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

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INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  Reducing Racial Disparities in Cancer Care with PINPOINT (Promoting Informed approaches in Precision Oncology and ImmuNoTherapy)

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1.0 Research Design

1.1 Purpose/Specific Aims

This community-engaged study develops a model intervention for increasing awareness, facilitating informed and shared decision making, and improving access to clinical trials and recommended cancer treatments in traditionally underserved populations.

A. Objectives

Employ a community-engaged approach, including a Community Advisory Board and key informant interviews, to a) assess knowledge, attitudes, beliefs, and sociocultural, clinical, and system-level factors (e.g. barriers) that may explain disparities in decisions about use of precision oncology in Black cancer patients; b) Utilize this information to guide the iterative development and pilot testing of an innovative, patient-centered and culturally tailored internet-based education and decision support intervention, "Promoting Informed approaches in Precision Oncology and ImmuNoTherapy (PINPOINT)," to reduce racial disparities in access to, and use of, guideline-based therapy and potentially save lives.

B. Hypotheses / Research Question(s)

We hypothesize that by the end of this project we will have developed a culturally acceptable PINPOINT intervention. We hypothesize that 80% of the pilot testing participants will report that the intervention prototype is acceptable and usable as defined by a mean acceptability score of 4 or higher and a mean feasibility score of 4 or higher. We hypothesize that 70% of the pilot testing participants will answer at least 70% of the knowledge questions correctly. We hypothesize that 70% of pilot testing participants will report feeling empowered to talk to their physician about precision oncology treatments, clinical trials, and tumor testing. The study findings will prepare the research team to conduct a randomized controlled trial for rigorous efficacy testing.

1.2 Research Significance

Racial disparities in cancer are well established, and despite efforts to ameliorate them, Black men and women continue to have lower cancer survival rates, lower rates of accessing quality and timely care compared to Whites.[1-6] A higher proportion of Blacks are diagnosed with more advanced stages of disease compared to Whites,[1] yet even when the disease is found early, with the highest potential to be cured, delays in treatment can lead to poorer outcomes. The reasons for this unequal burden appear to be due to a complex interaction between biological, environmental, social, system-level, and political factors. Racial differences in access to innovative cancer care technologies, particularly precision oncology may further widen the disparities gap.[7-12] Many challenges unique to racial disparities in precision oncology are emerging, and important questions need to be explored in order to develop effective solutions to promoting cancer health equity.

Precision oncology uses molecular profiling to identify and target alterations in an individual's tumor for improved cancer outcomes.[13] Molecularly targeted therapies, including immunotherapy, have revolutionized cancer care. Immunotherapy identifies and disrupts ways in which tumors evade the body's natural defenses, thereby activating the immune system to attack cancer cells.[14] For example, immune checkpoint inhibitors (ICIs) have been shown to induce clinically significant and sometimes long-lasting responses in many cancers.[15-17] ICIs are drugs that block immune checkpoints. By blocking these checkpoints, ICIs allow immune cells to respond more strongly to cancer. Monoclonal antibodies, another type of immune therapy, are immune system proteins developed in the lab that are designed to bind to specific targets on cancer cells. Treatment vaccines are used to treat cancer by boosting one's immune system's response to cancer cells. Immune system modulators enhance the

body's immune response against cancer by either affecting specific parts of the immune system or affect the immune system more globally.

Immune therapy, either alone or in combination with chemotherapy, are now part of the standard care for cancers such as breast, bladder, cervical, colorectal, head and neck, liver, lung, renal cell, skin, stomach, other solid tumors and non-Hodgkin's lymphoma. Despite the potential of immunotherapy to improve outcomes, Blacks receive less guideline-based care, including immunotherapy.[2,11,12,18-20] Because each patient responds differently to precision oncology treatments, it is crucial to pinpoint which patients would respond best to each treatment and match them appropriately. Yet Blacks are less likely to receive tumor sequencing than Whites[8,9,21,22] and are therefore less likely to be matched to the optimal treatment. Furthermore, Blacks are consistently and drastically underrepresented in clinical trials, and the efficacy and toxicity of immune therapy among minority populations are not well studied.[23] For example, clinical trials of ICIs for prostate cancer either do not report the racial composition of the sample or have an extremely low proportion of African Americans, ranging from 05%, despite the high proportion of Blacks who develop prostate cancer.[24-28] With so few Blacks participating in clinical trials, subgroup analyses are impractical, and therefore immune therapy response is understudied in this population.

Closing the disparities gap will require strategies to promote awareness, shared and informed decision-making, and empowerment for Black cancer patients to discuss tumor testing, innovative treatment options, and clinical trials.

1.3 Research Design and Methods

This project encompasses the meticulous development, feedback, and pilot testing of the PINPOINT web-based intervention designed to improve preparation for decisions about precision oncology. The developmental process will begin with the collection of qualitative data through Community Advisory Board input, continue with in-depth interviews from key stakeholders to enable prototype refinement, and end with pilot testing of the intervention. The decision aid is designed to: a) improve knowledge and awareness about clinical trials and precision oncology among Black cancer patients and families; b) foster informed/shared decision-making regarding guideline-based precision therapies; and c) promote favorable attitudes about clinical trials participation in an underrepresented population to speed the translation of research findings into practice and contribute to a needed evidence base of racially diverse precision oncology trials. Once completed, this study will have developed and refined an intervention that will be prepared for rigorous efficacy testing, followed by broad dissemination to Black cancer patients and families across the country.

A. Research Procedures

Community Advisory Board

We will convene a study-specific Community Advisory Board (CAB) comprised of Black patients and advocates, some of whom have served on our Cancer Community Action Board and Precision Oncology Workgroup. We will also include Black oncology healthcare providers and administrators for their perspectives on implementation. The CAB will have 8-10 members and will meet twice per year virtually. The CAB will review an initial prototype of the intervention and provide their input on the cultural relevance, design, implementation of the PINPOINT intervention, and interpretation and dissemination of findings, as well as assist with recruitment for key informant interviews and dissemination at the completion of the project period. The CAB will also help create a key informant interview guide, which will probe issues related to: a) attitudes, beliefs, and sociocultural, clinical, provider-level and system-level factors that may explain disparities in decisions about use of immunotherapy and clinical trial enrollment in Black cancer patients and b) information needs, preferences, and strategies for addressing barriers via an effective culturally relevant intervention. The CAB will also provide guidance on study implementation, interpretation of findings,

dissemination of results, and next steps. CAB members will be offered a stipend of $250-$400 per meeting depending on their time commitment and the length of the meeting. Once feedback is collected from the CAB, we will continue forward with the study.

