AIM1: Adequate Selection of Patients for Thyroid Biopsy: Evaluation of a Shared Decision Making Conversation Aid

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Aim 1. Adequate selection of patients for thyroid biopsy: evaluation of a shared decision making conversation aid

Abstract:

Thyroid nodules are commonly discovered and their evaluation and diagnosis precedes the epidemic of thyroid cancer that is harmful to patients and overwhelms the medical system. We hypothesize that the use of an electronic conversation aid during clinical visits can help patients and clinicians collaborate when deciding between performing a thyroid biopsy or following thyroid nodules with serial ultrasound. As a result, the use of this tool can lead to a more careful selection of patients that should undergo thyroid biopsy.

The proposed research seeks to: AIM1. Update a conversation aid prototype that was developed to support shared decision making in the diagnosis of thyroid cancer through evaluation of clinical practice and feedback from end users.

Background

We are living in an epidemic of thyroid cancer diagnoses that directly harms patients. The incidence of thyroid cancer in the United States has tripled during the last three decades, with >50, 000 patients diagnosed annually, mostly due to identification of small indolent cancers that would not be harmful if left undiagnosed and untreated. These patients receive risky treatment and suffer emotional and economic burden. For example: 1) the quality of life of patients with thyroid cancer is decreased when compared with patients with worse prognosis, 2) a diagnosis of thyroid cancer is associated with the highest incidence of bankruptcy and 3) the cost of caring for patients with thyroid cancer is expected to rise to $21 billion. This diagnostic and treatment journey leaves most patients with a diagnosis of thyroid cancer that only led to harm without improving the duration or the quality of their life. This reality of over-diagnosis and over-treatment affects 7 out of 10 women and 5 out of 10 men diagnosed with thyroid cancer in the United States.

This detrimental epidemic is partially attributed to the inadequate selection of patients who would benefit from a thyroid biopsy and thyroid cancer diagnosis. Six out of 10 people have thyroid nodules that can be detected by imaging. The diagnostic cascade that leads to the over-diagnosis of thyroid cancer begins most commonly with the incidental discovery of these nodules. Patient selection for thyroid nodule biopsy and thyroid cancer diagnosis is inadequate and leads to harm. To address this quality gap, recent practice guidelines recommend for careful selection of patients for thyroid biopsy and against biopsy of small thyroid nodules with low risk for thyroid cancer. However, the implementation of these recommendations, can be hindered by challenging clinical conversations with patients who are anxious about a potential cancer diagnosis and assume that more investigation is always better. Counseling about complex topics such as thyroid cancer risk and over-diagnosis can be difficult. In fact, most patients after a thyroid biopsy know little about these topics and are not routinely engaged in making the decision to further investigate thyroid nodules.

Shared decision-making (SDM) is a communication process in which patients and clinicians work together to decide the next best step. The use of conversation aids that support SDM helps patients make medical decisions that are consistent with their informed values, be more knowledgeable and active in the decision-making process and better understand concepts such as risk. In oncology, the use

of conversation aids can help overcome barriers for patient-centered care. To support SDM, promote patient centered care and help clinicians identify patients who would benefit from a thyroid nodule biopsy according to guideline recommendations, we have developed an electronic conversation aid for patients diagnosed with a thyroid nodule. This conversation aid includes a summary of the clinical evidence guiding patient selection for thyroid biopsy, the values of each diagnostic alternative (biopsy vs observation) and allows clinicians to incorporate the patients preferences and situation into the decision making process. We hypothesize that use of this conversation aid will support SDM, improve patient selection for thyroid biopsy and reduce the unnecessary diagnosis of thyroid cancer.

Specific Aims

AIM 1. **Field-test and update the conversation aid prototype.** We will enroll patients (30-75) and clinicians (10-15) who have used the conversation aid at the University of Florida (UF) and Mayo Clinic (MC) to evaluate the acceptability of its use and barriers to implementation. Post visit semi structured interviews and recordings of the clinical visits will be qualitatively analyzed after transcription. We hypothesize the conversation aid will be accepted and facilitate the decision making process.

