Study Protocol and Statistical Analysis Plan

Study Title: Care coordination for complex cancer survivors in an integrated safety-net system

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1**. Introduction and Purpose:**

Nearly 70% of the 13 million people living with cancer are "complex cancer survivors" who are also dealing with multiple other chronic conditions. The prevalence of complex cancer survivors is expected to continue growing because successful treatments result in longer survival and cancer diagnoses occur most often in older persons who are more likely to have multiple chronic conditions. The National Comprehensive Cancer Network (NCCN) emphasizes that managing survivors' needs includes caring for their other chronic conditions. These complex patients need highly coordinated care to ensure optimal outcomes for their cancers, co-existing chronic conditions, and overall quality of life, but no effective models for doing this exist.

This project is a pragmatic trial. We propose a quasi-experimental design where data will be collected both pre- and post-intervention on distinct cross-sections of patients with one or more highly prevalent ambulatory-sensitive chronic conditions (diabetes, hypertension, chronic lung disease, chronic kidney disease, depression, or heart disease) and newly diagnosed with breast or colorectal cancers (complex cancer survivors) in the Parkland Health & Hospital system (Dallas, TX). Guided by the *Primary Care Change Model,* Parkland will implement evidence-based care coordination strategies to improve care for complex cancer survivors in this integrated safety-net system as a part of quality assurance/quality improvement activities (Aim 1), then this study will comprehensively evaluate how these strategies are implemented in the safety-net setting (Aim 3), and whether implementing these strategies improves care coordination and care outcomes (Aim 2) within the Parkland Health and Hospital System.

2. Background:

Following initial cancer treatment, needs of complex cancer survivors are not well met, resulting in poor health outcomes. Management of a new cancer diagnosis often interrupts existing chronic disease care because patients undergo intensive oncology care for an extended period of time during which attention to their other conditions may wane. Further, patients with cancer often continue to be followed by oncologists after completion of initial treatment with little or no care coordination with primary care clinicians. Thus, care is fragmented and the providers siloed, resulting in suboptimal care quality. **The Institute of Medicine (IOM) argues a lack of system-level approaches to navigate survivors between primary and oncology care contributes to fragmentation and poor outcomes**. This is further complicated by ineffective use of clinical decision support tools (disease registries, alerts, referral tracking) and fragmented care delivery approaches. Effective care coordination organizes patient care activities and provider information-sharing to facilitate shared-care and appropriate service delivery.

The burden of cancer, multiple chronic conditions, and fragmented care is greatest among under- and uninsured minority patients. For example, nationally, African Americans have worse quality-of-care outcomes on 73 preventive and chronic disease care indicators. **Similar disparities in quality-of-care outcomes exist particularly for cancer survivors** who are racial/ethnic minorities, uninsured, and receiving care in safety-net health systems. **At Parkland Health & Hospital System (Parkland)-Dallas County's integrated safety-net system - 72% of cancer patients are racial/ethnic minorities, 70% are uninsured, and more than 60% have three or more chronic conditions**. Parkland preliminary data show only 43% of colorectal cancer survivors met guidelines for both cancer surveillance and appropriate diabetes care. Our application proposes innovative research to improve care for this vulnerable group of patients.

Despite a significant body of evidence regarding best strategies to improve care for patients with multiple chronic conditions, there is little research on complex cancer survivors. The IOM, Agency for Healthcare Research & Quality (AHRQ), and Institute for Healthcare Improvement all support care coordination as a mainstay of interventions to improve care quality for complex patients The 2007 AHRQ report, synthesizing 75 systematic reviews of care coordination interventions along with more recent research, shows that strategies with compelling evidence for improved outcomes include: (1) EMR-driven transitions using alerts and referral tracking; (2) intensive case management; and (3) team-based care. These strategies improve transitions in care processes, enhance continuity, reduce lack of follow-through on referrals, and ensure that patients receive all recommended care through regular information-sharing. They also demonstrate improved patient experience of care and clinical outcomes. Further, care coordination interventions conducted in integrated systems like Parkland – where primary and specialty care communicate through a common electronic medical record system (EMR) – have the greatest potential for improving outcomes. Evidence for effectiveness of case managers and automated reminders originated in insured integrated systems and have shown improvements in diabetes performance measures and cancer screening. Also, care coordination interventions among elderly patients with multiple chronic conditions show improved outcomes compared with those focusing on a single disease.

Although there is sufficient evidence for using these strategies for common medical conditions in primary care, their effectiveness in coordinating care for complex cancer survivors has not been evaluated. Therefore, in Aim 1, Parkland will implement these care coordination strategies for complex survivors as a part of quality assurance/quality improvement, and Aim 2 and Aim 3 will evaluate these strategies. We will use mixed methods to comprehensively evaluate implementation of care coordination strategies among complex cancer survivors at Parkland. **We use the empirically informed *Primary Care Practice Change Model* to guide our evaluation design.** This intervention mixed-methods evaluation will examine not only *whether* the selected strategies were effective, but also *how* and *why* they worked (or did not work) is critical to generating transportable findings necessary for broader dissemination.

