Participant Name: _____ **Date:** _____

Title of Study: Discontinuation of levothyroxine therapy for patients with subclinical hypothyroidism: a pilot randomized, double-blinded, placebo-controlled study

Principal Investigator: Spyridoula Maraka, MD, MS

VAMC: Central Arkansas Veterans Healthcare System, 598 Version 7, Date 10/01/2021

SUMMARY

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a research participant at any time before, during, or after the study, please contact the Institutional Review Board (IRB) at (501) 257-6521 for help. If you have questions about this study, you may contact the Principal Investigator, Dr. Spyridoula Maraka at 501-257-5848.

The research is being done to learn more about the effects of stopping treatment with levothyroxine (LT4; Synthroid®) for veterans who have subclinical hypothyroidism (SCH). SCH is a mild form of underactive thyroid.

If you agree to take part in the study, you will be asked to complete the following research activities:

- Come to the John L. McClellan Memorial Veterans Hospital to discuss the study
- Sign the informed consent and HIPAA forms for the study
- Come in for at least three in-person visits at this facility – at the beginning of the study, at about two months after starting the study medication, and at about six months after starting the study medication. You may be asked to come for additional (unscheduled) visit(s), if necessary.
- Give a blood sample (about 3.5 teaspoons) at each of these three times. You may be asked to give a blood sample at an additional (unscheduled) visit(s), if necessary.
- Complete questionnaires about quality of life at each of the 3 scheduled visits
- Let us take your vital signs (height, weight, blood pressure, pulse) at these visits
- Stop taking your pre-study LT4 medication at the beginning of the study and start taking the study medication (either placebo or your pre-study dose of LT4)
- Take the study medication once a day and record taking the medication in a study diary
- Let us collect health information from your medical records
- Complete a survey at the end of the study about your experience with the study
- Allow the study team to phone you four times during the study to check on your health and see if you have missed any doses of study medication. The study team may phone you an additional time (unscheduled), if necessary.

Your participation will last for about six months.

There are no direct benefits to you from taking part in this study. The most common risks of taking part are pain, bruising and/or infection from the blood draws, and loss of confidentiality of your health information. There is also a small chance that SCH-related symptoms (such as weight gain and fatigue) will get worse.

You do not have to take part in this research study.

Participant Name: _____ **Date:** _____

Title of Study: Discontinuation of levothyroxine therapy for patients with subclinical hypothyroidism: a pilot randomized, double-blinded, placebo-controlled study

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Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

INTRODUCTION

You are being invited to take part in a research study that is being carried out at the Central Arkansas Veterans Healthcare System (CAVHS). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. This study is being conducted by Spyridoula Maraka, MD, an endocrinologist at CAVHS. The study is funded by a grant from the Department of Veterans Affairs.

Read the information below closely and discuss it with family, friends, and healthcare providers if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

You are being asked to take part in this study because you have been diagnosed with subclinical hypothyroidism (SCH) and are taking the drug, levothyroxine (LT4; Synthroid®) for it. SCH is a mild form of an underactive thyroid. It could affect your metabolism (part of how your body converts what you eat and drink into energy). SCH is often treated with LT4, a synthetic thyroid hormone. LT4 is approved by the U.S. Food and Drug Administration (FDA).

Recent research has shown that LT4 treatment for SCH in people without symptoms does not provide benefits with regard to quality of life, thyroid-related symptoms, cardiovascular events (such as heart attack or stroke) or mortality. LT4 treatment for SCH may increase risks of irregular heartbeat, chest discomfort, shortness of breath, bone loss and fractures in people over age 65. **Recently, an expert panel recommended against LT4 treatment in most adults with SCH.**

LT4 has been widely used for the treatment of SCH. However, because LT4 treatment lacks benefits for most patients with SCH and may increase other health risks, it is important for us to see whether veterans treated for SCH are willing to stop LT4 treatment and how stopping treatment affects their health and quality of life.

Dr. Maraka is conducting this study to learn more about veterans' willingness to stop taking LT4 and to compare quality of life and treatment-related adverse events for participants who are assigned to stop taking LT4 and those who are assigned to continue taking LT4.

