask you questions about your current medicines such as how often you miss taking it and what symptoms you experience when this happens. We are asking these questions because we want to understand how you manage your medicines at home and what types of problems you might have with your medicines, including whether or not some of your medicines cost too much. These questions will be asked by trained research staff on our team and require approximately 60 minutes of your time during your hospital stay. Our staff will complete this interview when it is most convenient for you before you leave the hospital.

If our research team identifies a medicine you are taking that is unsafe or may cause problems for you or it is a medicine that is not listed in your Nashville VA Medical Center record, we will notify your hospital treatment team, whether or not you are in the intervention or control group.

Next, you will be randomly assigned to one of two groups: Control group or Intervention Group. Using a procedure like the flip of a coin, you will have a one in two chance of receiving the intervention instead of routine care. Below is a description of what you can expect based on your group assignment:

Control group simply means that you will receive routine hospital and skilled nursing facility care as it would normally be provided by the hospital and nursing facility teams. Our research team will still follow you through your hospital and nursing facility stay.

Intervention group means that a Physician, Clinical Pharmacist or Geriatric Nurse Practitioner from our team will talk to you about your medicines and try to identify specific medicines that you are willing to stop taking completely or medicines that can be reduced so that you take less of the medicine. If you are in this group, we will not make any changes to your medicines without your permission. In addition, we will make sure that your hospital treatment team and your other providers, such as your primary care doctor, are aware of these changes. A medicine can be added back or increased back to your original dose if you experience discomfort or other symptoms. With your

permission, we also will contact your pharmacies when you leave the hospital and/or the nursing facility to make sure that automatic refills are stopped for medicines you will no longer be taking and doses are adjusted appropriately if dose changes are made.

When will we contact you again? Someone from our team will contact you two different time points after you leave the skilled nursing facility: approximately one week (7-10 days) and three months (90 days). Each time we contact you, we will ask you some of the same questions we asked during your hospital stay to determine if you've experienced changes in your health or other symptoms. We will also ask you to tell us which medicines you are still taking each time we contact you. In addition, we will ask you if you've been to the emergency room or hospital since we last spoke to you. If you've been to a hospital other than the Nashville VA Medical Center, we will request permission to access your medical records from that hospital. We also will ask the nursing facility to share your medical record with us during your stay.

We will only use your health information to monitor your healthcare during the course of this study, such as when you return to the Nashville VA Medical Center or a different hospital. We also may use your health information to determine your health status if we are unable to reach you after you leave the nursing facility. In addition, we may use your health information to determine your use of healthcare services (e.g., VA charges) during the study

DESCRIPTION OF STUDY RELATED COSTS

There is no cost to you for taking part in this study.

PAYMENT FOR PARTICIPATION

You will not be paid for joining this study.

MEDICAL TREATMENT FOR RESEARCH-RELATED INJURY:

Every reasonable safety measure will be used to protect your well-being. The VA has the authority to provide medical treatment to participants injured by participation in a VA project. VA medical facilities will provide necessary medical treatment to you as a research participant if you are injured as a result of your participation in this study.

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Compensation may or may not be available to you under applicable state and federal law in the event that you suffer physical injury or illness arising from this study. By agreeing to participate in this study you are not waiving or giving up your legal rights to seek compensation. If you have questions you may contact the VA TVHS Institutional Review Board office at 615-873-6076 or the Research and Development Service office at 615-873-8694.

COMPENSATION FOR RESEARCH-RELATED INJURY

If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS

Risks Related to Confidentiality

- The primary risk to you would be a breach of confidentiality. Additionally, you may find participation to be time-consuming or inconvenient. There may be unknown or unforeseen risks associated with participating in the study. Because this study involves individual interviews, there is minimal risk to you regarding complications.

- We will minimize the risks to you in the following ways. Your identity and questionnaire responses will be protected by assigning you a separate study identification number which will be used on all data collection forms, keeping your data in locked areas and on protected computers, and letting only research staff have access to your information. All information collected about you will be used for research purposes only.

Risks Related to the Intervention

The most common side effects which you may experience are symptoms that result from stopping a medicine or reducing the dose of a medicine, including the return of the symptoms or condition for which the medicine was originally prescribed. Side effects may differ for different types of medicines, and your dose may be lowered over days or weeks to lessen the likelihood of side effects. Here is a summary of the possible side effects based on the type of medicine that is stopped or reduced and how frequently that side effect is expected to occur:

Medication Class	Potential Side Effect of Stopping the Medication	Expected Frequency of Side Effects

