

Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)

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CONTACT INFORMATION		
	For patient enrollments:	
	<p>Please refer to the patient enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN) which can be accessed at https://www.ctsu.org/OPEN_SYSTEM/ or https://OPEN.ctsu.org.</p> <p>Contact the CTSU Help Desk with any OPEN-related questions at ctsucontact@westat.com.</p>	
<p>The most current version of the study protocol and all supporting documents must be downloaded from the protocol-specific Web page of the CTSU Member Web site located at https://www.ctsu.org. Access to the CTSU members' website is managed through the Cancer Therapy and Evaluation Program - Identity and Access Management (CTEP-IAM) registration system and requires user log on with CTEP-IAM username and password. Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU RSS.</p>		
<p>For non-clinical questions (i.e. unrelated to patient eligibility, treatment, or clinical data submission) contact the CTSU Help Desk by phone or e-mail: CTSU General Information Line – 1-888-823-5923, or ctsucontact@westat.com. All calls and correspondence will be triaged to the appropriate CTSU representative.</p> <p>For detailed information on the regulatory and monitoring procedures for CTSU sites please review the CTSU Regulatory and Monitoring Procedures policy located on the CTSU members' website https://www.ctsu.org > education and resources tab > CTSU Operations Information >CTSU Regulatory and Monitoring Policy</p>		
<p>The CTSU Website is located at https://www.ctsu.org.</p>		

To submit site registration documents:	For patient enrollments:	Submit study data
<p>CTSU Regulatory Office 1818 Market Street, Suite 1100 Philadelphia, PA 19103 Phone – 1-866-651-CTSU Fax – 215-569-0206 Email: CTSUREgulatory@ctsu.coccg.org (for submitting regulatory documents only)</p>	<p>Please refer to the patient enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN) which can be accessed at https://www.ctsu.org/OPEN_SYSTEM/ or https://OPEN.ctsu.org.</p> <p>Contact the CTSU Help Desk with any OPEN-related questions at ctsucontact@westat.com.</p>	<p>Do not submit study data or forms to CTSU Data Operations. Do not copy the CTSU on data submissions.</p>

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I. Background

a. Introduction

Despite a plethora of literature documenting barriers to clinical trial accrual, there are a scant number of well-designed studies testing interventions to overcome these barriers and a limited number of evidence-based strategies in the literature¹. The rate of adult clinical trial participation remains stagnant at 3-5%² and this rate is even lower for minority and underserved populations. Over the past 5 years, 14% of cancer control and prevention trials supported by the legacy NCI Community Clinical Oncology Program (CCOP) and Minority Based Community Clinical Oncology Program (MB-CCOP) closed due to poor accrual and furthermore, 40% did not meet accrual goals (unpublished data). In addition to low accrual, there is a lack of understanding of the patient population screened for clinical trials who do not enroll; and for those that do enroll, demographic data collected on trials sponsored by the National Cancer Institute (NCI) is limited to age, gender, race, ethnicity and method of payment/insurance status. It is well known that racial/ethnic minorities experience a larger cancer burden compared to that of Caucasians and are more likely to present at a later stage of cancer with a less favorable treatment outcome³. Correlation of expanded patient demographics and clinical information to include socioeconomic status (SES) and method of diagnoses is one way to enhance our ability to evaluate potential differences in outcomes in clinical trials and factors influencing participation in clinical trials among minority and underserved populations. Inclusion of minority and underserved populations in cancer clinical trials not only is a mechanism to enhance our understanding of these disparities but also provides access to state-of-the-art care.