Key Informant Interviews

We will conduct 48 key informant interviews to refine the culturally tailored web intervention. Key informants will comprise three diverse stakeholder groups: 1) Black cancer patients; 2) relatives of Black cancer patients; and 3) providers/staff (oncologists, nurses, social workers, patient navigators and financial counselors in oncology settings) to yield a comprehensive picture of multilevel factors impacting decision-making and receipt of innovative cancer treatments. In collaboration with the CAB, we will use purposive, snowball sampling to identify and select a sample of 48 participants. These informants will be selected for their knowledge and ability to speak about their needs, preferences, experiences and the factors that impact tumor testing, guideline-based immunotherapy treatment, and clinical trials participation among Blacks from their perspectives as patients, relatives, and providers (including providers from community health sites that treat a large number of Black patients). Participants will be selected because of who they are and what they know, rather than by chance. All participants must be over 18, read and speak English fluently, be able to provide informed consent, and complete assigned study surveys and interviews. Patients must have been diagnosed with cancer or currently living with cancer (including metastatic cancer) and self-identify as Black or African American. Relatives must be the spouse, blood relative, or caregiver of a cancer patient who identifies as Black or African American. Table 1 reflects key informant eligibility criteria. We will select up to 20 participants representing each segment (patient, relative, and provider). We will work with the CAB to identify and contact potential informants through their social and professional networks. In addition, a trained staff member will conduct chart reviews of electronic medical records (EMR) at Rutgers Cancer Institute for patients who may be eligible. Additional recruitment will occur through community outreach, Rutgers listservs, and patient portals.

Table 1. Key Informant Eligibility Criteria

Patient Criteria	Relative Criteria	Provider Criteria
Age 18 and older	Age 18 and older	Age 18 and older
Self-identify as Black or African American	Spouse, blood relative, or caregiver of a cancer patient who identifies as Black or African American	Physician, nurse, social worker, patient navigator, or financial counselor
Able to read and speak English fluently	Able to read and speak English fluently	Able to read and speak English fluently
Able to provide informed consent	Able to provide informed consent	Able to provide informed consent
Able to complete 1 survey and an in-depth interview	Able to complete 1 survey and an in-depth interview	Able to complete 1 survey and an in-depth interview

Diagnosed with or currently living with cancer, including metastatic cancer		Work in oncology setting at participating clinical site

Once a list of potential participants is developed, the Program Assistant will make initial contact via email, letter, and/or telephone to invite them to participate in the study and schedule a telephone interview. Participants may also be recruited face-to-face in the clinic. Interested individuals will be further screened for eligibility by telephone. Study staff will provide, mail, or email the informed consent document to those who screen eligible and review the elements of consent in-person or by telephone, answering questions and ensuring complete comprehension. After reviewing the consent document, participants will provide their informed consent via REDCap with an electronic signature. Participants will then complete a baseline survey (online via REDCap, by phone, or on paper by mail) and staff will schedule the 1.5-hour in-depth interview. For patients, interviews will take place prior to the scheduled surgical oncology consultation. On the baseline surveys, participants will report demographic variables as well as answer questions assessing knowledge and attitudes toward tumor testing, precision oncology, immunotherapy, and clinical trials.

We anticipate that up to 20 interviews per segment will be conducted to reach thematic saturation.[29] We will conduct a first wave of up to 10 interviews per segment as initial interviews and as referral sources for a second wave of up to 10 confirming/disconfirming interviews.[30,31] A strength of this design is that the research evolves over time, maximizing the ability to identify additional key stakeholders from whom to obtain data.[32-34] Interviews will be conducted by a trained interviewer. Probes/questions will explore experiences and preferences focused on ODSF and SDM Model constructs such as: 1) beliefs and attitudes; 2) patient and family values/preferences for cancer treatment, including immunotherapy, 3) issues regarding consideration and understanding of treatment options, shared and informed decision-making, 4) how to enhance preparation for discussion about precision oncology with the oncologist (e.g., example patient video, patient questions and concerns that can be printed and/or sent to oncologist as text message or email in advance of appointment); 5) informational needs, 6) information seeking, and 7) barriers and facilitators. During the interview, participants will also view a prototype of the PINPOINT intervention, providing feedback as they explore the website and its features. The interviewer will take observational field notes regarding the participants' reactions, and usage data will be collected using an app.

Patients and relatives participating as key informants will be offered a $50 gift card incentive following completion of the interview. Institutional policies do not allow providers to receive this type of incentive payment.

Prototype Development

The intervention will be guided by best practices in health communication research and the International Decision Aid Standards Collaboration,[35] including balanced tailored information about treatment options, sufficient information to help ensure patients are knowledgeable about treatment options, and facts about treatments (e.g., mode of delivery, frequency, potential financial concerns, logistical issues, side effects, outcomes and probabilities, personal values related to options, and guidance in steps for communication and shared decision-making to match decisions with personal values). Findings obtained from CAB meetings, interviews, and surveys will be used to the inform production of a PINPOINT prototype. From the team's and others' experience (including patients), investigators determined that 8-10 minutes is the optimal dosage acceptable to patients that is needed to facilitate provider communication and informed and shared decision-making without losing engagement. Testimonials and techniques such as "drag and drop," "sliders," "hover features," and textboxes will maximize interactive opportunities and engagement. These

procedures have been effectively used to develop the research team's previous web interventions.[36-39] Programming of the intervention will be incorporated into HTML to ensure functionality on mobile devices (e.g., tablets and cell phones), browsers, and computers for maximum flexibility and to provide small segments of relevant information. Web tools will be integrated into the intervention's website. The design will be grounded in best practice health communication principles of user centered design (UCD), learner centered design (LCD), and the process of analysis, design, development, implementation, and evaluation (ADDIE).[40,41] In concert with the research team, Oxford Communications will develop and maintain the website; the group has prior experience on the team's projects.

Educational Website Pilot Testing

Following the in-depth interviews and initial modifications, we will pilot test the prototype with 33 newly diagnosed Black cancer patients. Clinical and demographic data, including contact information, cancer diagnosis, current and previous treatment, and other variables determining eligibility for immunotherapy will be abstracted from EMR by HIPAA-trained staff. See Table 2 for Pilot Testing eligibility criteria. Participants will be recruited from Rutgers Cancer Institute including RWJBH community oncology sites and CINJ, Newark, using the RWJBH Electronic Medical Record (EMR) database, EPIC. These participants will not participate in the key informant interviews, must speak and read English, and must be able to provide informed consent. Potentially eligible participants will be sent a letter inviting them to participate in the study. Research staff will contact individuals who do not opt out within two weeks, explain the study and screen for eligibility. Eligible and interested participants will complete an online informed consent via REDCap and then will be emailed a link to a pre-intervention survey that will assess demographic variables and baseline knowledge and attitudes. This survey may be completed any time between informed consent and immediately before the start of the pilot testing session.

Table 2. Pilot Testing Eligibility Criteria

Patient Criteria
Age 18 and older
Self-identify as Black or African American
Able to read and speak English fluently
Able to provide informed consent
Able to complete 2 surveys and an in-depth interview
Did not participate as a key informant
Newly diagnosed with a solid tumor cancer, (Stage I-IV)
Have not yet consulted with an oncologist regarding treatment options

For individuals who do not have internet access, study staff will offer to go to the participant's home and provide a hotspot and laptop in order to view the intervention.