Research Plan

We hypothesize that the use of a conversation aid in patients with thyroid nodules will enhance the collaboration between patients and clinicians, supporting SDM and lead to adequate and careful selection of patients that should undergo thyroid biopsy in accordance with current clinical practice recommendations. If successful, this innovative intervention will help close the gap between practice recommendations and adequate selection of patients for thyroid biopsy.

AIM 1. Field-test and update the conversation aid prototype

Setting. The Endocrinology, Ear, Nose and Throat (ENT) and Surgery Clinics at the University of Florida, FL and the Division of Endocrinology at Mayo Clinic, MN.

Participants and identification procedures.

1. **Patients**: Eligible patients would be identified by review of the upcoming clinic schedule of participating clinicians. We will include 30-75 English-speaking adults > 18 years old who present for evaluation of a thyroid nodule and discuss the need for thyroid biopsy. UF students and staff, will be included in the study, although not targeted. We will exclude patients with hyperthyroidism, pregnant patients and those in which the nodule of interest has already been biopsied or who have received counseling by a local specialist in the year before their visit.

2. **Clinicians:** We will enroll clinicians that counsel patients with thyroid nodules from the endocrinology, ENT and surgery divisions at UF and from the endocrinology division at MC.

Intervention. We have developed a conversation aid for patients with thyroid nodules and aim to field test this prototype. This conversation aid was developed using person-centered design procedures including direct observation of clinical encounters and integration of the best available evidence guiding the selection of patients for thyroid biopsy. We would use information from 1) direct evaluation of recorded clinical visits and 2) semi-structured interviews to identify areas that would need to be modified on this conversation aid and to explore barriers and facilitators to the use of this tool in clinical

practice. We will collect information related to past medical history and thyroid disease from electronic medical record review and clinicians will complete a post visit survey after each visit (pen and paper survey).

We will ask clinicians to use the prototype during clinical encounters in which they are counseling patients with thyroid nodules regarding the diagnostic alternatives of thyroid biopsy or surveillance with periodic thyroid ultrasound. Before clinicians use the tool, study personnel will review the conversation aid with participating clinicians and do a demonstration so that they are familiarized with the tool. These visits will be recorded and analyzed using qualitative research methods, after they have been transcribed.

In addition, patients and clinicians will be interviewed after their visit following an interview guide and clinicians will fill out a small questionnaire after each visit (pen and paper).

Enrollment

1) Patients. Patients would be invited to participate in the study once they have been roomed and are waiting to see their clinician. The study coordinator will verify eligibility with the patient. The consent process will take care in a private room. We will seek written informed consent, consent for video/audio recording and authorization for review of electronic medial records to obtain information related to their medical history and thyroid nodule features.

The study coordinator will quickly setup and start recording before leaving the room. The participants can stop this recording (video, aimed at the desk, or audio when the video camera is aimed at the ceiling) at any time.

2) Clinicians. Eligible clinicians are those who counsel patients with thyroid nodules. We will approach eligible clinicians at their convenience to discuss the goals of the study and their potential participation. We will obtain written informed consent and consent for audio/video recording.

3) Guest. If an eligible patient has a caregiver/guest with them we will seek the consent for participation given that their participation during the medical visit would be recorded and they may wish to participate in the post visit interview. If a guest does not want to participate, the patient would not be included in the study as we don't want to disrupt their visit dynamic. Informed consent and consent for audio/video recording will be obtained.

4) Other. Commonly, clinicians would work with scribes, students, and other ancillary staff. We will obtain consent for audio/video recording during the medical visit.

Measurements and Outcomes. The main outcome is an updated prototype based on qualitative assessment of feedback from patients and clinicians and evaluation of their clinical visits. We will conduct semi-structured interviews of patients and clinicians after using the conversation aid to identify barriers to implementation of the tool following the Consolidated Framework for Implementation Research Construct. We have focused on characteristics related to the intervention, outer setting and individuals.