Participant Name: _____ **Date:** _____

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Approximately 50 veterans will be enrolled in the study. Half will be assigned to continue their pre-study dose of LT4. The other half will be assigned to a placebo that does not contain their pre-study dose of LT4.

DURATION OF THE RESEARCH

This research study is expected to take approximately 2 years. Your individual participation in the project will take 6 months.

STUDY PROCEDURES

The study will involve 3 scheduled visits to CAVHS (at baseline, at 2 months and at 6 months) and 4 scheduled telephone visits (at months 1, 3, 4 and 5). It is possible you will be asked to come for an additional (unscheduled) visit(s) to CAVHS or allow an additional (unscheduled) telephone visit(s). If you decide to take part in this study, this is what will happen at each visit:

Baseline Visit
You will have an initial outpatient visit that will last about 30-60 minutes. During this visit, you will be asked if you are taking part in any other research studies. Your response will be documented in the CPRS note for this visit.

You will have your height, weight, blood pressure and pulse measured. You will be asked questions about your medical history and demographics (age, ethnicity and gender). You will be assigned a participant study ID.

You will be asked to allow the collection of a blood sample (up to 17ml or approximately 3½ teaspoons) and, if you are a woman of child-bearing potential, do a pregnancy test.

If you are eligible for the study based on results from the blood sample, you will be assigned by chance (like the flip of a coin) to either the LT4 group or the placebo group.

You will have a 1 in 2 chance of being assigned to each group. Neither you nor the Principal Investigator can choose your study group and neither you nor the Principal Investigator will know which study group you are in. However, in case of emergency, this information will be available.

If you are assigned to the LT4 group, you will continue to take LT4 at your current dose. If you are assigned to the placebo group, you will take the placebo medication daily. The placebo medication will look exactly like the LT4 medication, but it will not contain active ingredient. You will receive about an 8-week supply of your study medication (LT4 or placebo) at the end of this visit.

You will be asked to start taking the study medication the next day. The study medication will be taken once daily. You will be given a study medication pill diary and asked to complete it daily throughout the study.

You will be asked to fill out questionnaires about your quality of life and symptoms of hypothyroidism. We hope that you will answer all the questions, but you can skip any question you don't want to answer. The questionnaires will take about 5-10 minutes to complete.

Telephone Visit 1 (Month 1)
Approximately 4 weeks after you start taking the study medication, the Principal Investigator or Research Coordinator will call you on the telephone. They will ask you how you are feeling, if you have experienced any adverse events and if you are taking the study medication as prescribed.

Clinic Visit (Follow-up 1)
You will be asked to return to the CAVHS research clinic 6 – 8 weeks after you start taking the study medication.

You will be asked to bring any remaining study medication with you to the visit. You will also be asked to bring your study medication pill diary with you. The Principal Investigator or Research Coordinator may review the pill diary during the visit to make sure you are taking the study medication correctly. You will be given enough study medication at the end of this visit (or mailed after the visit) to last another 2 months.

You will be asked to fill out questionnaires about your quality of life and symptoms of hypothyroidism. These are the same questionnaires that you completed at the beginning of the study.

You will have your weight, blood pressure and pulse measured.

You will be asked to provide a blood sample at this visit (up to 17ml or approximately 3½ teaspoons). The study team will review the results of the blood sample to see how your thyroid is functioning.

Telephone Visit 2 (Month 3)
Approximately 12 weeks after you start taking the study medication, the Principal Investigator or Research Coordinator will call you. You will be asked about how you are feeling, if you have experienced any adverse events and if you are taking the study medication as prescribed.

Telephone Visit 3 (Month 4)
Approximately 16 weeks after you start taking the study medication, the Principal Investigator or Research Coordinator will call you again to ask how you are feeling, if you have experienced any adverse events and if you are taking the study medication as prescribed.

Another supply of study medication will be mailed to you after the call. This supply should last until the end of the study.