Patients will complete a follow-up survey after their appointment with their treating oncologist. Patient follow-up surveys can be completed online, over the phone, or on paper by mail, depending on participant preference. These surveys will assess post-interview knowledge and attitudes toward tumor testing, precision oncology, immunotherapy, and clinical trials. Staff will call participants to confirm that their appointment was completed prior to sending the follow-up survey. On the follow-up survey, patients will be asked about their attitudes, knowledge, and interactions with their provider. A $50 gift card incentive will be offered upon completion of each survey (baseline and follow-up survey). Participants will be required to complete both surveys and view each main section of the educational website (About, Personalized Cancer Treatment, Clinical Trials, and Resources) to receive an additional $50. If participants complete all study materials online and within 1 week of receiving them, they will receive an additional $25 for a potential total incentive of $175.

B. Data Points

This is a formative research study with the goal of developing an intervention prepared for efficacy testing in a future study. We will assess the variables listed in Table 3 before and after the interviews and conversations with their oncologists for preliminary data, which will inform the future study.

Table 3. Measures

Measure	Description
CAB Engagement	Number of CAB members who participate, number and length of meetings, and the discussion during the meetings. Discussions minutes will be analyzed using qualitative coding, and key themes will be reported and incorporated into the intervention. During the last CAB meeting, members will rate the intervention and overall study based on those key themes to measure how effectively we implemented their input.
Recruitment	Reasons for non-eligibility and declining participation will be summarized; proportion of people approached and eligible for the study (target: 65%); proportion of eligible people enrolled (target: 70%).
Retention	Retention rate at follow-up and reasons for dropout will be summarized.
Feasibility	Feasibility will be determined by meeting recruitment and retention goals (proportion of people approached and eligible for the study target 65%, proportion of eligible people enrolled target 70%, completion rate target 70%).
Acceptability	4-item (AIM) measure of perceived intervention acceptability (α=0.89).[49]
Appropriateness	4-item (IAM) measure of perceived intervention appropriateness (α=0.87).[49]
Qualitative Experience	Suggestions for improvement and overall helpfulness and acceptability of PINPOINT; perceived informativeness and quality will be treated.
PINPOINT engagement	Recording website use (e.g., length of use), navigation patterns, and features used.
Content Relevance	Type of benefits experienced and aspects of the intervention most liked and disliked
Decisional Conflict	The Decisional Conflict Scale (DCS) measures 5 dimensions of decision making (feeling: uncertain, uninformed, unclear about values, unsupported; ineffective decision making)
Decision Self-Efficacy	11-item scale measuring self-confidence in one's decision-making about treatment, tumor genomic testing, and clinical trials enrollment (α=0.92).[51,52]

Decision Regret Scale	Valid and reliable 5-item self-report measure of distress or remorse following a healthcare decision (α=0.92).[53]
Decision Satisfaction Scale	6-item scale measuring self-satisfaction with health care decisions (α=0.86).[72]
Shared Decision-Making	4-item survey measuring the extent to which healthcare providers engage patients in shared decision-making (α=0.78-0.87).[54]
Empowerment	Single-item patient-reported outcome reflective of perceived empowerment as a result of intervention sequence (α=0.76).[55]
Patient Engagement	13-Item measure that assesses knowledge, skill, and confidence for participant activation (PAM) and self-management. (α=0.92)[56]
Knowledge	In consultation with content experts, we will develop and pilot a knowledge survey regarding precision oncology, immunotherapy, genomic testing to guide therapeutic decisions, and clinical trials.
Attitudes, Values, Preferences	Attitudes, preferences and intention to participate in a clinical cancer trial;[57,58] attitudes toward clinical trials, tumor sequencing; attitudes toward immunotherapy; values (e.g., risks/benefits); financial concerns;[59] cancer fatalism;[60] medical/health system distrust (α=0.77);[61] perceived racial discrimination.[62]
Tumor sequencing	Scheduled or completed tumor genomic sequencing at time of follow-up assessment.
Demographic and Clinical factors	Age, education, household income, race/ethnicity, marital status, employment and insurance, type of cancer, stage of disease, treatment, health literacy index.[63]

C. Study Duration

The study will last approximately two years. Each participant enrolled in the key informant interviews will be expected to attend a virtual interview session that lasts approximately 1.5 hours and complete written or online surveys. The total estimated duration for each participant is 2 hours. Each participant enrolled into the pilot testing will be expected to take part in a pilot testing session to view and utilize the educational website intervention, as well as complete two surveys. The total expected duration for each participant is up to 2 hours to view the educational website and complete baseline and follow up surveys.

D. Endpoints

We will conduct two rounds of key informant interviews, followed by prototype modifications after each round. We will also conduct one round of pilot testing.

1.4 Preliminary Data

Recently, we conducted a series of focus groups as part of the iCARE study: "Improving Communication About cancer Risk gEnes" (Protocol # 2019001647) to better understand their informational needs and preferences, and if and how patients with hereditary cancer mutations talk about their genetic testing results with family members in order to develop an evidence based web intervention to facilitate genetic health conversations and address the disparities gap related to cancer genetic services. While this study focused on hereditary cancer mutations and cancer risk, the identified facilitators and barriers to genetic testing and conversations about genetic health information, as well as preferences and suggestions for the online intervention, including sociocultural factors such as medical mistrust and fear, will be incorporated into our POINPOINT intervention prototype.

Fifty-three participants were enrolled, including 15 Black/African American cancer patients, 5 Hispanic/Latino cancer patients and 3 Black relatives and 6 Hispanic relatives. Participants were asked to complete pre- and post-discussion surveys and participate in a 2-hour online focus group discussion

using Microsoft Teams. Transcripts of the discussions and qualitative survey data were analyzed by two independent coders using a coding manual with a priori codes. Key themes were reported. Identified barriers included lack of relational closeness, cultural dynamics, geographic distance, young age, medical mistrust, fear of upsetting a family member, lack of genetic health information geared towards men, low digital health literacy, and barriers to accessing technology. Specifically, among Black and Hispanic or Latino focus group participants, concerns about discrimination, payment or insurance strain, and healthcare mistrust were expressed. Recommendations to combat these barriers were a family meeting with a doctor/provider, genetic test results explanation, appointment with genetic counselor, a website, books and articles, advice from family and friends or advice from doctor or provider. Some participants also expressed concerns with not being able to find cancer and genetic health information related to their specific personal and familial situations. Many participants liked the idea of creating a website to store personalized information about themselves and their families in order to make more educated decisions about genetic counseling and testing. The results of these focus groups will contribute to the prototype development.

Additional data from the Community Advisory Board (CAB) feedback will be incorporated into the study design and help shape key informant interviews, the intervention design and content as well as the usability testing process. This study-specific CAB is comprised of Black patients and advocates, some of whom have served on our Cancer Community Action Board and Precision Oncology Workgroup. We will also include Black oncology healthcare providers and administrators for their perspectives on implementation.

1.5 Sample Size Justification

Previous pilot studies with at least 10 participants have demonstrated feasibility in behavioral interventions,[64] but we will collect robust data from a variety of stakeholders.

- **Key Informant Interviews**

We will recruit 20 Black cancer patients, 15 relatives or spouses of Black cancer patients, and 13 oncology providers for the key informant interviews. We expect a total of 48 key informants to participate.

- **Pilot Test Interviews**

We will pilot test the new prototype with 33 Black cancer patients. We expect a total of 33 to participate in this part of the study.