Patients will be interviewed after their clinical visit and physicians will be interviewed after they have used the tool in 3-5 clinical encounters; we will also ask clinicians to fill a post-visit questionnaire (pen

and paper) addressing the topics of interest. This interviews would be recorded and transcribed for analysis.

The interview for patients will be conducted in person in a private room immediately after their visit, when feasible and acceptable by patients. However, we will offer the opportunity to set up a visit time for the interview up to 7 days after their initial visit as they might have other appointments. We will also offer the opportunity to complete the conversation remotely (e.g. UF zoom account) to facilitate enrollment.

The interview for clinicians will be conducted in person or remotely at a convenient time after the clinicians have used the tool in 3-8 clinical encounters.

We will evaluate the recordings of the clinical visit to complement the findings of the interviews as they relate to the use of the tool in clinical practice. We plan to use a grounded theory approach for our qualitative analysis, an inductive method in which a theory is developed entirely based on analysis of the data. In addition, we will review the recordings of the clinical encounters to verify fidelity (extent to which the tool was used during the visit) to the use of the tool during practice.

Sample size and Statistical Analysis. Qualitative research methods allow researchers to obtain an in depth understanding of a particular phenomenon by focusing on individual experiences. Sample size is usually determined by reaching a saturation point, where new themes are no longer identified; a priori sample size is not specified. However, in the field of SDM in oncology, thyroid cancer and thyroid nodules, previous qualitative studies have included 6-25 participants. As such, we anticipate evaluating 3-8 clinical encounters per clinician following a purpose sampling strategy to allow similar numbers of encounters from each clinician and including patients with different characteristics that would make the encounters more informative. In addition, we will obtain descriptive statistics about the patients' and clinicians' characteristics.

Data management

Patients approached by study staff that agree to participate will be captured in the remote data capture system (REDCap). Potential eligible patients found to be ineligible or eligible but who decline participation will be captured as well. The reason for ineligibility or reason for decline will be captured along with patients' age, sex, and race/ethnicity.

Data from the medical record will be obtained for all enrolled patients that agree to capture demographic and clinical data.

All video recording will be stored in a secure drive to which only the study personnel will have access.

Clinical information and survey data would be stored into REDCAP and available only to study personnel.

The transcription of recordings required for qualitative analysis will be completed by a third party company. Audio recordings will be send electronically (https://thelai.com/ , Landmark Transcription)

Possible Discomforts and Risks

The participants in the study will not be expose to any significant risks.

This study does not involve any procedures, medications or tests. However, we will be recording the medical encounters during routine care, which might make participants uncomfortable. We will offer the option of audio recording only if preferred and underline with participants that the recording can be stopped at any time.

We will approach patients for enrollment once they are roomed and this could result in a minimal delay in the clinic schedule. To avoid interruption, we will discuss with clinicians before approaching patients during clinic time and if they are running behind, we will not approach the patient. We have completed a study following this approach in our outpatient clinics, and have had no issues related to timing.

In addition, in the case of the patients in AIM1, they will be asked to participant in a post visit interview. This might represent burden in terms of time. The interview focuses on questions related to their clinical visit and no sensitive topics would be evaluated. This interview will be completed in a private room. Similarly, clinicians on Aim1, will be asked to participate in an interview to provide feedback on the conversation aid and complete a short questionnaire after each visit, that might represent a burden in terms of time.

Possible Benefits

The participants of the study would not receive any direct benefit. However, the information obtained from this study will help us refine and test a tool that aims to improve the quality of the conversation between patients and clinicians when discussing the need of thyroid biopsy. This tool will be beneficial for patients diagnosed with thyroid nodules in the future.

Conflict of Interest

None of the investigators has any conflict of interest in regards to patents, owning stock or serving as consultant

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UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

Title of this study: Adequate selection of patients for thyroid biopsy: evaluation of a shared decision making conversation aid

Researchers:

Principal Investigator: Naykky Singh Ospina, MD, MSc
Phone number – 352-273-8656

You are being asked to participate in a research study.