The profile of patients accrued to NCI-sponsored clinical trials lacks both racial/ethnic and socioeconomic diversity. Accrued patients tend to be insured, highly educated and of higher socioeconomic means⁴. Ten years after Sateren's report⁴, our understanding of the influences social determinants have on clinical trials enrollment remains poor due to the lack of accurate data regarding patients screened for and enrolled onto NCI clinical trials. The NCI Community Oncology Research Program (NCORP), a network of diverse community oncology practices, provides an opportunity to collect this important but missing clinical trials screening and expanded demographics in order to better understand the complex and multifactorial influences affecting clinical trial participation. Also missing from the existing data is the context of care, within the communities themselves where most cancer and at risk of cancer patients receive care which is the focus of NCORP. NCORP's clinical trials portfolio includes cancer control, prevention, screening, symptom science, and cancer care delivery research. Investigators also enroll patients into NCI-treatment trials.

A clinical trial screening tool protocol has been developed to facilitate the formulation of research questions; particularly those evaluating factors related to populations that are underrepresented in clinical trials, and address cancer care disparities. This protocol is designed to allow the collection, storage and abstraction of clinical and demographic data obtained during the screening process, using the Oncology Patient Enrollment Network (OPEN), the same informatics system used by investigators participating in NCI-sponsored trials. The protocol is not a scientific study; rather, a method to implement the screening tool and allow the collection and analyses of expanded data with informed consent. The tool, based on a screening log successfully used within the NCI Community Cancer Centers Program (NCCCP)⁵, has been streamlined and integrated into the sites' workflow by using OPEN. The following sections describe additional background information detailing the three, targeted areas of the tool: clinical trial accrual, enhanced demographic and clinical data collection, and method of diagnosis.

b. Clinical Trial Accrual

The complexity of low clinical trial participation is reflected in its persistence over time and across many types of trials. In order to increase participation, knowledge of trial- specific and site-specific barriers is useful to

develop tailored strategies versus attempting to develop generic strategies for global barriers that may not be relevant. Participants in the 2010 NCI ASCO Clinical Trial Symposium generally agreed that different strategies must be tailored to the trial and consideration should be given to the trial type, their research questions and their study design¹. A better understanding of trial- specific and site-specific barriers to enrollment might shed light on other important factors influencing enrollment such as the type of cancer care organization (e.g. health systems, safety net hospitals versus office practices) and/or insurance status of the patient at the time of diagnosis.

Trial availability is an important factor to take into account when considering accrual rates. There has been an intentional shift from phase III to phase II treatment trials in the NCI Clinical Trials Network (NCTN), specifically NCI's Precision Medicine Initiative trials. Trial complexity has increased along with more selective eligibility due to the increased use of targeted therapies. Similar to the treatment environment, NCORP's symptom science has shifted its focus from trials based on empirical evidence to a focus on gaining a better understanding of the biologic mechanisms of symptoms, toxicities and populations at risk for certain symptoms. Hence, there is an increase in the collection of biospecimens and correlative studies embedded in symptom trials. It is critical to understand how these paradigm shifts will affect all populations screened for clinical trials.

Lastly, comorbidities are a common barrier to clinical trial enrollment among minority populations⁶. However, the obesity epidemic poses extraordinary challenges to enrollment in the presence of stringent trial eligibility. In a study conducted by Campbell et al⁷ at a historically black medical institution, 17.1% of African American patients screened for a clinical trial were deemed ineligible due to comorbidities. According to Campbell, to address this barrier it is critical to consider these comorbidities in the exclusion/inclusion criteria and the design of clinical trials. However, we must first collect co-morbidity data in a uniform manner for patients screened for NCI trials. Campbell also cites the importance of capturing the treatment that patients with comorbidities receive off protocol and the outcome. Though this is beyond the scope of this project, collection of such data may be considered in the future to inform how patients with certain comorbidities may be enrolled on a clinical trial with close monitoring and management.