The key informant interviews and pilot testing will stop when it is determined that data saturation has been reached. Data saturation is reached when no new information on the topic is gained.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

PINPOINT Intervention

Once developed and fully implemented, newly diagnosed Black cancer patients will be asked to access and engage with the educational website/intervention prototype before their clinic visit or in the clinic immediately before their appointment with their treating oncologist. Based upon our experience, the vast majority of patients, including low income and minority patients, are able to use their phones, computers, iPads, and similar devices for decision-making interventions. The

foundational part of the educational website is expected to take approximately 10 minutes to complete, and the website will allow patients to seek additional information tailored to their preferences and needs, which may take up to an additional 20 minutes. It will contain factual content, graphics, narration, video clips, and chatbot, and will empower patients to ask questions and voice concerns with their clinician.

We envision that the intervention be comprised of four main sections that include: 1) precision oncology; 2) clinical trials; 3) "Learn More" screens; and 4) discussion points and questions for the treating clinician. Additionally, users can interact with an optional chatbot (i.e., conversational agent). The precision oncology section will provide background information on precision oncology (including immunotherapy), who is eligible (including importance of tumor genomic testing to guide therapeutic decisions), issues to consider such as pros/cons, possible side effects/toxicities, common concerns/questions (e.g., financial burden, estimated response and survival rates), patient values/preferences, and importance of discussing these issues with the treating clinician (and strategies to foster communication). The clinical trials section will provide general clinical trial information, address common misconceptions (e.g., clinical trials are a last resort), facilitators and potential benefits, and barriers (e.g., awareness, randomization, placebo, distrust, fear, standard vs. experimental care). Although not all participants will be eligible for a clinical trial with molecularly targeted agents and/or immunotherapy, members of the CAB strongly recommended including this information as critical to alert patients to the possibility of being eligible for a trial in the future and would be useful to raise awareness and receptivity. "Learn More" screens will be optional and will allow patients to obtain more information on certain topics.

The intervention prototype will also include a search function, short videos of patient testimonials, patient-provider interaction about immunotherapy and clinical trials, as well as a list of questions/concerns that the patient could print (or save electronically) and take with them to their provider visit. An optional chatbot will be available in the corner of the screen. Users can ask the chatbot questions about any of the material on the website or request additional information. The chatbot will also be able to help patients search for molecularly targeted and immunotherapy clinical trials and offer additional resources (such as websites and online support groups).

B. Dependent Variables or Outcome Measures

The results of this study will contribute to intervention development, with efficacy testing in a future study. However, for preliminary data, we will assess the following outcome variables (described in the text and table above): feasibility, acceptability, appropriateness, usability, decisional conflict, decision self-efficacy, decision regret, shared decision-making, knowledge, empowerment, patient engagement, attitudes, and scheduled or completed tumor sequencing.

1.7 Drugs/Devices/Biologics

N/A

A. Drug/Device Accountability and Storage Methods N/A

1.8 Specimen Collection

A. Primary Specimen Collection

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Processing**: N/A
- **Storage**: N/A
- **Disposition**: N/A

B. Secondary Specimen Collection

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Processing**: N/A
- **Storage**: N/A
- **Disposition**: N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: During the COVID pandemic, staff will conduct interviews and pilot testing sessions using their work phones and laptops at home. When able, they will conduct interviews and pilot testing sessions from Rutgers Cancer Institute .

- **Process of Data Collection**: Research staff trained in HIPAA compliance, human subject research ethics, and Good Clinical Practice will collect data. Eligibility data and contact information will be extracted from the EMR at participating sites by research staff. Eligibility will also be collected/confirmed during recruitment calls made by study staff. Survey data and interview data will be collected by research staff. Participants can complete the surveys online by accessing a secured link sent through REDCap. Participants may also choose to complete surveys on the phone or by paper. Study staff will enter the data from paper or phone surveys into REDCap and ensure accuracy. Key informant interview data will be transcribed verbatim from recordings by a transcription service. Transcripts will be coded by study staff. Website usage data will be captured by an application (e.g., Apollo) and stored without identifiers.

- **Timing and Frequency**: Data collection during the key informant interviews will occur during a pre-interview survey submitted virtually through RedCap or completed over the phone with trained research staff. During the phone interview data collection will occur via recorded interaction between the key informant and research staff when viewing study materials and answering study questions. During the pilot testing segment of the study participants will submit a pre-and-post interview survey via RedCap.
- **Procedures for Audio/Visual Recording**: Consent to record participants interviews via Zoom will be included in the consent form. Recordings will be stored on a HIPAA-compliant server and only accessible by study staff. The recordings will be sent via secure email to an approved vendor for transcription.

- **Study Instruments**: Key informants and pilot testing participants will complete questionnaires to assess demographics and self-report measures. These questionnaires will be refined with input from the CAB prior to study initiation. Demographic variables will include: age, education, household income, race/ethnicity, marital status, employment and insurance, type of cancer, stage of disease, treatment, and health literacy. The Health Literacy Index consists of three 5point Likert scale items shown to be effective in detecting inadequate health literacy.[63] We will also include open-ended and Likert-scale questions to evaluate knowledge, cancer fatalism, financial concerns, health system distrust, perceived racial discrimination, perceived risks and benefits of tumor testing, as well as attitudes, preferences, and intentions regarding clinical trials, tumor testing, and immunotherapy. These measures are described below.

  For patient pilot testing participants, we will also assess the following measures on the baseline and follow-up surveys: 1) Decision conflict will be measured using the 16 item Decisional Conflict Scale which measures personal perceptions of: a) uncertainty in choosing options)

modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making; and c) effective decision making such as feeling the choice is informed, values-based, likely to be implemented and expressing satisfaction with the choice. 2) The Decision Self-Efficacy Scale consists of 11 items measuring self-confidence in one's decision-making about treatment, tumor genomic testing, and clinical trials enrollment (α=0.92).[51,52] 3) Decision regret will be assessed with a valid and reliable 5item self-report measure of distress or remorse following a healthcare decision (α=0.92).[53] 4) Participants will rate shared decision making using a 4-item instrument measuring the extent to which healthcare providers engage patients in shared decision-making (α=0.78-0.87).[54] 5) In consultation with content experts, we will develop and pilot a knowledge questionnaire regarding precision oncology, immunotherapy, tumor testing to guide therapeutic decisions, and clinical trials. 6) We will assess attitudes, preferences and intention to participate in a clinical cancer trial;[57,58] attitudes toward clinical trials, genomic testing; attitudes toward immunotherapy; values (e.g., risks/benefits); financial concerns;[59] cancer fatalism;[60] medical/health system distrust (α=0.77);[61] perceived racial discrimination.[62] 7) Empowerment will be measured using a patient reported enablement instrument (PEI, α=0.76). 8) Patient engagement will be drawn from the valid and reliable 13-item Patient Activation (PAM) measurement that assess patient knowledge, skill, and confidence for self-management (α=0.92). 9) Intervention Appropriateness (IAM) and Acceptability of Intervention (AIM) will be individually measured by 4-item instruments (α =0.89) post intervention interaction. [49] 10) Participants will also be asked to report whether they have scheduled or completed tumor genomic sequencing at time of the follow-up assessment. 11) The Satisfaction with Decision (SWD) scale consists of 7 items measuring satisfaction with one's health care decisions, (α=0.86). [72]

Ethnographic Studies, Interviews, Or Observation: Key informant interview guides will be developed in collaboration with the study CAB. Probes/questions will explore experiences and preferences focused on Ottawa Decision Support Framework (ODSF)[65] and Shared DecisionMaking Model (SDM)[66,67] constructs such as: 1) beliefs and attitudes; 2) patient and family values/preferences for cancer treatment, including immunotherapy, 3) issues regarding consideration and understanding of treatment options, shared and informed decision-making, 4) how to enhance preparation for discussion about precision oncology with the oncologist (e.g., example patient video, patient questions and concerns sent to oncologist as text message or email in advance of appointment); 5) informational needs, 6) information seeking, and 7) barriers and facilitators. During the interviews, participants will also view a prototype of the PINPOINT intervention, providing feedback as they explore the website and its features. The interviewer will take observational field notes regarding the participants' reactions, and usage data will be collected using an app.