Telephone Visit 4 (Month 5)
Approximately 20 weeks after you start taking the study medication, the Principal Investigator or Research Coordinator will call you. As in earlier calls, they will ask you how you are feeling, if you have experienced any adverse events and if you are taking the study medication as prescribed.

Clinic Visit (Follow-up 2)
You will be asked to return to the CAVHS research clinic approximately 24 weeks after you start taking the study medication.

You will be asked to bring any remaining study medication with you to the visit. You will also be asked to bring your study medication pill diary with you. Study staff will collect the pill diary and any remaining study medication from you.

You will be asked to fill out questionnaires about your quality of life and symptoms of hypothyroidism. These are the same questionnaires that you completed at the beginning of the study and at your 2-month visit.

You will also be asked to answer questions about your experience during the study (End of Study survey). The study team will ask for your permission to record the discussion. The discussion will take about 10 minutes. The recording will be used by the study team to make sure that your answers were recorded completely on the survey. The recording will not be used for any other purpose.

You will be asked which group you think you were assigned to, that is, whether you think you were taking LT4 or placebo during the study. Additionally, you will be asked whether you took any pre-study LT4 by mistake during the study.

You will have your weight, blood pressure and pulse measured.

You will be asked to give another blood sample at this visit (up to 17ml or approximately 3 ½ teaspoons).

The Principal Investigator and/or Research Coordinator will discuss the plan to return your care to the clinician who was treating your thyroid condition before you started the study. This will be the final visit for the study and will complete your participation.

Unscheduled Visit or Telephone Call
If necessary, the study team may ask you to complete an additional (unscheduled) study visit or allow an additional (unscheduled) telephone call. It is possible that the study team may ask you to give another blood sample (up to 17ml or approximately 3 ½ teaspoons) during the unscheduled visit to recheck the levels of your thyroid and/or lipids. During an unscheduled telephone call, as in earlier calls, the study

team may ask you how you are feeling, if you have experienced any adverse events and if you are taking the study medication as prescribed.

Women of Child-bearing Potential

You will be asked at the initial study visit if you are pregnant or plan to become pregnant in the next 6 months. Fluctuations in thyroid hormone levels may be harmful to a fetus. Because of these risks, women cannot take part in this study if they are pregnant.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods, such as a condom or diaphragm, used with spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)

You must agree to use birth control for the entire duration of the study.

If you decide to participate, you will be expected to:

- Take the study medication as instructed.
- Keep your study appointments. If you miss an appointment, please contact the Principal Investigator or Research Coordinator (501-681-3695) to reschedule as soon as you know you will miss the appointment.
- Tell the Principal Investigator or Research Coordinator if you believe you might be pregnant.
- Keep the study medication in a safe place for your use only and away from children.
- Fill out your study medication pill diary as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Principal Investigator or Research Coordinator if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the Principal Investigator. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the study team may invalidate the results of this research, as well as of the other studies.

The blood samples collected for this study will not be used for commercial profit. The blood samples, vital signs (height, weight, blood pressure, and pulse), and questionnaire responses are being collected solely for research purposes.

Participant Name: _____ **Date:** _____

Title of Study: Discontinuation of levothyroxine therapy for patients with subclinical hypothyroidism: a pilot randomized, double-blinded, placebo-controlled study

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The information collected on you (demographics, medical history, vital signs, questionnaires, study medication compliance, adverse events) will be recorded in the study record. The study record will be kept at CAVHS in a secured area with restricted access. These source documents will contain your participant study ID (a number assigned to you at the beginning of the study).

The research team will ask your permission to audio record your responses during the discussion at the final visit regarding your experiences during the study. The recording will only be used to make sure the study team correctly recorded your responses on the survey. The recording will not be used for any other purpose. The recording will not be shared outside of the study team.

All data will be managed to minimize the risk of loss of confidentiality. Data will be stored in locked file cabinets, on VINCI servers (VA Informatics and Computing Infrastructure) and on a secure VA server in a password protected VA computer network as appropriate. The study team will only access the data needed for completion of study activities. The Principal Investigator will monitor study procedures to ensure compliance with all CAVHS and VA policies.

POSSIBLE RISKS OR DISCOMFORTS

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.

