Study Title: AIM 2: Adequate Selection of Patients for Thyroid Biopsy: Evaluation of a Shared Decision Making Conversation Aid

NCT# : NCT04463719

10/31/2022

UF | Institutional Review Board
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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 to see if clinicians and patients are able to talk about thyroid nodules better if they use different formats to guide their conversations. You will be involved until you complete a 6-9 month follow up survey.

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 you to:

1) Receive counseling regarding your thyroid nodule using different formats to guide the conversation.

2) audio or video record your clinical visit (for analysis and transcription)

3) have you complete a survey after your visit (in person/phone/mail/electronic),

4) allow us to contact you in 6-9 months for a phone/mail/electronic survey and

5) 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 survey will take 10-15 minutes of your time. 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 a 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, the results of this study will allow us to better understand the best way to help patients and clinicians communicate.

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, you will be asked to:

1) Receive counseling regarding your thyroid nodule using different formats to guide the conversation
2) Audio or video recording of your clinical visit (for analysis and transcription)
3) Complete a survey after your visit
4) Allow us to contact you in 6-9 months for a phone/mail/electronic survey
5) Review your medical records to obtain information related to your medical history and thyroid nodule.

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 6-9 months phone/mail survey.

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 50 patients and their guests (100, on average 2 per patient) and 15 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 survey today and in 6-9 months (phone/mail/electronic) and review of your medical record. Participating in the post visit interview will require 10-15 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 information 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

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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 see if clinicians and patients are able to talk about thyroid nodules better if they use different formats to guide their conversations.

  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, that will be used in analysis and transcribed

- **How long you will be in the study**:

  You will be involved in this study until the clinic visit that you are attending as a guest is completed.

- **How many people will be in the study**:

  We plan to enroll up to 15 clinicians, 50 patients and 100 guests (assuming an average of 2 per patient).

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

  Having the clinical visit recorded can be uncomfortable or feel strange. You can turn off the recording at any time. Lastly, your recordings would be securely stored in the University of Florida restricted servers, however, there is always a potential risk of data breach.

  There is no direct benefit to you for participating in this study, however, the results of this study will allow us to better understand the best way to help patients and clinicians communicate.

- **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

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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 evaluate different communication approaches for patients with 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 or following your regular routine (to be analyzed and transcribed),

  2) Have you complete a baseline questionnaire and 3) a post visit questionnaire after each visit in which you counsel patients with thyroid nodules enrolled in the study.

- **How long you will be in the study**:

  You will be involved until we complete patient enrollment (anticipated 18 months).

- **How many people will be in the study**:

  We plan to enroll up to 15 clinicians, 50 patients and 100 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 baseline and post visit questionnaire to take 5 minutes to complete. Lastly, your recordings would be securely stored in the University of Florida restricted servers, however, there is always a potential risk of a breach in the firewall.

There is no direct benefit to you for participating in this study, however, the results of this study will allow us to better understand the best way to help patients and clinicians communicate. You might also learn different strategies for discussing management options for patients with 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**:

  any unexpected discomforts associated with participation in this study will be discussed with participants as soon as the research team because 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

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