Included in the pilot testing session, participants will be asked additional questions to assess the following: 1) Risks and benefits of tumor testing will be rated on 5-point Likert scales. 2) Knowledge questions from the surveys will be included in the pilot testing session to determine user understanding. 3) Participants will be asked to rate overall helpfulness, informativeness, and quality of the intervention. 4) Empowerment will be rated using the PEI described above.

- **Subject Identifiers**: All participants will be assigned a study ID. Only the recruitment tracking database will link the ID with the participants' identifying information, and access to the database will be restricted to only those study staff who are responsible for contacting participants. Identifying information, including name, address, and contact information (phone numbers and email addresses), will be extracted from EMR and/or will be obtained during recruitment calls by study staff and entered directly into the recruitment tracking database.

B. Secondary Data Collection

- **Type of Records**: N/A
- **Location**: N/A
- **Inclusion/Exclusion**: N/A
- **Data Abstraction Form(s)**: N/A

1.10 Timetable/Schedule of Events

Table 2. Study Timeline

	Year 1												Year 2											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Prepare initial study materials	■	■	■	■																				
Develop PINPOINT prototype	■	■	■	■	■	■																		
CAB meetings			■						■							■							■	
Develop interview guide			■	■																				
IRB approval					■																			
Recruit key informants					■	■	■	■	■	■	■	■	■	■	■	■	■							
Interviews and surveys						■	■	■	■	■	■	■	■	■	■	■	■	■						
Analyze interview data							■	■	■	■	■	■	■	■	■	■	■	■	■					
Modify prototype												■	■	■	■	■	■	■	■	■	■	■		
Recruit for pilot testing																		■	■					
Pilot testing																				■	■			
Analyze pilot data																					■	■		
Finalize intervention																					■	■	■	
Disseminate findings																					■	■	■	■

2.0 Project Management

2.1 Research Staff and Qualifications

Anita Y. Kinney, PhD, RN, FAAN, FABMR (Principal Investigator) is a Professor in the Department of Biostatistics and Epidemiology in the School of Public Health and Director, Center for Cancer Health Equity, Rutgers University, and Associate Director for Population Sciences and Community Outreach, Rutgers Cancer Institute . Much of her work focuses on addressing disparities and promoting health equity in clinical genetics, public health genomics and genetic risk communication in cancer patients and their families, and cancer care delivery. She has extensive experience with community engagement, leading multi-site randomized controlled trials of behavioral and informed decision-making interventions in diverse populations, settings and contexts and mixed-methods projects. She also has considerable clinical experience as a nurse/nurse practitioner in medical oncology settings at other cancer centers. Dr. Kinney will be responsible for overall scientific administration of the project and community engagement strategies, oversight of data collection including in-depth interviews, pilot testing, and the Community Advisory Board (CAB).

Shawna Hudson, PhD is Professor and Research Division Chief for the Department of Family Medicine and Community Health at the Rutgers Robert Wood Johnson Medical School (RWJMS). She is also a Professor in the Department of Health Education & Behavioral Science at the Rutgers School of Public Health (SPH) as well as an active and full research member of the Cancer Prevention & Control Program at Rutgers Cancer Institute . Dr. Hudson, a health services researcher trained in medical sociology and mixed methods research, specializes in primary care research. She has cultivated strong content expertise in cancer survivorship, working with vulnerable populations and the intersections of community health, primary care and specialty care. Dr. Hudson co-leads the Community Engagement Core of the *New Jersey Alliance for Clinical and Translational Science*, lending her expertise in minority patient recruitment, community outreach, mixed-methods research, and patient study cohort development. In the proposed study, Dr. Hudson will be a co-investigator and contribute to qualitative data collection and analysis. She will actively contribute to interpreting data and reporting findings at conferences and in peer-reviewed publications.

Shridar Ganesan, MD, PhD is a Professor of Medicine, Associate Director for Translational Science, Director of Comprehensive Genomics Shared Resource, Co-Leader of Clinical Investigations and Precision Therapeutics Program, and Section Chief, Cancer Biology at the Rutgers Cancer Institute . Dr. Ganesan has extensive experience in clinical analysis of patient data in precision medicine settings as well as translational study of solid tumors. He is a board-certified medical oncologist and has considerable experience in the cancer care delivery, genomic sequencing, and precision medicine. As co-investigator, Dr. Ganesan will provide clinical expertise and contribute to website content development and refinements, interpreting data, and reporting findings at conferences and in peer-reviewed publications.

Coral Omene, MD, PhD is a board-certified medical oncologist specializing in breast cancer treatment and research, with a focus on cancer health equity. She has expertise in precision oncology research for breast cancer, particularly the triple negative subtype which disproportionately afflicts African American women. Dr. Omene is also an advocate for clinical trials participation in diverse populations. As co-investigator, Dr. Omene will provide clinical expertise, contribute to website content development, engage with the CAB, and assist with data interpretation and dissemination of results at conferences and peer-reviewed publications.

Additional research support will be fully trained on all study procedures, and possess necessary experience required to perform their tasks.

2.2 Research Staff Training

All staff will be properly trained with CITI, EPIC and receive full protocol training.

2.3 Resources Available

Drs. Kinney, Hudson, Ganesan, and Omene have their own offices at RBHS Campus in New Brunswick. This space includes adjoining administrative and research staff space. All project staff have their own desk and file storage space. If necessary, for public health and safety, investigators and staff may work remotely from home using Rutgers-issued laptops. The team has email and internet access, shared file storage space, and geographically distributed printing. Study-related data will be stored on a HIPAA-compliant server.

2.4 Research Sites

Recruitment will take place at The Rutgers Cancer Institute Both key informant interviews and usability testing will be held online and hosted by study staff using HIPAA-compliant Zoom. Participants may also call into the sessions using a telephone.