Risks associated with stopping LT4

Stopping LT4 in patients who have low levels of thyroid hormone can lead to new or worsening symptoms of hypothyroidism (such as weight gain, fatigue, cold intolerance, body aches, muscle weakness, edema, depression, constipation, hair loss, dry skin, brittle nails, menstrual abnormalities, neck pain/discomfort, memory trouble and cognition issues).

If you are assigned to receive placebo for the 6 months of the study, there is a very small risk that these side effects could develop. You will be monitored for these side effects and you should notify the Principal Investigator or Research Coordinator if you experience any of these problems.

Participants assigned to stop LT4 (those who receive placebo) also face a risk of developing a severe form of underactive thyroid. This is unlikely to happen because the study team will be carefully monitoring thyroid levels throughout the study period.

Risks associated with continuing LT4

Treatment with LT4 could result in cardiovascular protection or cause harm. Given the lack of high quality evidence, the study team will exclude participants with severe dyslipidemia or high cardiovascular risk.

Risks associated with drug interactions

LT4 interacts with the following drugs: anticoagulants, anti-convulsants, anti-arrhythmics, antidiabetics, beta-blockers, antidepressants, sympathomimetics, cardiac glycosides, antineoplastics, nonsteroidal

anti-inflammatory drugs, sex hormones, lipid regulating drugs, and general anesthetics. However, it should be noted that interactions are generally weak and without clinical relevance for the treatment of SCH with LT4.

Risks associated with blood collection

Blood collection for research purposes will take place three times during the study. The amount of blood collected for research purposes will not be more than 17ml (about 3.5 teaspoons) per study visit.

Physical risks from blood collection include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick (blood draw). Both discomfort and bruising should disappear in a few days. The blood samples will be collected in accordance with best practices to minimize these risks.

Risks associated with collection of quality of life information

You might feel some discomfort in answering the questions in the study questionnaires. You may be unaware of the extent to which you are experiencing symptoms, such as depression or memory loss. However, the study questions are similar to those encountered in clinical care and the Principal Investigator has tried to use only the necessary measures that would have relevance to you.

Risks associated with allergic reaction to LT4

As with any medication, allergic reactions are a possibility. Allergy to LT4 is extremely rare. If you experience a significant rash, wheezing or other allergy symptoms, please notify the Principal Investigator or Research Coordinator.

Risks associated with pregnancy

Fluctuating thyroid hormone levels may be harmful to a fetus. Because of these risks, women cannot take part in this study if they are pregnant. If you are sexually active and able to become pregnant, you must use birth control for the entire duration of your participation in the study. Acceptable methods of birth control are: (1) hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants, (2) barrier methods, such as a condom or diaphragm, used with spermicide (a foam, cream, or gel that kills sperm), or (3) an intrauterine device (IUD).

If you miss a period, or think you might be pregnant during the study, you must tell the Principal Investigator immediately. The Principal Investigator may ask for your permission to collect information about the outcome of your pregnancy and your newborn.

Risks of the usual care you receive are not risks of the research. 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. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

Participant Name: _____ **Date:** _____

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CONFIDENTIALITY

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

- Your social security number (SSN) is required as part of the informed consent process and in order to compensate you for your time and effort during the study. Paper documents that include your SSN or the last 4 of your SSN will be stored in a locked file cabinet in the Research Coordinator's locked office at CAVHS.
- Paper records containing personal information about you will be created during study visits. The information will include demographics (age, gender, ethnicity), dates of study visits, dates of study procedures (blood collection, vitals, questionnaires), vital sign information, blood sample results, study questionnaires, adverse events and study medication compliance. Your name and SSN will not be included on these records. Instead, you will be assigned a study ID that will be used on these records. These records will also be kept in locked file cabinets in the Research Coordinator's locked office at CAVHS.
- At your last study visit, you will be asked to allow the study team to record the discussion of your study experiences. You will only be identified in the recording by your study ID. The recording will be used to make sure that the study team correctly recorded your responses to the questions. The recording will be stored in a locked file cabinet in the Research Coordinator's locked office. It will not be shared outside the VA.
- Electronic data will be stored on VINCI servers and on a secure VA server assigned to the Principal Investigator for this project. The servers can only be accessed by approved VA personnel from behind the VA firewall.
- Study staff will only access the data needed for completion of study activities.
- The Principal Investigator will ensure that access to data is removed for any research staff member who leaves the study or no longer requires the access to the data.
- All research staff members will maintain current privacy training. The data will only be used for the IRB-approved research. All information will be treated as confidential and safeguarded in accordance with the Privacy Act of 1974 and all applicable laws and regulations.