c. Enhanced Demographic and Clinical Data Collection

Cancer health disparities persist and pose an increasing challenge given the changing demographics within the United States, the shifting therapeutic approach to cancer care and the current health care environment. The size of the foreign-born population has increased over the last three decades, from 14.1 million in 1980 to 40.0 million in 2010⁸. In addition to the growing Hispanic population, there has been an increase in Asian and Pacific Islanders (Chinese, Filipinos) and African immigrants who have settled in nontraditional immigrant states such as Minnesota and the Dakotas^{9,10}. A shift in cancer treatment from empirical to molecular/genomic-based therapy has occurred and the impact this may have on timely access to state of the art care is unknown for minority and underserved populations. The frequency of genetic markers by race, SES or gender is unknown and it would be helpful to know who is most likely to benefit from genomic-based therapies¹¹. Lastly, the cost of cancer care continues to rise while patient access to care is changing with the advent of affordable care organizations and hospital owned private practices. Socioeconomic status, gender and race/ethnicity are predictors of health services utilization and health outcomes, including cancer. Though often considered separately, Williams and colleagues argue that considering these social factors jointly can provide a greater understanding of how they impact health care access, utilization, quality and outcomes¹¹.

Over the past four years, The Division of Cancer Prevention has led several collaborative efforts to address cancer health disparities and identify priority research areas relevant to clinical trials. Key issues raised during these meetings included the need to collect more detailed demographic and clinical data to address health care

disparities and improve the care of patients while treated on a clinical trial. Additional topics included management of comorbidities and enhancing collaborations among NCORP Research Base Groups.

d. Method of Diagnosis

Advances in molecular technology are increasing our understanding of differences in invasive and pre-malignancies that are indolent versus aggressive histologies. Currently, information about methods of diagnosis is not collected. The collection of the method of diagnosis is a priority research goal within NCORP and is especially important in the science and implementation of cancer prevention and screening trials. These data will help to determine the molecular characterization of the cancer diagnosis, identify those cancers that are more likely to transform into malignant tumors, develop interventions, and develop better approaches in risk/benefit stratification for patients. The Division of Cancer Prevention is a leader in the evolving research areas of overdiagnosis to which method of diagnosis is a critical component in determining whether overdiagnosis or underdiagnosis occurs in many cancer types. In addition to the information revealing potential biological differences, the method of diagnosis may influence the time from diagnosis to accessing clinical trials and influence the decision to participate in clinical trials. Another important question to address is how diversity of cancer care practices influences both the method of diagnosis and the action following the diagnosis. A screening tool is a mechanism through which method of diagnosis can be collected in conjunction with other clinical trials data, and confirmed in a verified manner through engagement of both the patient and a member of the health care team.

e. Current and Past Use of Clinical Trial Screening Tools

Screening tools have been used to identify local and national strategies to increase accrual; to screen for trial eligibility; to determine trial availability to meet the needs of special populations; and to track enrollment¹²⁻¹⁷. NCCCP spent 5 years developing a clinical trial screening database that focused on four cancer types and a limited number of NCI trials that all sites agreed to open at their institutes. The tool was designed to increase enrollment to select NCI sponsored trials with a focus on enhancing enrollment of minority and underrepresented populations⁵. Over 4,000 patients were screened using the NCCCP Screening and Accrual Log over a 3-year period. Of these patients, 53% of eligible patients declined to participate, mainly due to lack of desire to participate (43%) and preference for standard of care (39%) indicating the need to enhance ongoing efforts to increase clinical trial awareness and education about clinical research. The major reason for ineligibility was comorbidities; however, detailed information on the comorbidities was not obtained limiting the ability to inform decision-making or clinical management. Further analysis of the data by Langford et al¹⁸ revealed there were no racial/ethnic differences in clinical trial enrollment refusal rates. However, physical and medical conditions were associated with ineligibility among non-Hispanic blacks, elderly and males overall.

The NCCCP screening tool proved to be essential for the sites' understanding of the barriers to clinical trial research. Twenty of the 21 sites expanded use of the tool to include all clinical trials open at their sites. Benefits of the tool beyond identification of enrollment barriers included evaluating how well they were accruing to individual trials; managing their trial portfolio by having a grasp of what trials they easily accrued to versus those that were more challenging; gaining insight into their sites' demographics; assessing staff performance in patient recruitment; and identifying staffing needs for screening efforts. Experienced NCCCP sites such as those within the Community Clinical Oncology Program (CCOP) and those sites new to research benefitted equally.

