Reducing Racial Disparities in Cancer Care With PINPOINT (Promoting INformed Approaches in Precision Oncology and ImmuNoTherapy)

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RUTGERS
Cancer Institute
of New Jersey
RUTGERS HEALTH

Rutgers, The State University of New Jersey
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New Brunswick, NJ 08903-2681

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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Reducing Racial Disparities in Cancer Care with PINPOINT (Promoting INformed approaches in Precision Oncology and ImmuNoTherapy)

Principal Investigator: Anita Y. Kinney, PhD, RN, FAAN, FABMR

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rightsby agreeing to take part in this research or by signing this consent form.

Who is conducting this study?

Dr. Anita Kinney is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who arepart of the research team. Dr. Kinney may be reached at 732-235-8979 and at the address below:

Rutgers Cancer Institute
195 Little Albany St.
New Brunswick, NJ 08901
Phone: 732-235-8979

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: This study is sponsored by the American Cancer Society.

Why is this study being done?

The purpose of this study is to provide feedback on an educational website prototype and assess knowledge, attitudes, beliefs, and sociocultural, clinical, and system-level factors (e.g. barriers) that may explain disparities in decisions about the use of precision oncology (personalized cancer treatment) in Black cancer patients. This information will be used to refine the development of an internet-based education and decision support intervention called PINPOINT (Promoting Informed approaches in Precision Oncology and ImmuNoTherapy).

Who may take part in this study and who may not?

Eligible participants are self-identifying Black or African American individuals who have been diagnosed with cancer or are currently living with cancer, including metastatic cancer. You may also participate if

you are a spouse, blood relative, or caregiver of a Black or African American cancer patient, or if you work as a physician, nurse, social worker, patient navigator, or financial counselor in oncology.

Why have I been asked to take part in this study?

You are being asked to take part in this study because you self-identify as a Black or African American cancer patient, are a spouse, blood relative, or caregiver of a Black or African American cancer patient, or a provider working in an oncology setting.

How long will the study take and how many subjects will take part?

A total of 48 people will participate in this study. The total length of time the study will last is 2 years but your participation will only last up to 2 hours. With your permission, you may be contacted for future research. You may decline or accept future participation.

What will I be asked to do if I take part in this study?

Each participant enrolled as a key informant will be expected to attend a virtual interview session lasting about 1.5 hrs and complete a survey.

The survey will be completed online via REDCap, by phone, or on paper by mail before the interview. The interview will be conducted individually with a trained research team member. During the interview, you will be asked questions about your experiences, views, and preferences. You will also view a prototype of the PINPOINT online intervention and provide feedback to the interviewer as you explore the website and its features. The interviewer will take observational field notes to document your reactions, and usage data will be collected using an app.

The session may be done by telephone, video chat (e.g., Zoom), or in-person (access to a computer will be provided for in-person sessions). We will record the sessions using screen-sharing software and notetaking on your navigation of the prototype with an emphasis on problems you encounter with the website. The video and audio recording(s) will be used for quality assurance, possible use as a teaching tool to those who are not members of the research staff (i.e. for educational purposes) and data analysis by the research team.

What are the risks of harm or discomforts I might experience if I take part in this study?

We do not believe that there are any risks to taking part in this study. However, you may be bothered by some of the questions asked during the study. They are similar in many ways to risks experienced by those who participate in shared decision making with their providers and seek online education and information about health topics outside of a research study. There are potentially three main risks to participants in this study:

Initial discomfort/embarrassment: Participants will be asked questions of a sensitive or personal nature, which could potentially cause some discomfort or embarrassment while answering. If this happens, you can skip those questions or withdraw from the study altogether. If you decide to quit the study, your responses will NOT be saved.

Concerns about televideo sessions with website tracking and screensharing capability. Although some adults may feel more comfortable utilizing televideo, website tracking, and screensharing technology, others may feel less comfortable with this process and have concerns. Pilot testing sessions will be conducted and recorded using HIPAA-compliant Zoom. You will be provided with written instructions

for using this technology and research staff will troubleshoot any technical problems by telephone. The intervention prototype is a secure, password-protected website that tracks user analytics. These data will be de-identified and stored on HIPAA-compliant servers. Recordings will be used for transcription purposes only.

Privacy and loss of confidentiality: Breach of confidentiality is a risk of harm, but a data security plan is in place to minimize such a risk. Nevertheless, there is still the potential for unintentional breach of confidentiality for participants. All efforts will be taken to maintain privacy and confidentiality. We are aware that data will contain demographic and personal health information, and consistent measures will be employed to protect the security and confidentiality of these data. Tracking, survey, and interview data will be securely stored in a study database. Participants will be assigned a study ID, and the analyses will be limited to the variables necessary for the completion of the proposed study, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data.

Are There Any Benefits To Me If I Choose To Take Part In This Study?

There are no direct benefits to you for taking part in this study. However, you may find satisfaction in contributing to research and you may learn new information relating to cancer education and clinical trial participation.

What Are My Alternatives If I Do Not Want To Take Part In This Study?