1. Blood Pressure Lowering Medications	• Increase in blood pressure • Chest pain, shortness of breath	• Common (>10%) • Rare (<1%)
2. Diuretic Medications (water pills)	• Leg swelling, weight gain, shortness of breath	• Common (>10%)
3. Sedative / Hypnotic Medications (sleep or calming medicines)	• Insomnia, tremor, anxiety, • Seizures	• Common (>10%) • Rare (<1%)
4. Antidepressants	• Nausea, diarrhea, abdominal pain, sweating, headache, dizziness, cold and flu-like symptoms, anxiety, irritability, trouble sleeping • Mood changes, agitation, distress, restlessness, rarely suicidal ideation	• Uncommon (1-10%) • Rare
5. Medications for Constipation (Laxatives)	• Constipation	• Uncommon (1-10%)
6. Opioids (pain medicines)	• Moderate to Severe Pain (Pain level ≥ 6) that patient is unable to tolerate • Signs of withdrawal (restlessness, runny nose, goose flesh, sweating, muscle cramps, insomnia, nausea, diarrhea, pain, secretion of tears, increased heart rate, dilation of the pupils, breathlessness, decrease or impairment in daily function)	• Common (>10%) • Rare (<1%)
7. Urinary Incontinence Medications (bladder medicines)	• Return of incontinence symptoms	• Common (>10%)
8. Vitamins and Supplements	• None	• None

9. Gastrointestinal Reflux Disease / Dyspepsia Medications	• Return of dyspepsia, upper gastrointestinal symptoms	• Common (>10%)
10. Aspirin	• Chest pain, stroke	• Rare (<1%)

Measures to be taken to minimize potential risks include:

- Your symptoms will be monitored by the nurses during your hospital and skilled nursing facility stay as part of routine care. A medicine can be added back or increased back to your original dose at any time if you experience discomfort or other symptoms.
- Medicines related to a transplant procedure, HIV anti-retrovirals, or chemotherapy treatment will not be stopped or reduced by our study team.
- If you return to the hospital during the study, physicians on our team will review your medical record to determine if you were having a more serious reaction to stopping or reducing one or more medicines. We ask that you or a family member notify our research team as soon as possible if you are hospitalized anywhere other than Nashville VA Medical Center during this study.
- Among patients who are discharged from the hospital to skilled nursing facilities, death and hospitalization are common (> 10% occurrence). Studies to date, however, have not shown that reducing medications increases the risk of hospitalization or death among older patients.

ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

a) **The benefits to science and humankind that might result from this study**: This study may help us determine the best way to stop or reduce medicines for older patients who are prescribed 5 or more medicines. This study also may help to identify the health benefits, if any, of reducing medicines in terms of reducing common symptoms among patients discharged from the hospital. These common symptoms include: confusion, feelings of sadness, falls, leaky bladder, and feeling less hungry or losing weight without trying. We may also learn more about the side effects of reducing medicines. Finally, this study may help us understand how reducing medications might improve how well a patient takes a medicine and the cost of their medicines including the use of health services (e.g., emergency room, hospital visits).

b) **The benefits you might get from being in this study**: You may or may not benefit from participating in this study.

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ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE

You are not required to take part in this research study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment. If you decide not to be in this study, you will receive routine care as it is normally provided by both the Nashville VA Medical Center treatment team and the skilled nursing facility staff.

The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related illness or injury.

RESEARCH RESULTS

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you will be notified so you can make a decision whether or not to continue your participation in this study.

Once you have agreed to participate in the study, all information collected about you will be linked to a study identification number. The information linking you to the study identification number will be stored in password-protected files on the VA HSR&D server, a large secured computer network. Study personnel will transport the paper forms from the Nashville VA Medical Center to the Vanderbilt Center for Quality Aging for data entry into VA REDCap databases (via VPN access since the datafiles will be behind the VA firewall). Paper forms are stored in locked file cabinets within locked offices at the Center for Quality Aging. Follow-up telephone calls will be made from the Center for Quality Aging. Once the data has been checked, entered and cleaned, it will be transported to the VA GRECC for storage in locked file drawers. Only the research staff of this study has keys to the file drawers. The server is located in a secure room. The research staff will retain paper and electronic forms of data as in accordance with the VA Records Control Schedule. All computers that access the server are password-protected. Data is accessed in a folder set up to house data related to that project. Access to this folder is granted only to researchers working on the project and system administrators.

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If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

DISPOSITION OF RESEARCH DATA AND/OR SPECIMENS

This research study is anticipated to last 3 years. This study involves access of PHI date/limited data set for research as listed: name, address, birthdate, admission date, SNF referral date, last 4 of Social Security number; phone numbers, fax, and email addresses for follow-up.

The research data will be stored at and retained in your research record in accordance with Veterans Health Administration (VHA) and Federal Records Control Schedule policies after the study is completed.

- Sensitive Research data (hard copy such as signed consent forms, questionnaires) are stored: VA TVHS GRECC locked file cabinets, 4th floor

- Electronic sensitive research data (computer spreadsheets/CFRs/code linking to names), VA TVHS Server, Dr. Simmons' office at Vanderbilt Center for Quality Aging.
    - o De-identified research data (hard copy and electronic data) VA TVHS Server, VA REDCap database, Dr. Mixon's locked office and encrypted desktop, Dr. Simmons' office at Vanderbilt Center for Quality Aging.
    - o Your health data will be stored within VA REDCap database.