3.0 Multi-Center Research

N/A

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

In collaboration with the CAB, we will use purposive, snowball sampling to identify and select a sample of 48 participants for the key informant interviews.[32] These informants will be selected for their knowledge and ability to speak about their needs, preferences, experiences and the factors that impact tumor impact tumor testing, guideline-based immunotherapy treatment, and clinical trials participation among Blacks from their perspectives as patients, relatives, and providers (including providers from community health sites that treat a large number of Black patients). We will select up to 20 participants representing each segment (patient, relative, provider). We will work with the CAB to identify and contact potential informants through their social and professional networks. In addition, a trained staff member will conduct chart reviews of electronic medical records (EMR) at The Rutgers Cancer Institute , University Hospital, Newark and RWJBH for patients who may be eligible. Additional recruitment will occur through community outreach, Rutgers listservs, RWJBH, UH, and patient portals.

Following key informant interviews 33 newly diagnosed Black cancer patients will be recruited from Rutgers Cancer Institute , University Hospital, Newark and RWJBH as participants in a pilot study.

B. Recruitment Details

Once a list of potential key informants is developed, the Program Assistant will make initial contact via email, letter, and/or telephone to invite them to participate in the study and schedule a telephone screening call. For patients that are identified from the medical record system, research staff will send a recruitment letter to their preferred mailing address and wait one week for opt out return letter. If research staff does not hear back from patient through mail, research staff will begin to attempt making contact via phone. Participants may also be recruited face-to-face in the clinic. Flyers and brochures will be used for community outreach efforts and word of mouth.

For pilot testers, potential participants will also be recruited from RWJBH and UH via clinician referral. Research staff will provide study flyers for clinicians to inform potentially eligible participants about this study. Once providers receive participants' permission to be contacted by study staff, providers will notify our research team. Staff will either call patients or send out a letter inviting them to participate in the study. Research staff will also identify potentially eligible participants and ask for permission from the provider to approach participants. Research staff will contact individuals who do not opt out within one week, explain the study, and recruit those who are interested in participating.

C. Subject Screening

Interested individuals will be further screened for eligibility via telephone by study staff using a recruitment script, developed in collaboration with the CAB.

- **Inclusion Criteria**

  Patient key informants must be age 18 or older, self-identify as Black/African American, diagnosed with cancer or currently living with cancer, able to read and speak English fluently, able to provide informed consent, and able to complete surveys and an in-depth interview.

  Relative key informants must be a spouse, blood relative, or caregiver of a cancer patient who identifies as Black/African American. They must be age 18 or older, able to read and speak English fluently, able to provide informed consent, and able to complete surveys and an in-depth interview.

Provider key informants must be either a physician, nurse, social worker, patient navigator, or financial counselor. They must work in an oncology setting at a participating clinical site, be able to read and speak English fluently, able to provide electronic informed consent, and able to complete surveys and an in-depth interview.

Patient pilot testers must be age 18 or older, self-identify as Black/African American, newly diagnosed with a solid tumor (Stage I-IV) have not yet consulted with their oncologist regarding treatment options, life expectancy of at least six months, able to read and speak English fluently, able to provide informed consent, and able to complete two surveys.

- **Exclusion Criteria**

  Key informants and pilot testers will be excluded from the study if they do not meet the inclusion criteria. Pilot testers will be excluded from the study if they previously participated as a key informant and also do not meet inclusion criteria.

4.2 Secondary Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

The total number of key informants will be 48. The total number of pilot testing participants will be 33.

B. Total Number of Subjects If Multicenter Study: N/A

C. Feasibility

Participants will be recruited using a variety of methods, including snowball sampling, community recruitment, social media and patient portal recruitment, and reviews of EMR data. We anticipate no problems reaching our target accrual goals.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**

  Informed consent will be obtained prior to key informant interviews and usability testing via REDCap with an electronic signature from eligible participants after study staff has ensured complete comprehension of the informed consent document during a scheduled call between the study staff and participant. If the participant does not have access to the internet, study staff can mail the consent form to their preferred mailing address and go over the consent over the phone at a scheduled time to ensure competency. Participants will also complete a paper or electronic HIPAA authorization for study staff to abstract data from the EMR. Individuals will not be eligible to participate in the study without completing both the informed consent and HIPAA authorization.

- **Ongoing Consent**

  N/A

- **Individual Roles for Researchers Involved in Consent**
  Trained study staff will provide the electronic consent form and verbally review the consent form with each participant prior to the interview/pilot testing session. If the participant does not have access to the internet, study staff can mail the consent form to their preferred mailing address and go over the consent over the phone at a scheduled time to ensure competency. Study staff will then save and document all electronic informed consent documents from REDCap prior to distributing or emailing baseline surveys.

- **Consent Discussion Duration**
  The informed consent discussion is expected to take approximately 5 minutes.

- **Coercion or Undue Influence**
  We will inform participants that they are not required to take place in the key informant interviews or usability testing and that they are free to leave at any time. Participants will be informed that they have the choice to either dial-in using a phone, video call in or only audio call in via Zoom meeting and must have access to a computer. We will also remind participants that they do not need to share or discuss anything that makes them feel uncomfortable.

- **Subject Understanding**
  After reviewing each section of the consent form, study staff will pause and ask for questions and ensure subject understanding of the entire consent form.

B. Waiver or Alteration of Consent Process ▪ **Waiver or Alteration Details** N/A
▪ **Destruction of Identifiers** N/A ▪ **Use of Deception/Concealment**
N/A

a. **Minimal Risk Justification**
   N/A
b. **Alternatives**
   N/A
c. **Subject Debriefing** N/A

C. Documentation of Consent ▪ **Documenting Consent**
Trained research staff members will perform full informed consent about the procedures of the study for all potential participants. Study staff will provide or mail or email the informed consent document to those who screen eligible and review the elements of consent in-person or by telephone, answering questions and ensuring complete comprehension. Participants will be instructed that they may decline to participate or withdraw from the study at any time. They will be assured that their decision to give, withhold, or retract consent will not in any way influence their present or future medical care. The person obtaining consent will answer any questions that potential participants have. If, at a later time, they have any questions, they will be told that they can contact the principal investigators and will be given their telephone numbers. Participants will also be informed that if they have any questions regarding their rights as research participants, they may contact the Office of Research at Rutgers University; the telephone numbers will also be listed on the informed consent form. Participants will also complete a paper or electronic HIPAA authorization for study staff to abstract data from the EMR.

- **Waiver of Documentation of Consent –** Consent will be taken over the telephone by Rutgers Cancer Institute study staff if patients opt to consent verbally.

4.5 Special Consent/Populations

- **Minors-Subjects Who Are Not Yet Adults** ▪ **Parental Permission** N/A ▪ **Non-Parental Permission** N/A ▪ **Assent Process** N/A ▪ **Documentation of Assent** N/A
  - **Reaching Age of Majority During Study** N/A **B. Wards of the State**

  N/A
- **Research Outside of NJ Involving Minors**

  N/A

C. Non-English-Speaking Subjects▪ **Process for Non-English-Speaking Subjects** N/A
- **Short Form Consent for Non-English Speakers** N/A

D. Adults Unable to Consent / Decisionally Impaired Adults

N/A
- **NJ Law-Assessment of Regaining the Capacity to Consent** N/A
  - **Capacity to Consent a. NJ Law-Selecting A Witness**

    N/A

    b. Removing a Subject

    N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

The only expense that participants are expected to incur is for parking at Rutgers Cancer Institute if needed for in-person interviews, but we will validate the parking for participants who use the valet service so that they will not have to pay for valet parking.