The NCORP Screening Tool

In an effort to broaden our understanding of who is screened for NCI clinical trials and the barriers to clinical trial participation, NCORP has developed a clinical trials screening tool. Use and testing of screening tools has been encouraged by cancer care organizations nationally including: NCI¹, American Society of Clinical Oncology (ASCO)¹; American College of Surgeons' Commission on Cancer to address accrual to cancer

trials¹⁹; and by the NCI/ASCO/American Association of Clinical Research (AACR)/American Cancer Society (ACS) Cancer Disparities Research Think Tank: Charting the Future of Cancer Disparities Research²⁰. The overall objective of this protocol is to determine if such a screening tool within NCORP can further its' research agenda focused on addressing health care disparities and increasing clinical trial accrual, especially among minority and underserved populations.

NCORP will expand the effort to study more directed demographic data along with specific diagnosis variables to improve overall understanding of patients who are screened and accrued to clinical trials as well as the barriers that prevent clinical trial participation. These data will be imbedded within familiar clinical trial data collection vehicles to diminish impact to the sites. Data analysis will focus on minority and underserved populations. Data from the tool will help investigators, for instance in hard to recruit trials, better understand the population screened for their trials and the barriers that prevent accrual in order that they can design trials that will meet the needs of the patient population they are targeting. Collection of broader demographic data will allow NCORP investigators to use this data to generate hypotheses and to develop concepts focusing on disparities research and cancer care delivery research, a new area of research in NCORP. Further, data from the tool will be used in evaluating aspects of the NCORP program such as the development of new concepts to move disparities and cancer care delivery research forward and participation of minority and underserved populations in clinical trials. The data from the tool will also be used as part of the sites' progress report, providing data on screening efforts versus enrollment.

In summary, an important aspect of conducting clinical research is to enhance enrollment so that trial accrual more accurately reflects the broader population that will/may ultimately benefit from the trial results and to collect information from patients that will inform future research questions and better trial development/structure. Implementation of a patient clinical trials screening tool within NCORP will provide data to enhance patient enrollment to clinical trials, including minority and underrepresented populations. The NCORP Clinical Trials Screening Tool will also provide a unique opportunity to collect expanded demographic and clinical data to increase our understanding of who is or is not enrolled in NCI sponsored trials and address research questions related to disparities in cancer care and cancer care delivery. The NCORP Clinical Trials Screening Tool will add eight elements that are not currently being collected including marital status, rural status, education level, employment status, annual income, insurance status at time of clinical trial screening, method of diagnosis and comorbidities.

f. Feasibility

Focus groups were developed to address the feasibility of implementing a screening tool in NCORP. Representatives for each NCORP Research Base formed one group (n= 18) and the second was comprised of representation from the NCORP Community and Minority Underserved (MU) sites (n=11). The Research Bases were resoundingly in favor of the tool and felt the tool will help investigators recognize challenges with accrual early, allowing time to address trial-specific barriers. They viewed the tool as a way to heighten awareness of the trials among research staff and physicians. Also, they believed the data could be used to refine their recruitment plans. All were in agreement that more detailed demographic data would help formulate future research questions, especially for disparities and cancer care delivery research.

To reduce redundancy and burden on oncology practices in the NCORP community and minority/underserved sites, a protocol was developed that allows for the collection of expanded demographic and clinical data with informed consent in the same manner as confidential information is collected from patients for all NCI supported clinical trials. Sites new to NCORP or who currently do not collect data on barriers to accrual had the highest interest in the tool. Nearly all of the sites currently collect some form of screening data, some in much greater depth than the NCORP Screening Tool will collect. Uniform, standardized collection of demographic

and screening data is essential to move the NCORP research agenda forward. The data will also promote mentoring by the sites, sharing accrual strategies and methods for reaching disparate populations.