Your alternative is not to take part in this study.

How Will I Know If New Information Is Learned That May Affect Whether I Am Willing To Stay In The Study?

During the study, you will be updated about any new information that may affect whether you are willingto continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will There Be Any Cost To Me To Take Part In This Study?

There are no costs to participating in this study.

Will I Be Paid To Take Part In This Study?

Participants will receive a $50 gift card after completing all interviews and surveys as compensation for their time. Those identified as providers will be excluded from receiving the gift card incentive due to institutional policies.

How Will Information About Me Be Kept Private Or Confidential?

All efforts will be made to keep your personal information in your research record confidential, but totalconfidentiality cannot be guaranteed. Identifiable information will not be stored with your responses. Instead, your responses will be assigned a subject number which will be stored separately from your identifiable information so others will not know which responses are yours. These study IDs will help maintain confidentiality. A study database will be hosted at Rutgers Cancer Institute in New Brunswick, NJ on secure computing servers with secure data entry and submission for all other sites. No information that can identify you will appear in any professional

presentation or publication. There may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

The research team may use or share your information collected or created for this study with the followingpeople and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The sponsors of this research study is the American Cancer Society.

What Will Happen To My Information—data, recordings and/or images—Collected For This Research After The Study Is Over?

- All information will remain confidential and de-identified and stored in password protected and encrypted databases and de-identified data may be shared with other investigators for future research.

What Will Happen If I Do Not Wish To Take Part In The Study Or If I Later Decide Not To Stay In The Study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or youmay change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected aboutyou, but you must do this in writing to the PI, Dr. Anita Kinney (ak1617@sph.rutgers.edu):

Anita Y. Kinney, PhD, RN
Professor, Department of Epidemiology & Director, Center for Cancer Health Disparities
School of Public Health,
Associate Director for Cancer Health Equity Cancer Institute of New Jersey
Rutgers University
195 Little Albany Street
New Brunswick, NJ 08903-1384

Who Can I Contact If I Have Questions?

If you have questions about taking part in this study, you can contact the PINPOINT research team at (XXX) XXX-XXXX or XXX@cinj.rutgers.edu.

If you have questions about your rights as a research subject, you can contact the IRB Director at: New Brunswick/Piscataway HealthSci IRB (732) 235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149 or email us at humansubjects@ored.rutgers.edu.

Please keep this consent form if you would like a copy of it for your files.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print):_____

Audio/Video Addendum to Consent Form

You have already agreed to participate in a research study entitled: PINPOINT conducted by Dr. Anita Kinney, PhD, RN. We are asking your consent to allow us to both video and audio record you as part of the research. You do not have to consent to be video recorded in order to take part in the main research, but you must agree to audio recording for transcription purposes in order to participate.

The video and audio recording(s) will be used for quality assurance, possible use as a teaching tool to those who are not members of the research staff (i.e. for educational purposes) and data analysis by the research team.

The audio and video recording(s) may include the following information that can identify you: video of you, or your voice. Participants will have the option to either dial in using a phone, video call or only use audio. Each speaker will be given an identification number for transcription purposes. Recordings will be reviewed by the study team to verify transcription accuracy and then will be destroyed. Transcripts will not include identifiers.

The audio and video recordings and transcripts will be uploaded onto designated HIPAA (Health Insurance Portability and Assurance Act) compliant, password-protected network drive maintained and protected by a firewall and saved without identifiers or link to subjects' identity. Recordings will be destroyed once we have obtained de-identified transcripts. The de-identified transcripts will be retained indefinitely but will not include any identifiable information to you.

After information that could identify you has been removed, de-identified audio and video responses maybe used by or distributed to investigators for other research without obtaining additional informed consentfrom you.

Your signature on this form permits the investigator named above to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name (Print):_____

Subject Signature_____ Date _____

Investigator/Person Obtaining Consent Name (Printed):_____

Signature_____Date _____

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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Reducing Racial Disparities in Cancer Care with PINPOINT
(**P**romoting **IN**formed approaches in **P**recision **O**ncology and **I**mmu**N**o**T**herapy)

Principal Investigator: Anita Y. Kinney, PhD, RN, FAAN, FABMR

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Who is conducting this study?
Dr. Anita Kinney is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Kinney may be reached at 732-235-8979 and at the address below:

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New Brunswick, NJ 08901
Phone: 732-235-8979

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: This study is sponsored by the American Cancer Society.

Why is this study being done?
The purpose of this study is to provide feedback on an educational website and assess knowledge, attitudes, beliefs, and sociocultural, clinical, and system-level factors (e.g., barriers) that may explain disparities in decisions about the use of precision oncology (personalized cancer treatment) in Black cancer patients. This information will be used to refine the development of an internet-based education and decision support intervention called PINPOINT (Promoting Informed approaches in Precision Oncology and ImmuNoTherapy).

Who may take part in this study and who may not?
Eligible participants are self-identifying Black or African American individuals who have recently been diagnosed with cancer, including metastatic cancer.