B. Compensation/Incentives

Participants will receive a $50 gift card after their key informant interview session for their time. Participants identified as providers will be excluded from receiving the gift card incentive due to institutional policies prohibiting acceptance of this kind of incentive.

Participants taking part in the pilot testing will receive a $50 gift card after completing each survey. If participants complete both surveys and view all the main sections of the PINPOINT educational website (About, Personalized Cancer Treatment, Clinical Trials, and Resources), they will receive an additional $50 gift card. If the study participants complete all study materials online and within 1 week of receiving them, participants will receive an additional $25 for a potential of $175. The gift cards will be distributed to each participant after he/she has completed the baseline and follow-up survey. Participants may mail their surveys back to the Cancer Health Equity Office. Participants will be provided with free valet parking for in-person pilot testing if need be.

C. Compensation Documentation

Participants are provided compensation at the end of the key informant interview and for the pilot testing session. Gift cards will be mailed following the completion of the baseline and follow-up surveys for the pilot test participants. Project staff will maintain a checklist of activities required for each participant. Among the items on the checklist is one to ensure that they received their compensation. This information is also input by project staff into a participant tracking database. Participants will also sign a receipt form to acknowledge receipt of the gift card and give or mail it to the study staff (using a prepaid envelope).

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects ▪ Reasonably Foreseeable Risks of Harm

The potential risks are judged to be minor, as they are similar in many ways to risks experienced by those who participate in shared decision making with their providers, online education and information-seeking about health topics, and tumor sequencing 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 potentially could cause some discomfort or embarrassment in answering these types of questions.
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.

Privacy and loss of confidentiality. All efforts will be taken to maintain privacy and confidentiality as described below. Nevertheless, there is still the potential for unintentional breach of confidentiality for participants.

Methods of protecting against these risks are outlined below.

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  This minimal risk study is not expected to have any additional risk of harm for individuals with existing conditions.

- **Other Foreseeable Risks of Harm**
  N/A

- **Observation and Sensitive Information**
  The presence of a researcher is necessary for the interviews and is not expected to negatively impact the interview dynamic.

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects: N/A

C. Risks of Harm to Non-Subjects: N/A

D. Assessment of Social Behavior Considerations

In the unlikely event that during participation in the study, a participant indicates that he or she may be in imminent danger to themselves or others, the patient's physician will be contacted by the research team immediately after the interview. The physician or their designee will follow up with the participant on the same day, and if necessary, arrange for treatment.

E. Minimizing Risks of Harm

All participants will provide informed consent before the start of the interviews/pilot testing. The autonomy of participants will be protected by informing all participants of the purpose of the study and allowing them to opt out of participation without repercussion. Participants will also be able to refuse any question they do not want to answer and withdraw from the study at any time.

Initial discomfort/embarrassment. Participants will be asked questions of a sensitive or personal nature (e.g., medical history, psychological functioning), which potentially could cause some discomfort or embarrassment in answering these types of questions. All study staff will be trained

to deal with these situations, and every effort will be made to address each participant's concerns or problems in the most supportive and empathic manner. Surveys will be facilitated by staff trained to be both sensitive and responsive. Confidentiality will be maintained at all times.

Concerns about tele-video sessions with website tracking and screensharing capability. Key informant interviews will be conducted and recorded using HIPAA compliant Zoom. Participants 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.

Privacy and loss of confidentiality. 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, as described below. 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. The only identifiable information that will be linked to the study ID on the surveys is the participant's preferred mailing address. The purpose of confirming their preferred mailing address is to send the incentive for participation. This identifiable data will be stored in a password protected and encrypted data base that only study personnel have access to. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data.

- **Certificate of Confidentiality**
  N/A

- **Provisions to Protect the Privacy Interests of Subjects**
  All participant demographic, clinical, interview, intervention usage, and patient-reported data will be stored in the Rutgers Cancer Institute database. These data will be maintained on a secure computing infrastructure behind the institutional firewall certified to store protected health information. We will take consistent measures to protect the confidentiality of these data. The only identifiable information that will be linked to the study ID on the surveys is the participant's preferred mailing address. The purpose of confirming their preferred mailing address is to send the incentive for participation. This identifiable data will be stored in a password protected and encrypted data base that only study personnel have access to. All investigators and project staff will be required to complete the online human subjects and good clinical practice training, which is mandated by the Institutional Review Board (IRB). Study IDs will be assigned for individuals who participate to help maintain confidentiality. All identifying data will be stored in secured and password protected files separate from all other research information, which will be identified by study identification number alone. The study database will be restricted to only those individuals who are authorized to work on the study and have appropriate protection of human subjects' certification. Individual user accounts with passwords will be used to log and restrict access to the database. Specific privilege assignments within the database will also be employed to limit the types of functions that authorized users can perform to those functions that are appropriate for their role in the study. Access to individually identifiable private information about participants will be limited to the Principal Investigators and those co-investigators or study team members involved in duties related to direct patient contact (e.g., research staff performing recruitment or interviews). Other co-investigators or study team members not involved directly in recruitment activities (e.g., statistician, data analyst) will not have access to identifiable participant or patient information. The use of network firewall technologies should prevent data security problems

that include unauthorized internal access to data, external access to data, and malicious intent to destroy data and systems. Controlled user access will ensure that only appropriate and authorized personnel are able to view, access, and modify study data. All modifications to data will document user access and data associated with the modification, as well as values prior to modification.

F. Potential Benefits to Subjects

There are no guarantees that participants will benefit from taking part in this study, but people often find satisfaction in contributing to research. In addition, participants may benefit from engaging with the PINPOINT prototype, which is designed to a) improve knowledge and awareness about clinical trials and precision oncology among Black cancer patients and families; b) foster informed/shared decision-making regarding guideline-based precision therapies; and c) increase favorable attitudes about clinical trials participation in an underrepresented population to speed the translation of research findings into practice and contribute to a needed evidence base of racially diverse precision oncology trials.

The benefits of this study include significant potential for public health impact. This study will contribute to the development of an online intervention, which may increase representations of Black cancer patients in clinical trials, improve scientific understanding of how diverse populations respond to innovative cancer treatments, improve diffusion of innovative cancer treatments in underserved communities, reduce mistrust and improve communication and shared decision-making between Black cancer patients and their providers, and improve cancer health equity.

We are balancing the risk of potential discomfort and the low risk of loss of privacy against developing a tool to reduce cancer health disparities. We believe the benefits to research subjects and others outweigh the minor risks of participation.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

We will work with the CAB to identify and contact potential informants through their social and professional networks. In addition, a HIPAA-trained staff member will conduct chart reviews of electronic medical records (EMR) at Rutgers Cancer Institute , University Hospital, Newark and RWJBH for patients who may be eligible. Additional recruitment will occur through community outreach, Rutgers listservs, RWJBH, UH, and patient portals.

Once a list of potential participants is developed, study staff will make initial contact via email, letter, and/or telephone to invite them to participate in the study and schedule a telephone interview. Participants may also be recruited face-to-face in the clinic. Interested individuals will be further screened for eligibility by telephone.

Tracking, survey, and interview data will be securely stored in a study database. 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.

