THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Utilization of the natural history of medullary thyroid carcinoma to inform advanced disease management
2019-0769

Subtitle: Aim 1 & 2

Study Chair: Elizabeth G. Grubbs

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to learn more about how medullary thyroid cancer (MTC) develops and progresses.

This is an investigational study.

Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

You will be on study for about 3 years.

The study will be performed at no cost to you.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 2,030 participants will take part in this study. Up to 1,200 will take part at MD Anderson.

If you agree to take part in this study, you will be asked to complete questionnaires 2-4 times each year. This will depend on how often the study team thinks it is needed. The questionnaires will be about your health and how things like finances and quality of life effect your experience with the disease. The baseline questionnaire (the first time you take it) will take 30 to 40 minutes. All questionnaires after that will be shorter, ranging from 10 to 25 minutes. The questionnaires may be delivered by email, over the phone or regular mail, depending on your preference. If mailed, you will be given a prepaid envelope for return.

The study staff may also reach out to you in the future about a third part of this study, if you qualify, and ask if you are interested in participating.

Your questionnaires and data will be given a code number. No identifying information will be directly linked to your questionnaire except for dates including date of birth, dates of surgical procedures and of medical treatments related to your disease, dates of disease recurrence, and date of death and zip codes at time of diagnosis (optional). Only the researcher in charge of the bank and other researchers designated by the study chair will have access to the code numbers and be able to link the questionnaires and medical history to you.

Data from this study may be sent to researchers at other institutions. Information sent outside of MD Anderson will be de-identified (meaning no identifying information will be linked to your data) except for zip code at time of diagnosis (if you choose to provide it) and dates including date of birth, dates of surgical procedures and of medical treatments related to your disease, dates of disease recurrence, and date of death so that outside researchers cannot learn your identity from the information that they receive. These dates are only used to characterize your disease occurs over time.

2. POSSIBLE RISKS

MD Anderson and others can learn about cancer and other diseases from your **banked data**. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with your data, and these reports will

not be put in your health records. If this information were released to you, your family, or third parties, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job. In the future, people who may do research with your data may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy but cannot ensure complete privacy.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. Physical copies of data will be stored in an MD Anderson-approved, long-term, off-site storage center, and electronic data will be kept indefinitely on MD Anderson services behind an institutional firewall. Your study data and paper records will not be destroyed; they will be kept permanently.

If you withdraw your authorization for storage of data (to be performed in writing), the data collected up to that point can be used and included in the data analysis, but no further information about you will be collected.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will be given a $10 gift card for each series of questionnaires you complete at each time point. A participant who completes questionnaires at every time point may receive up to $120 over the three-year period.

Additional Information

4. You may ask the study chair (Dr. Elizabeth G. Grubbs, at 713-792-6940) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and the FDA and/or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

You may withdraw your consent to future research at any time. If you do not want your data to be used for future research, tell the study coordinator. However, any data that has already been released and used in research may continue being used, to preserve the scientific integrity of the analysis.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:

- The Office for Human Research Protections (OHRP)
- The IRB and officials of MD Anderson
- University of California - San Francisco
- The Ohio State University
- Colorado University
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can

identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2019-0769.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE
A witness signature is only required for vulnerable adult participants.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Utilization of the natural history of medullary thyroid carcinoma to inform advanced disease management 2019-0769

Subtitle: Aim 3

Study Chair: Elizabeth G. Grubbs

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to learn more about how medullary thyroid cancer (MTC) develops and progresses. Researchers want to learn if frequent monitoring can provide information to improve care for the disease.

This is an investigational study.

Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

Your active participation on this study will last about 12 weeks.

The study will be performed at no cost to you.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 2,030 participants will take part in this study. Up to 1,200 will take part at MD Anderson.

If you agree to take part in this study, you will be asked to complete a short questionnaire and measure your blood pressure every day from when you start this study until your first follow-up appointment for treatment (up to 12 weeks). The questionnaire will be about daily symptoms you could experience and will take 2 minutes to complete.

You will be provided with a blood pressure device and instructed on how to use it. The questionnaire will be performed using an app or email. The study staff will give you more information about this.

If you do not prefer to use the app or email, you may still participate in the study by reporting your blood pressure and daily assessments in a log provided to you.
At the end of the study, you will be asked to complete questionnaires about your overall experience with using the blood pressure monitor and the daily symptom assessments that you completed as part of this study. These questionnaires should take about 10 - 15 minutes to complete.

The study staff may also reach out to you in the future with IRB-approved questionnaires and ask if you are interested in completing these questionnaires at certain time points during the study.

As part of your standard care when starting therapy for MTC, you are asked to check and record your daily blood pressure as well as any symptoms of concern and provide these to your clinical team weekly. You are also asked to more immediately report to your clinical team any blood pressures outside of the specified ranges given to you by your clinical team. The study collects this same information for research purposes. Because a system is already in place to report side effects, the staff will not be clinically monitoring the data collected in this study. Research data will not be reviewed or reported to your clinical team, and you should follow the instructions of your clinicians for reporting adverse effects.

Your questionnaires and data will be given a code number. No identifying information will be directly linked to your questionnaire except for dates including date of birth, dates of surgical procedures and of medical treatments related to your disease, dates of disease recurrence, and date of death and zip code at time of diagnosis (optional). Only the researcher in charge of the bank and other researchers designated by the study chair will have access to the code numbers and be able to link the questionnaires and medical history to you.

Data from this study may be sent to researchers at other institutions. Information sent outside of MD Anderson will be de-identified (meaning no identifying information will be linked to your data) except for zip code at time of diagnosis (if you choose to provide it) and dates including date of birth, dates of surgical procedures and of medical treatments related to your disease, dates of disease recurrence, and date of death so that outside researchers cannot learn your identity from the information that they receive. These dates are only used to characterize your disease occurs over time.

2. POSSIBLE RISKS

MD Anderson and others can learn about cancer and other diseases from your **banked data**. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with your data, and these reports will not be put in your health records. If this information were released to you, your family, or third parties, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job. In the future, people who may do research with your data may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy but cannot ensure complete privacy.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. Physical copies of data will be stored in an MD Anderson-approved long-term off-site storage center, and electronic data will be kept indefinitely on MD Anderson services behind an institutional firewall. Your study data and paper records will not be destroyed; they will be kept permanently.

If you withdraw your authorization for storage of data (to be performed in writing), the data collected up to that point can be used and included in the data analysis, but no further information about you will be collected.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be

reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

The funding for the blood pressure monitor will be provided from the U.S. Food and Drug Administration under the grant titled, *A novel natural history study of medullary thyroid carcinoma: Incorporating the patient perspective to inform advanced disease management*. The blood pressure monitor in this study will be provided at no cost to you.

You will receive no compensation for taking part in this study, but you will be allowed to keep the blood pressure monitor after you complete this study.

Additional Information

4. You may ask the study chair (Dr. Elizabeth G. Grubbs, at 713-792-6940) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and the FDA and/or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

You may withdraw your consent to future research at any time. If you do not want your data to be used for future research, tell the study coordinator. However, any data that has already been released and used in research may continue being used, to preserve the scientific integrity of the analysis.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:

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- Study monitors and auditors who verify the accuracy of the information
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The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

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

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

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PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2019-0769.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE
A witness signature is only required for vulnerable adult participants.

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PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

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