II. Objectives

- 1) Implement a screening tool in NCORP to collect broader demographic and clinical data to generate hypothesis and research questions in the following areas of research: cancer screening, cancer prevention, symptom science, cancer care disparities, comparative effectiveness and cancer care delivery research.
- 2) Collect expanded demographic and clinical data (e.g., SES, co-morbidities, method of diagnosis) across the NCORP network to help identify and best characterize patients that are screened but not enrolled and for patients that participate in NCI trials, to understand how these variables may impact outcomes.
- 3) Enhance an understanding of site- specific and trial-specific accrual barriers that will inform the development of effective strategies to improve accrual, particularly for minority and underserved populations.
- 4) Provide data for internal and external evaluation of NCORP's first RFA cycle and reissuance.

III. Eligibility

- 1) All patients (pediatric and adults) screened for selected NCORP trials supported by the Division of Cancer Prevention (DCP). These trials include symptom and toxicity management, prevention, screening, post-treatment surveillance and comparative effectiveness. Cancer care delivery clinical trials will be included if the primary aim focuses on a patient intervention. A screened patient will be defined as one meeting the following minimum eligibility criteria per the protocol being screened for:
 - a) Cancer diagnosis including stage and histology or pre-malignancy
 - b) Age range specified in the protocol for which the patient is being screened
 - c) Indication for the study intervention (e.g., symptom, toxicity)
- 2) A legally authorized representative may consent for a participant with impaired decision making.

IV. Registration Procedures

CTEP Investigator Registration Procedures

Food and Drug Administration (FDA) regulations and National Cancer Institute (NCI) policy require all investigators participating in any NCI-sponsored clinical trial to register and to renew their registration annually.

Registration requires the submission of:

- A completed ***Statement of Investigator Form*** (FDA Form 1572) with an original signature
- A current Curriculum Vitae (CV)
- A completed and signed ***Supplemental Investigator Data Form*** (IDF)
- A completed ***Financial Disclosure Form*** (FD) with an original signature

Fillable PDF forms and additional information can be found on the CTEP website at <http://ctep.cancer.gov/investigatorResources/investigator_registration.htm>. For questions, please contact the **CTEP Investigator Registration Help Desk** by email at <pmbregpend@ctep.nci.nih.gov>

CTEP Associate Registration Procedures / CTEP-IAM Account

The Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) application is a web-based application intended for use by both Investigators (i.e., all physicians involved in the conduct of NCI-sponsored clinical trials) and Associates (i.e., all staff involved in the conduct of NCI-sponsored clinical trials).

Associates will use the CTEP-IAM application to register (both initial registration and annual re-registration) with CTEP and to obtain a user account.

Investigators will use the CTEP-IAM application to obtain a user account only. (See CTEP Investigator Registration Procedures above for information on registering with CTEP as an Investigator, which must be completed before a CTEP-IAM account can be requested.)

An active CTEP-IAM user account will be needed to access all CTEP and CTSU (Cancer Trials Support Unit) websites and applications, including the CTSU members' website.

Additional information can be found on the CTEP website at

<http://ctep.cancer.gov/branches/pmb/associate_registration.htm>. For questions, please contact the **CTEP Associate Registration Help Desk** by email at <ctepreghelp@ctep.nci.nih.gov>.

V. Patient Enrollment

Potential study participants will be asked to participate in the screening tool study at the time they are screened for a cancer control or prevention trial. Patients can be registered to DCP-001 once eligibility for and enrollment status to the trial for which the patient is being screened for has been determined. Participants may be screened for more than one cancer control and prevention trial. The DCP-001 informed consent document only needs to be signed once. Following informed consent, the participant will be asked several demographic questions and questions related to clinical trial participation. Clinical information requested by the tool will be obtained from the participant's medical record by a member of the research team.