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

N/A

A. Special Populations

N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

Digital recordings of key informant interviews will be transcribed verbatim and transcripts and qualitative data from surveys and field notes will be managed using qualitative data analysis software. Independent coding of data will be conducted by at least two team members with discrepancies reviewed at team meetings and resolved through consensus.[68] Investigators will compare and contrast interviews within and across stakeholder groups as part of an iterative cycling process of reading, summarizing, and re-reading the data using the five phases of qualitative interpretive analysis described by Miller and Crabtree:[32] 1) The describing phase will begin with an immersion-crystallization analysis approach in which data are initially read to identify overarching, organizational themes.[69] 2) Themes are used to create a "codebook" that is used to tag and sort data.[43] Coded text is sorted and summarized using an editing style to create an organizing scheme for interpretative analysis. 3) The connecting phase makes sense of the data at a new level. Themes and patterns are captured in 5-10 page "analytical narratives" of each stakeholder group. 4) The corroborating/legitimating phase seeks additional data to confirm or refute insights from initial analyses using multiple data sources and investigators to review interpretations to control bias. 5) The representing the account phase, shares and refines final findings with target audiences and our advisory committees in the form of summaries and visual presentations. This five-step process results in interpretive summaries of stakeholder perspectives, particularly with respect to the core features that enhance knowledge and awareness about precision oncology and clinical trials, preparation for discussion about precision therapies with the oncologist, and informed and shared decision-making. To validate the accuracy of the findings, the investigators will employ mixed method research best practices,[30,70,71] including member checking, assessing reliability with two coders and triangulation, and presentation of negative or discrepant data to the CAB to ensure interpretations are minimally impacted by bias.

Frequencies and means will be calculated and reported for demographic variables (age, education, household income, race/ethnicity, marital status, employment and insurance, type of cancer, stage of disease, and treatment). Health literacy will be scored, and the mean will be reported. Open-ended survey items will be coded and analyzed using the qualitative analysis methods described above. Mean ratings of overall helpfulness, perceived informativeness, and quality of the intervention will be measured using a 5point Likert scale, with a mean value of 4 representative of positive results.

We hypothesize that use of PINPOINT prototype will yield increased knowledge and more positive attitudes/intentions regarding clinical trials, tumor sequencing, and immunotherapy (at follow-up). Using t-tests, we will examine change in these variables. We also predict that participants will report low levels of decisional conflict based off a 16 item 5 response categories Decisional Conflict Scale (DCS) and decision regret measured by taking the mean of the 5 items and converting them to a score ranging from 0-100 by subtracting by 1 and multiplying by 25, with higher numbers indicating greater regret.[53] Additionally, we predict high levels of shared decision-making following engagement with the intervention. Shared decision making will be a 4-item measurement. [54] Each response is scored as either a 0 (a little, not at all, No) or 1 (yes, a lot, or some). The total points are summed and result in a score of 0-4 with higher scores indicating more shared decision-making. We also predict that PINPOINT will yield increased levels in perceived

benefits of tumor testing. Participants will rate on 5-point Likert scales the perceived benefits and perceived risks of tumor testing. T-tests will be conducted to assess change in perceived benefits. Because this is a small pilot test, we will not conduct significance testing but analyze the data for patterns and appreciable differences. These data will inform a larger randomized control trial that will test efficacy of the intervention. We will also calculate the number of participants who scheduled or competed tumor genomic sequencing at the time of follow-up.

Participants will be asked to complete a baseline and follow-up survey to assess demographics, knowledge, preferences, beliefs, and attitudes, as described above. These data will provide preliminary evidence regarding feasibility, acceptability, and preliminary efficacy of the intervention.

6.2 Data Security

We will take several precautions to avoid any breach of confidentiality. We will use identification numbers instead of names of participants on all study forms and in any study database. The numbers and names will be linked to a master list that will be accessible only to the research team. The master list will be kept in a locked file cabinet and in a computerized tracking system that will be password protected behind the Rutgers CINJ firewall. All study records and forms will be stored in locked file cabinets and password protected files on secure servers. Recordings from the CAB meeting and key informant interviews will be stored securely with access limited to research team members.

6.3 Data and Safety Monitoring

N/A

6.4 Reporting Results

A. Individual Subjects' Results

After concluding this study as well as the future efficacy study, and after developing manuscripts for publication, we will disseminate the results of our work to participants, and their families. All data will be reported in aggregate and no individual identifying information will be disclosed.

B. Aggregate Results N/A

C. Professional Reporting

Results will be published in scientific journals and presented at conferences. No identifying information will be shown in any of these presentations, abstracts, or manuscripts.

D. Clinical Trials Registration, Results Reporting and Consent Posting

The current study will not require clinical trials registration, results reporting, and consent posting. The future clinical trial will follow all federal regulations as necessary.

6.5 Secondary Use of the Data

The data, without identifiers, will be used for a future large-scale, randomized control trial that will test the efficacy of the refined intervention prototype. This is stated in the informed consent document.
Participants will be asked at the completion of their surveys whether or not they would like to be contacted for future research by the research study team. The surveys and survey data are stored in a password protected and encrypted data base. Participants will be told that they have the option to decline future participation in research studies or be open to being contacted again by only the research team.

7.0 Research Repositories – Specimens and/or Data

Data entry and storage systems and procedures are in place at Rutgers Cancer Institute. With IRB approval, all participant demographic, clinical and patient-reported data will be stored in the Rutgers Cancer Institute study database. These data will be maintained on a secure computing infrastructure behind the institutional firewall certified to store protected health information. We will take consistent measures to protect the

confidentiality of these data. All investigators and project staff will be required to complete the online human subjects and good clinical practice training, which is mandated by the Institutional Review Board (IRB). Study IDs will be assigned for individuals who participate to help maintain confidentiality. All identifying data will be stored in secured and password protected files separate from all other research information, which will be identified by study identification number alone. 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. The REDCap study database, into which information about participant contact and data from all surveys will be entered, will be restricted to only those individuals who are authorized to work on the study and have appropriate protection of human subjects' certification. Individual user accounts with passwords will be used to log and restrict access to the database. Specific privilege assignments within the database will also be employed to limit the types of functions that authorized users can perform to those functions that are appropriate for their role in the study. Access to individually identifiable private information about participants will be limited to the Principal Investigators and those co-investigators or study team members involved in duties related to direct patient contact (e.g., genetic counselors and research staff performing telephone interviews for participants who do not respond to mailed surveys). Other coinvestigators or study team members not involved directly in recruitment activities (e.g., statistician, data analyst) will not have access to identifiable participant or patient information. The use of network firewall technologies should prevent data security problems that include unauthorized internal access to data, external access to data, and malicious intent to destroy data and systems. Controlled user access will ensure that only appropriate and authorized personnel are able to view, access, and modify study data. All modifications to data will document user access and data associated with the modification, as well as values prior to modification. The informed consent document will outline the plan to utilize the de-identified data in a future research study testing the efficacy of the developed intervention.

8.0 Approvals/Authorizations

A Letter of Cooperation from Oxford Communications is attached. This letter outlines the scope of work for the development of the PINPOINT web-based tool and its maintenance.

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