Before you agree to take part in this study, Dr. Singh Ospina or her representative will tell you:

- Why the study is being done and what will happen to you if you take part in the study:

  The goal of this research project is to obtain feedback for educational materials that have been developed for patients and clinicians to discuss the management of thyroid nodules.

  If you were to participate in this research study we will like to: 1) audio or video record clinical visits in which you counsel patients with thyroid nodules using our thyroid nodule conversation aid, 2) interview you after you have used the thyroid nodule conversation aid in 3-5 encounters and 3) have you complete a post visit questionnaire after each visit in which you use the thyroid nodule conversation aid.

- How long you will be in the study: You will be involved in this research project until you counsel 8-10 patients using our conversation aid and complete an interview to provide us with feedback.

- How many people will be in the study: We plan to enroll up to 17 clinicians, 260 patients and 520 guest (assuming an average of 2 per patient).

- The possible foreseeable risks, discomforts, and benefits of this research:

  Having your clinical visit recorded can be uncomfortable or feel strange. You can turn off the recording at any time. We anticipate the post visit interview will take 15-20 minutes of your time. These recordings will be send electronically to a third party for professional transcription, in order to conduct analysis. Lastly, your recordings and feedback would be securely stored in the University of Florida restricted servers, however, there is always a potential risk of a data breach.

There is no direct benefit to you for participating in this study, however, you might benefit from learning the information presented in the educational materials. In addition, we will use your feedback to modify and update our educational materials, to help patients and clinicians discuss the management of thyroid nodules.

- Alternatives to being in the study: You can decide not to participate in this study and routinely counsel your thyroid nodule patients.

- How your study records will be maintained and who will have access:

  Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

  Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

  If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

- If it will cost you anything to take part in this study: There would be no cost to you if you participate in this study.

- When or if you may be told about new findings which may affect your willingness to keep taking part in this study: as soon as the research team is aware of them.

- 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.

If you agree to participate in this study, you will be given a signed copy of this document.

You may contact Dr. Naykky Singh Ospina, MD, MSc at (352) -273-8656 at any time if you have questions about the research or if you think that you have been hurt by the research.

You may contact the Institutional Review Board at the University of Florida Health Science Center at (352) 273-9600 if you have questions about your rights as a research subject or what to do if you are injured.

You may choose not to be in this study or you may quit being in the study at any time and there will be no penalty and no loss of any benefits you are entitled to.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

_____	_____
Signature of Person Obtaining Consent	Date
_____	_____
Consent and Authorization of Patient	Date

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

Title of this study: Adequate selection of patients for thyroid biopsy: evaluation of a shared decision making conversation aid

Researchers:

Principal Investigator: Naykky Singh Ospina, MD, MSc
Phone number – 352-273-8656

You are being asked to participate in a research study.

Before you agree to take part in this study, Dr. Singh Ospina or her representative will tell you:

- Why the study is being done and what will happen to you if you take part in the study:

  The goal of this research project is to improve our educational materials for thyroid nodules based on your opinion of which parts worked well and which ones need improvement.

  If you were to participate in this research study we will like to: 1) audio or video record the clinical visit you are attending as a guest and 2) ask you to participate in an interview after this visit.

- How long you will be in the study: You will be involved until we complete your post visit interview.
-
- How many people will be in the study: We plan to enroll up to 17 clinicians, 260 patients and 520 guests (assuming an average of 2 per patient).

- The possible foreseeable risks, discomforts, and benefits of this research:

  Having your clinical visit recorded can be uncomfortable or feel strange. You can turn off the recording at any time. We anticipate the post visit interview will take 15-20 minutes of your time. These recordings will be send electronically to a third party for professional transcription, in order to conduct analysis. Lastly, your recordings and feedback would be securely stored in the University of Florida restricted servers, however, there is always a potential risk of a data breach.

There is no direct benefit to you for participating in this study, however, we will use your feedback to modify and update our educational materials, to help patients and clinicians discuss the management of thyroid nodules.