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. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. A copy of your signed and dated consent and HIPAA forms will be placed in your medical record(s).

There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting Agency

(GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of CAVHS. The Department of Veterans Affairs requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research participants. By signing this document, you consent to such inspection.

Participants' information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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

POTENTIAL BENEFITS

There are no direct benefits to you from your taking part in this research study. However, taking part in the study may contribute to the safe and effective use of LT4 among veterans with mildly underactive thyroid in the future.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You may choose not to take part in this study. If this is your decision, you can continue your LT4 treatment. LT4 is FDA-approved and is available to you as part of routine care with a prescription. You can discuss thyroid treatment options with your primary care physician or other healthcare providers. You do not have to participate in the study to receive treatment for your thyroid condition.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants:
Neither you nor your insurance will be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and services, you will still pay these co-payments for VA care and services that are not part of this study.

Study staff will try to schedule study visits on days when you have another VA appointment. If this is not possible, you may decide to take time off work to complete the study visit. This could result in a loss of work pay.

Payment Offered for Participation:

If you decide to participate in this study, you will receive the following to assist with any transportation costs and time:

- Baseline visit: $50

- Clinic visit (Month 2): $50
- Clinic visit (Month 6): $50
- Completion of all study activities, including the End of Study survey: $100

If you come to all the study visits, complete all the study activities and complete the End of Study survey, you will receive a total of $250. You will be paid within 4-6 weeks after each clinic visit you complete. Payment will be by check or by electronic transfer of funds according to CAVHS procedures. Your name, SSN, address and date of visit are required to process the funds. An Internal Revenue Service (IRS) Form 1099, which documents that you received income, will be generated using your Social Security Number.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility.

This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

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:

Dr. Micheal Knox at (501) 681-3695 and

AFTER HOURS:

Dr. Spyridoula Maraka at (312) 286-8136.

Emergency and ongoing medical treatment will be provided as needed. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

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, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctors or other staff, and it will not affect the usual care that you receive as a patient.

You should tell the Principal Investigator or Research Coordinator if you decide to stop. You will be told whether any additional tests need to be done for your safety. The study team will help arrange for your medical care to continue.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected. However, information already collected about you in the study will continue to be used. Blood samples already used cannot be withdrawn. You may decide to stop taking the study medication or you may be instructed to stop taking the study medication, but you will be invited to continue in the study to the end (Month 6). You will receive compensation for completed visits as outlined above.

SIGNIFICANT NEW FINDINGS

Sometimes during the course of a research study, new information becomes available that might change a person's decision to stay in the study. If new information becomes available about LT4 or about stopping LT4, the Principal Investigator will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, the Principal Investigator and Research Coordinator will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. The Principal Investigator could also decide that it is in your best interests to withdraw you from the study. If so, she will explain the reasons and arrange for your usual medical care to continue.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The Principal Investigator may stop you from taking part in this study at any time:

- if it is in your best interest
- if you do not follow the study rules
- if the study is stopped

ADDITIONAL CONTACT INFORMATION

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint or offer your input with a person who is not part of the study team, you can contact the IRB Administrator at (501) 257-6521, the Research Compliance Officer at (501) 257-6980, or the Research and Development Coordinator at (501) 257-4816.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Principal Investigator and/or Research Coordinator has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Participant Name: _____ **Date:** _____

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By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. copy of this signed consent will also be put in your medical record.

_____ / /

Signature of Participant Date

_____ / /

Signature of Person Obtaining Consent Date