- This research study is anticipated to last 3 years. The research data will be stored at VA TVHS GRECC 4th floor and retained in your research record after the study is completed. All research data must be retained indefinitely in accordance with VHA and Federal Record Control Schedule policies after study completion. VA TVHS Privacy Officer's approval must be obtained prior to destruction of VA sensitive research data.

CONTACT INFORMATION

If you have questions about this study, wish to express concerns or complaints about the research, or to report a research-related injury, you can contact:

- Principal Investigator, Dr. Amanda S. Mixon at this phone number 615-936-3710 during the day or 205-335-4562 nights or weekends.

- Alternate Contact Person, Dr. Sandra Simmons at this phone number: 615-343-6729.

If you have general questions about giving consent or your rights as a participant in this study or wish to discuss problems or concerns, offer input, or you want to make sure this is a valid VA study, or request information you can call the VA Tennessee Valley Healthcare System (VATVHS) Institutional Review Board Office at (615) 873-6076 or the Research and Development Service Office at (615) 873-6940.You may also contact the VATVHS Patient Advocate at (615) 873-7225 to discuss problems or concerns and ask questions not related to the consent process, offer input, or request information.

CONFIDENTIALITY AND PRIVACY

Your rights of privacy will be maintained in the following manner. Your medical records will be maintained according to this medical center's requirements and the Privacy Act of 1974. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigators, the sponsor (when applicable), and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the VA Office of Research Oversight, the VA TVHS Research Compliance Officer, the Food and Drug Administration (FDA), state regulatory authorities, and legally authorized parties.

Your permission is provided on behalf of the study participant to allow access to his/her medical information and a description of the study participant's rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as described in the separate Authorization for Use and Disclosure of Personal Health Information for Research Purposes which will be provided your reference. The study participant's verbal assent to participate in the study will be requested upon regaining the capacity to self-consent.

During the study, if you express symptoms of depression that may need clinical treatment or if we learn you are having thoughts about suicide or hurting yourself or others, research staff will ask you more questions about your thoughts. Based on your response, we may provide you with help to get treatment. This may include:

- working with you to contact your doctor,
- contacting a trusted family member, or a therapist to discuss your thoughts,
- or working with you on a plan that may include getting you to a hospital for safety.

In these cases, the research team may share information about your condition with other health care providers. The VA also has a national crisis hotline that you can call anytime: 1-800-273-8255 (1-800-273-TALK) and press 1.

STATEMENT OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY

Signatures. I agree to participate in this research project as described in this consent form. I will be given a signed copy of this consent form for my records. I have read or have had this consent form read to me.

- This study has been explained to me and all of my questions have been answered by the person obtaining consent. 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. If I have questions later, I understand I can contact the researcher or a member of the research team.
- If I do not take part in this study, 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.
- I have been told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered.
- I will receive a copy of this consent form and HIPAA Authorization form; a copy will be forwarded to the VA Tennessee Valley Healthcare System Research Compliance Office.

I agree to participate in this research project as you have explained in this document. **Note: ALL signatures and date of signatures below *are required* for a legally effectie research consent.**		
_____ Participant's Name (Print)	_____ Participant's full **SSN**	_____ Date
_____ LAR/Surrogate Name (Print)	_____ LAR/Surrogate's Signature	_____ Date

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_____ Witness Name (Print) *Witness can not be a research member	_____ Witness Signature	_____ Date
_____ Name of person (Print) obtaining authorization and consent	_____ Signature of person obtaining authorization and consent	_____ Date

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LEGALLY AUTHORIZED REPRESENTATIVE DECISION MAKER CONSENT

In the event the study participant is unable to consent for himself/herself, and the investigational treatment as outlined in the attached consent form is an available treatment option, consent may be obtained from a legally authorized representative decision maker. A legally authorized representative is an individual who is: a) appointed under the Durable Power of Attorney (DPA) for Health Care; b) a court-appointed guardian; and/or c) an individual actively involved in the life of the study participant and who appears to be acting in the best interests of the patient, so that the legally authorized representative's decision would reasonably be considered what the study participant would have chosen to do. The order of priority for legally authorized representative decision making is as follow: spouse, adult son or daughter (18 years or older), parent, or adult brother or sister (18 years or older) or close friend. Other relatives are not eligible to serve as legally authorized representative decision makers.

STATEMENT OF LEGALLY AUTHORIZED REPRESENTATAIVE DECISION MAKER:

I, _____, am the _____ (relationship to the study participant) of _____ (name of the study participant). I have read and understand this consent form. I have had the opportunity to ask questions, and all of my questions have been answered. I understand that an investigational treatment may be administered to _____ (name of the study participant. I believe receiving such treatment is in his/her best interests and is consistent with what he/she would have decided had he/she been able to do so.

_____ _____
Signature of Legally Authorized Representative Decision Maker — Date

_____ _____
Signature of Witness (required) — Date

_____ _____
Signature of Person Obtaining Consent — Date

*A copy of the court document of Durable Power of Attorney or Legal Guardian must be attached if surrogate consent is obtained.