Why have I been asked to take part in this study?
You are being asked to take part in this study because you self-identify as a Black or African American cancer patient.

How long will the study take and how many subjects will take part?
A total of 33 people will participate in this study. The total length of time the study will last is 2 years but your participation will only last up to 2 hours. With your permission, you may be contacted for future research. You may decline or accept participation.

What will I be asked to do if I take part in this study?
Each participant enrolled in the pilot testing phase of the study will be required to take part in viewing each section of the educational website (About, Personalized Cancer Treatment, Clinical Trials, and Resources), as well as completing two surveys (online, by phone, or on paper by mail). Participants will complete a baseline survey before viewing the educational website and then complete a follow-up survey after seeing their treating oncologist. You will also be asked to sign a HIPAA authorization form electronically or on paper, if needed, so that the researchers can collect data from your medical records. If you choose to sign the HIPAA authorization form by paper, we will mail you a paper copy of the HIPAA authorization form with a pre-stamped envelope to mail back the signed HIPAA authorization form. If you choose to electronically consent to the study, you will be asked to sign the consent form online and sign the HIPAA authorization form online.

What are the risks of harm or discomforts I might experience if I take part in this study?
We do not believe that there are any risks to taking part in this study. However, you may be bothered by some of the questions asked during the study. They are similar in many ways to risks experienced by those who participate in shared decision making with their providers and seek online education and information about health topics outside of a research study. There are potentially three main risks to participants in this study:

Initial discomfort/embarrassment: Participants will be asked questions of a sensitive or personal nature, which could potentially cause some discomfort or embarrassment while answering. If this happens, you can skip those questions or withdraw from the study altogether. If you decide to quit the study, your responses will NOT be saved.

Concerns about website tracking. Although some adults may feel more comfortable about website tracking, others may feel less comfortable with this process and have concerns. The educational website is a secure, password-protected website that tracks user analytics. These data will be de-identified and stored on HIPAA-compliant servers.

Privacy and loss of confidentiality: Breach of confidentiality is a risk of harm, but a data security plan is in place to minimize such a risk. Nevertheless, there is still the potential for unintentional breach of confidentiality for participants. All efforts will be taken to maintain privacy and confidentiality. We are aware that data will contain demographic and personal health information, and consistent measures will be employed to protect the security and confidentiality of these data. Tracking and survey data will be securely stored in a study database. Participants will be assigned a study ID, and the analyses will be limited to the variables necessary for the completion of the proposed study, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data.

Are There Any Benefits to Me If I Choose to Take Part in This Study?
There are no direct benefits to you for taking part in this study. However, you may find satisfaction in contributing to research and you may learn new information relating to cancer education and clinical trial participation.

What Are My Alternatives If I Do Not Want To Take Part In This Study?

Your alternative is not to take part in this study. You do not have to permit use of your medical information, but if you do not give permission, you cannot take part in this research study.

How Will I Know If New Information Is Learned That May Affect Whether I Am Willing To Stay In The Study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will There Be Any Cost to Me to Take Part in This Study?
There are no costs to participating in this study.

Will I Be Paid to Take Part In This Study?
All participants will receive a $50 gift card after completing each of the two surveys as compensation for their time. Participants will receive an additional $50 gift card for completing both surveys and viewing each section of the PINPOINT educational website (About, Personalized Cancer Treatment, Clinical Trials, and Resources). If participants complete all study materials online and within 1 week of receiving them, participants will receive an additional $25 for a potential total incentive of $175.

How Will Information About Me Be Kept Private Or Confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Identifiable information will not be stored with your responses. Instead, your responses will be assigned a subject number which will be stored separately from your identifiable information so others will not know which responses are yours. These study IDs will help maintain confidentiality. A study database will be hosted at Rutgers Cancer Institute in New Brunswick, NJ on secure computing servers with secure data entry and submission for all other sites. No information that can identify you will appear in any professional presentation or publication. There may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

The research team may use or share your information collected or created for this study with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The sponsor of this research study the American Cancer Society.

What Will Happen to My Information—data, recordings and/or images—Collected For This Research After The Study Is Over?
- All information will remain confidential and de-identified and stored in password protected and encrypted databases. Your de-identified information may be shared with other investigators in future research.

What Will Happen If I Do Not Wish to Take Part In The Study Or If I Later Decide Not To Stay In The Study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to the PI, Dr. Anita Kinney (ak1617@sph.rutgers.edu):

Anita Y. Kinney, PhD, RN
Professor, Department of Epidemiology & Director, Center for Cancer Health Disparities School of Public Health,
Associate Director for Cancer Health Equity Cancer Institute of New Jersey
Rutgers University
195 Little Albany Street New
Brunswick, NJ 08903-1384

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If you have questions about your rights as a research subject, you can contact the IRB Director at: New Brunswick/Piscataway HealthSci IRB (732) 235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149 or email us at humansubjects@ored.rutgers.edu.

Please keep this consent form if you would like a copy of it for your files.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print):_____

Signature: _____ Date: _____