Patient enrollment will be facilitated using the Oncology Patient Enrollment Network (OPEN). OPEN is a web-based registration system available on a 24/7 basis. To access OPEN, the site user must have an active CTEP-IAM account (check at <<https://eapps-ctep.nci.nih.gov/iam/index.jsp>>) and a 'Registrar' role on either the LPO or participating organization roster.

All site staff will use OPEN to enroll patients to this study. It is integrated with the CTSU Enterprise System for regulatory and roster data. OPEN can be accessed at <https://open.ctsu.org> or from the OPEN tab on the CTSU members' side of the website at <https://www.ctsu.org>.

Prior to accessing OPEN, site staff should verify the following:

- All eligibility criteria have been met within the protocol stated timeframes.

- All patients have signed an appropriate consent form and HIPAA authorization form (if applicable).

Downloading Site Registration Documents:

Site registration forms may be downloaded from the *DCP-001* protocol page located on the CTSU members' website. Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU RSS.

- Go to <https://www.ctsu.org> and log in to the members' area using your CTEP-IAM username and password
- Click on the Protocols tab in the upper left of your screen
- Click on the *NCORP* link to expand, then select trial protocol #DCP-001.
- Click on the Site Registration Documents link

Requirements For DCP-001 Site Registration:

- CTSU IRB Certification (for sites not participating via the NCI CIRB)
- CTSU IRB/Regulatory Approval Transmittal Sheet (for sites not participating via the NCI CIRB)

Submitting Regulatory Documents:

Submit completed forms along with a copy of your IRB Approval *and Model Informed Consent* to the CTSU Regulatory Office, where they will be entered and tracked in the CTSU RSS.

CTSU Regulatory Office

1818 Market Street, Suite 1100

Philadelphia, PA 19103

Phone: 1-866-651-2878

Fax: 215-569-0206

E-mail: CTSURegulatory@ctsu.coccg.org (for regulatory document submission only)

Checking Your Site's Registration Status:

Check the status of your site's registration packets by querying the RSS site registration status page of the members' section of the CTSU website. (Note: Sites will not receive formal notification of regulatory approval from the CTSU Regulatory Office.)

- Go to <https://www.ctsu.org> and log in to the members' area using your CTEP-IAM username and password
- Click on the Regulatory tab at the top of your screen
- Click on the Site Registration tab
- Enter your 5-character CTEP Institution Code and click on Go

VI. Protocol Implementation

IRB Approval: Each investigator or group of investigators at a clinical site must obtain IRB approval for this protocol and submit IRB approval and supporting documentation to the CTSU Regulatory Office before they can be approved to enroll patients. Study centers can check the status of their registration packets by querying the Regulatory Support System (RSS) site registration status page of the CTSU members' website by entering credentials at <https://www.ctsu.org>. For sites under the CIRB initiative, IRB data will automatically load to RSS.

Sites participating on the NCI CIRB initiative that are approved by the CIRB for the study are not required to submit separate IRB approval documentation to the CTSU Regulatory Office for initial, continuing or amendment review. **However, sites must submit a Study Specific Worksheet for Local Context (SSW) to the CIRB (via IRBManager) to indicate their intention to open the study locally. The CIRB's approval of the SSW is then communicated to the CTSU Regulatory Office for compliance in the RSS.** The Signatory Institution must inform the CTSU which CIRB-approved institutions aligned with the Signatory Institution are participating in a given study so that the study approval can be applied to those institutions. Other site registration requirements (e.g., laboratory certifications, protocol-specific training certifications, or modality

credentialing) must be submitted to the CTSU Regulatory Office or compliance communicated per protocol instructions.

Once approval is obtained, the NCORP sites will implement the screening protocol throughout its local clinical trial network (all components and sub-components). It is expected that the NCORP sites will enroll and obtain informed consent for the screening tool study for **all patients screened for all NCORP cancer control and prevention trials** over a three-year period. After the project has been described to the potential participant and informed consent is obtained, a member of the research team will ask the patient several demographic questions, obtain clinical information from the medical record and ascertain whether or not the patient was enrolled on the clinical trial, and if not, the reason(s). This is a one-time encounter with the patient though will occur each time the person is screened for a cancer control and prevention trial.

