**Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator:** Sandra F. Simmons, PhD and Eduard E. Vasilevskis, MD, MPH **Revision Date: August 20, 2018**
**Study Title:** A Randomized Controlled Trial to Deprescribe for Older Patients with Polypharmacy Transferred from the Hospital to Skilled Nursing Facilities
**Institution/Hospital:** Vanderbilt University Medical Center

This informed consent applies to adults hospitalized at Vanderbilt University Medical Center who are age 50 or older and who plan to go to a Skilled Nursing Facility for post-acute care when they leave the hospital.

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

You do not have to be in this research study. You may choose not to be in this study and you will still receive routine treatments, as you normally would from the hospital treatment team, without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

**1. What is the purpose of this study?**
You are being asked to take part in this research study because you are aged 50 or older and plan to go to a Skilled Nursing Facility when you leave Vanderbilt University Medical Center. You also currently take 5 or more medicines to treat your health conditions. The purpose of this study is to reduce the number of medicines you take, 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, the risk of symptom or condition return when a medicine is stopped or reduced.

**2. What will happen and how long will you be in the study?**
If you agree to participate in this study, someone from our research team (trained research assistant, licensed nurse, or pharmacist) will interview you while you are in the hospital. We 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 require approximately 45 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.

Next, you will be randomly assigned to one of two groups: Control Group or Intervention Group. Random assignment means that the chance of you being in one group versus the other is like flipping a coin. 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 potentially inappropriate medicines that you are willing to reduce the dose of or stop taking completely so that you take fewer medicines. 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 and agree with our recommendations. We also will call the nurse practitioner in the nursing facility each week during your stay to review your medicines and any symptoms you might experience as a result of stopping or reducing a medicine. A medicine can be added back or increased back to your original dose if you experience discomfort or other symptoms. With your permission, if applicable, 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.

For BOTH Groups
When will we contact you again? Someone from our team will contact you at three different time points after you leave the nursing facility: approximately one week, two months (60 days) and three months (90 days). We will call you via telephone within one week and again approximately two months (60 days) later. Approximately 90 days after you leave the nursing facility, a nurse, pharmacist, and/or social worker from our team will visit you at home. If you have an appointment at Vanderbilt University Medical Center close to 90 days after you leave the skilled nursing facility, we will try to arrange to see you at Vanderbilt on the same day as that appointment instead of coming to your home. Each telephone call will require approximately 30 minutes and the home visit will require approximately one hour of your time.

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. 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 Vanderbilt University 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 Vanderbilt University 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., Medicare charges) during the study.

### 3. Costs to you if you take part in this study:

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

### 4. Side effects and risks that you can expect if you take part in this study:

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<br>• Chest pain, shortness of breath | • Common (>10%)<br>• Rare (<1%) |
| 2. Diuretic Medications | • Leg swelling, weight gain, shortness of breath | • Common (>10%) |
| 3. Sedative / Hypnotic Medications | • Insomnia, tremor, anxiety,<br>• Seizures | • Common (>10%)<br>• Rare (<1%) |
| 4. Antidepressants | • Nausea, diarrhea, abdominal pain, sweating, headache, dizziness, cold and flu-like symptoms, anxiety, irritability, trouble sleeping<br>• Mood changes, agitation, distress, restlessness, rarely suicidal ideation | • Uncommon (1-10%)<br>• Rare (<1%) |
| 5. Medications for Constipation (Laxatives) | • Constipation | • Uncommon (1-10%) |
| 6. Opioids | • Moderate to Severe Pain (Pain level >= 6) that patient is unable to tolerate<br>• Signs of withdrawal (restlessness, runny nose, goose flesh, sweating, muscle cramps, insomnia, nausea, diarrhea, pain, secretion of tears, increased heart rate, dilation of the | • Common (>10%)<br>• Rare (<1%) |

| | | |
|---|---|---|
| | pupils, breathlessness, decrease or impairment in daily function | |
| 7. Urinary Incontinence Medications | • 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%) |

Your symptoms will be monitored by the nurses during your hospital and skilled nursing facility stay, and the nurse practitioner from our team will call the facility nurse weekly to review your medicines and any symptoms you might be experiencing as a result of changes in your medicines. A medicine can be added back or increased back to your original dose at any time if you experience discomfort or other symptoms. 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 Vanderbilt University Medical Center record, we will notify your hospital treatment team and/ or your other providers, whether or not you are in the intervention or control group.

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 Vanderbilt University 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.

Medicines related to a transplant procedure, antiretroviral therapy for HIV, or chemotherapy treatment will not be stopped or reduced by our study team.