- Alternatives to being in the study: You can decide not to participate in this study and attend the clinical visit as a guest today.

- How your study records will be maintained and who will have access:

  Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

  Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

  If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

- If it will cost you anything to take part in this study: There would be no cost to you if you participate in this study.

- When or if you may be told about new findings which may affect your willingness to keep taking part in this study: as soon as the research team is aware of them.

- 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.

If you agree to participate in this study, you will be given a signed copy of this document.

You may contact Dr. Naykky Singh Ospina, MD, MSc at (352) -273-8656 at any time if you have questions about the research or if you think that you have been hurt by the research.

You may contact the Institutional Review Board at the University of Florida Health Science Center at (352) 273-9600 if you have questions about your rights as a research subject or what to do if you are injured.

You may choose not to be in this study or you may quit being in the study at any time and there will be no penalty and no loss of any benefits you are entitled to.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Consent and Authorization of Patient Date

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Adequate selection of patients for thyroid biopsy: evaluation of a shared decision making conversation aid

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Naykky Singh Ospina, MD, MSc
Phone number – 352-273-8656

4. Who is paying for this Research Study?

The sponsor of this study is National Cancer Institute.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The goal of this research project is improving our educational materials for thyroid nodules based on your opinion of which parts worked well and which ones need improvement. You will be involved until you complete the post visit interview.

b) What is involved with your participation, and what are the procedures to be followed in the research?

If you were to participate in this research study we will like to : 1) audio or video record your clinical visit, 2) interview you after your visit to obtain your opinion on our educational materials and 3) review your medical records to obtain information related to your medical history and thyroid nodule.

c) What are the likely risks or discomforts to you?

Having your clinical visit recorded can be uncomfortable or feel strange. You can turn off the recording at any time. We anticipate the post visit interview will take 15-20 minutes of your time. These recordings will be send electronically to a third party for professional transcription, in order to conduct analysis. Lastly, your recordings and clinical information would be securely stored in the University of Florida restricted servers, however, there is always a potential risk of data breach.

d) What are the likely benefits to you or to others from the research?

There is no direct benefit to you for participating in this study, however, we will use your opinion to modify and update our educational materials, to help patients and clinicians discuss the management of thyroid nodules.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

You can decide not to participate in this study and meet with your clinician to discuss how to manage your thyroid nodule.

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.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

You will receive counseling for your thyroid nodule.

7. What will be done only because you are in this Research Study?

If you agree to participate:

1.We will record (audio or video) your clinical visit using a small camera. You, your clinician, and any visitors can turn off the recorder at any time.

2. Your clinician will use the educational materials we have developed with you in your visit.

3. We will interview you after your visit to obtain feedback. This interview can happen immediately after the visit and up to 7 days from today. We will record this interview.

4. We will review your electronic medical record, to obtain information related to your past medical history and thyroid history.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect demographic information, past medical history and thyroid disease information from review of your medical record.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Your active participation will last until you complete the post visit survey in the next 7 days.
This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We expect to enroll up to 260 patients and their guests (520, on average 2 per patient) and 17 clinicians.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Your participation requires recording of your medical visit, a post visit interview and review of your medical record. Participating the post visit interview will require 15-20 minutes of your time. Additionally, unauthorized review of the data generated in this study could occur.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform

one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

Although you may not directly benefit from participating in this research study, there is potential benefit to people in the future as a result of the information gathered in this study.

13b. How could others possibly benefit from this Research Study?

In this study, we aim to obtain feedback to update educational material that can help patients and clinicians discuss the management of thyroid nodules, allowing both parties to be engaged in the decision-making process.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

You can decide not to participate in this study and discuss the management of your thyroid nodule with your doctor.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- None.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

There would be no cost to you if you participate in this study.

17. Will you be paid for taking part in this Research Study?

There is no compensation for participating in this study
.

18. What if you are injured while in this Research Study?

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time. You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Singh Ospina, or *[his/her]* successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Singh Ospina has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

Signature Date