NCORP personnel will train the users at each of the NCORP community and MU sites. The training will be in multiple formats; be available in advance of protocol activation and for additional training needs throughout the lifecycle of the protocol; and will include the following information:

1. Protocol overview;
2. Use of the screening protocol prior to entering data into the system;
3. Standardized data element identification and definition;
4. Proper data entry;
5. How to run reports and
6. How to edit data.
7. Local SOP for screening protocol data collection

VII. Data Collection and Evaluation

The NCORP Screening Tool will be accessed via the web-based NCI trial registry system, OPEN, in the same manner as other case report forms. Each investigator or group of investigators at a clinical site must complete a study local context form and submit to the CIRB before they can be approved to enroll patients. In order to access OPEN all site users must have an active CTEP IAM account and password; an active roster status on the Lead Protocol Organization (LPO) roster; and a “Registrar Role” on the LPO roster or the Participating Organization (PO) roster in RSS to be able to enroll patients. NCORP sites will then access and complete the Screening Tool Case Report Form for each trial to which a patient is screened.

Patient identified data will NOT be included by design. However, a record ID will be provided by the OPEN system in order that each site can develop standard operating procedures (SOP) in the event that a record requires edit/delete/update. Sites will be required to develop local procedures for matching a record ID with a specific patient for the purpose of making changes to the entry they submitted to the Screening Tool. At no time will the patient be identified to NCI and NCI will not have access to patient identifying information. However, those participants with rare cancers may be at a higher risk of a breach in confidentiality simply through single or limited instance of disease. Each site will be responsible for the development of the SOP, the training for the SOP, oversight of performance to the SOP, and the management of this process. In the event that a record needs correction for any reason, standard audit procedures will be enlisted for recording who on what date/time made what changes and for what reason. Expected data corrections include, human error, consent issues, and patient request for deletion.

In the event that a patient removes consent for data included in the database, the NCORP site will need to contact **the protocol chair** with the OPEN ID #. The OPEN database administrator will delete the record for the OPEN ID and inform the site and NCI of the deletion.

The degree of missing data and edit reason codes will be included in the evaluation of the tool. It is expected that there will be a need to discuss the data collected with sites to ensure data is standardized and elements are well understood in order that the data used to inform change is accurate and measurable.

VIII. Human Subjects Protection

There will be no patient identified data collected in the Screening Tool. At no time will patient identifiable data be shared with NCI or collected within the OPEN system. Informed consent will be obtained from each screened patient for the collection and analysis of demographic and screening data.

Adverse Event (AE) Reporting and Monitoring: Not applicable. This is a questionnaire-based study without investigational treatment.

IX. Access to Data/Data Reports

The NCI, NCORP sites and NCORP Research Bases will have access to screening data for each protocol, though the data will be limited according to the requestor's role. Screening data will be made available through OPEN on-demand computer generated reports that can be filtered by several variables, such as trial date range, number, site, etc. The NCORP sites will only have access to their own site data and will NOT have access to another sites data. All data captured within OPEN for the screening protocol will be de-identified by design. Each site will be required to have a local SOP for recording OPEN ID's for each record completed that can be used by the site internally to re-identify a patient locally for internal auditing purposes only. On-demand computerized reports available to the sites will NOT contain these OPEN ID's. The NCORP Research Bases will have access to cumulative data from all sites but only for the protocols they sponsor and in a read-only format. They will NOT have access to other sponsors data. The data will consist of all of the screening data for each protocol they sponsor in the de-identified form provided by the sites but will NOT contain OPEN ID's. The NCI will have access to all screening data provided to the screening protocol for each trial it is associated with in the de-identified form provided by the sites.

X. References

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