**5. Risks that are not known:**
There may be risks to this study that are not known.

**6. Payment in case you are injured because of this research study:**
If it is determined by Vanderbilt University Medical Center and the Investigator, with input from the National Institutes of Health & Aging, that an injury occurred as a direct result of the intervention done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt University Medical Center** to treat the injury.

There are no plans for Vanderbilt University Medical Center or the National Institutes of Health & Aging to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any

additional care. There are no plans for Vanderbilt University Medical Center or the National Institutes of Health & Aging to give you money for the injury.

**7. Good effects that might result from this study:**

a) **The benefits to science and humankind that <u>might</u> result from this study**: This study may help us determine the best way to stop or reduce medicines for older patients who are taking five 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.

**8. Other treatments you could get if you decide not to be in this study:**

If you decide not to be in this study, you will receive routine care as it is normally provided by both the Vanderbilt University Medical Center treatment team and the skilled nursing facility staff.

**9. Payments for your time spent taking part in this study or expenses:**

You will be paid for participating in this study up to a total of $50. The first payment of $10 will be made when you complete the interview we conduct while you are in the hospital. The second payment of $40 will be made when you complete the last interview 90 days after you leave the nursing facility. You will only be paid $40 if you complete all three interviews after you leave the nursing facility (one week, 60-days and 90-days). If you complete fewer than three interviews after you leave the facility, your payment will be $13 for one interview and $26 for two interviews. There are no costs to you for participating in this study.

**10. Reasons why the study doctor may take you out of this study:**

Your doctor may take you out of this study if they believe that stopping or reducing any of your medicines may lead to greater health risk than benefit for you. This may be because your doctor believes that all of your prescribed medicines are helping your symptoms and/or medical conditions. If you chose to be in this study and you are assigned to the intervention group, we will make every attempt to discuss our recommendations for stopping or reducing your medicines with each of your doctors, in addition to you, before any changes are made to your medicines.

**11. What will happen if you decide to stop being in this study?**

If you decide to stop being part of the study, you can tell anyone on our team at any time. Deciding to not be part of the study will not change your regular medical care at Vanderbilt University Medical Center or the skilled nursing facility in any way.

**12. Who to call for any questions or in case you are injured:**

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Sandra Simmons, PhD at (615-343-6729) or Eduard Vasilevskis, MD,

Chief of Hospital Medicine at (615-936-2187)**.** If you cannot reach either of us via phone, please page the study doctor at **(615-831-4048)**.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**13. Clinical Trials Registry.**
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.

**14. Confidentiality:**
All data collected as part of this study will be stored at the Vanderbilt University Center for Quality Aging in secure, locked filing cabinets and offices only accessible by the research team. Electronic data will be stored on a Vanderbilt University server that is username and password protected and, again, only accessible by the research team.

The National Institutes of Health & Aging and/or the Vanderbilt research team may share your information, without identifiers, to others or use it for other research projects not listed in this form. The National Institutes of Health & Aging, the Vanderbilt research team, Drs. Simmons and Vasilevskis and their research team staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study has support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as elder abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

**15. Authorization to Use/Disclose Protected Health Information**
All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by the Vanderbilt University Medical Center and/or the research team as a result of your healthcare. This includes data gathered for this research study that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Drs. Simmons and Vasilevskis and their study team may share the results of your study and/or non-study linked information related to your medicines and your responses to our interview questionnaires, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, the National Institutes of Health & Aging, members of the Data Safety and Monitoring Board that will oversee our research team and the skilled nursing facility that you go to after you leave the Vanderbilt University Medical Center. Federal privacy rules may not apply to these groups; they have their own rules to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Simmons or Dr. Vasilevskis in writing and let either of them know that you withdraw your consent. Their mailing address is: Vanderbilt Center for Quality Aging, 2525 West End Avenue, Suite 350, Nashville, TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

**If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.**

**STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY**

**I have read this consent form and the research study has been explained to me verbally. All of my questions have been answered, and I freely and voluntarily choose to take part in this study.**

| | |
|---|---|
| Date | Signature of patient/volunteer |

Consent obtained by:

| | |
|---|---|
| Date | Signature |

| Printed Name and Title | Time |
|---|---|

**Principal Investigator:** Sandra F. Simmons, PhD and Eduard E. Vasilevskis, MD, MPH **Revision Date: August 20, 2018**
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## Statement by Surrogate Agreeing to Patient's Participation

I, _____ [name of decision-maker/surrogate],
am the _____ [state relationship to participant]
of _____ [state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/___
Signature of Health Care Decision-Maker/Surrogate Date

_____ ___/___/___
Signature of Witness Date

_____ __/___/___
Name and Signature of person obtaining consent Date