3. Study Procedures:

We expect approximately 1000 new survivors with ≥ 1 prevalent chronic condition to be eligible. We will not include patients diagnosed with in situ and metastatic disease (Stages 0 and IV) due to insufficient evidence for routine follow-up and management; many of the latter continue indefinitely on active treatment for symptom management. The chronic conditions we selected for inclusion are the most prevalent conditions cancer survivors have at Parkland as well as nationally.

Aim 1: (Quality assurance/quality improvement) ***Parkland will implement system-level EMR-driven evidence-based care coordination strategies;*** **(1)** EMR-driven registry to facilitate patient transitions between primary care and oncology care, **(2)** co-locate a nurse practitioner trained in care coordination within a complex care team, and **(3)** enhance teamwork through coaching and technical assistance.

- **Strategy 1:** Using the Epic Reporting Workbench, Parkland EMR data will be extracted in order to create a registry of complex cancer patients to facilitate transitions primary care and oncology care.
- **Strategy 2:** During Year 1 of this study, Parkland will educate clinicians and staff about the proposed system change and train primary care physicians on ways to identify and refer survivors to the complex care team. Parkland will designate a new complex care team for

eligible patients. This team will be housed within a Parkland community oriented primary care clinic. Due to the acuity and complexity of the needs of complex cancer survivors, the team will be staffed by a primary care physician and a nurse practitioner, and will include an RN/LVN nurse, a medical assistant, a social worker, and a mental health counselor.

- **Strategy 3:** Parkland will map team workflow around all aspects of delivering care to complex cancer survivors, establishing team goals, train team members in all aspects of cancer survivorship care including providing booster training sessions and coaching, enhance communication, set ground rules to make decisions, and finally pro-actively create standing orders to empower non-physician team members to share care delivery. Parkland will facilitate primary care teams in developing systems needed to enhance teamwork and implementing incremental practice change initiatives through quality improvement cycles.

Aim 2: (Research Component) ***Test effectiveness of the care coordination strategies using a quasi-experimental study, with system- and patient-level outcomes measured before and after implementation.***

System-level hypothesis: The primary outcome is proportion of complex cancer survivors meeting quality of care guidelines for multiple chronic conditions and follow-up cancer surveillance. We will use clinical care guidelines for chronic disease care and *National Comprehensive Cancer Network* (NCCN) guidelines for cancer surveillance to determine if patients are eligible for services. We will also determine whether patients received guideline-appropriate cancer surveillance, e.g., whether colorectal cancer patients received CEA testing every 6 months, endoscopy surveillance, and CT scans annually. We will also measure rates of ED and hospitalizations (secondary outcomes) for ambulatory care-sensitive chronic conditions at the same time points as the primary outcomes. The outcome measure will be derived from quality scores for: (a) chronic disease care and (b) cancer follow-up care. We will create these scores by, first, determining for each patient the percentage of eligible guideline-recommended services received and clinical targets met, then, calculating the percentage of patients that met 100%, 75%, and 50% of these indicators. The 75% and 50% composites are less stringent and assess percentage of patients who achieved success on fewer indicators. Finally, we will calculate a composite overall care score that includes both chronic disease and cancer follow-up score. Computing composite scores will allow us to measure not only changes separately in chronic disease care and cancer follow-up care but also changes in overall care. This extends current research beyond single-disease measures to focus on overall care quality.

Patient-level hypothesis: Patient-reported care coordination assessed via Patient Perception of Care Scale, which has been validated in primary care and is associated with improvements in reported problems with care coordination. We will use the EMR-generated registry to randomly select 866 complex cancer survivors to survey 402. Surveys will be administered three times by phone – once prior to their initial visit with the complex care team (baseline) and twice thereafter at 6 and 12 months. Prior to fielding surveys, we will conduct 15 cognitive interviews (with patients who will be excluded from the larger project) to ensure measures not already validated in Spanish are adapted for language, literacy and culture.

Aim 2 Statistical analyses: We will use segmented logistic regression and linear mixed regression models to assess effect of care coordination strategies on system and patient outcomes.

To evaluate system-level hypotheses, the design is a repeated cross-sectional study with outcomes

measured for distinct cross-sectional samples of patients at five points. To analyze these data, we will first use chi-square tests to compare proportion of eligible patients meeting guidelines at 12 and 24 months before implementation to proportion of patients meeting guidelines 12, 24 and 36 months after system-level strategies are in place. We will then use segmented logistic regression models to identify the time point at which observed trend in proportion of patients meeting guidelines. We expect a significant p-value for change in proportion of patients meeting guidelines after implementation of system-level strategies. Conversely, we expect the trend for proportion of patients meeting care guidelines before implementation to be stable with a larger p-value. This trend, in conjunction with additional qualitative information gathered about implementation (Aim 3), will provide evidence that implemented strategies resulted in changes in outcomes.

> **Power/sample size:** To demonstrate a minimum increase of 10% in the primary outcome after implementation of system-level strategies as compared to before implementation, a sample of 170 patients at each time point will provide 80% power at the 0.05 significance level based on the chi-square test for comparing proportions. We have many more patients than needed; as system-level outcomes will be evaluated using EMR data, we will include all eligible patients and conduct subgroup and sensitivity analyses to better characterize effects.

For the patient-level hypothesis, the design is a repeated measures study with outcomes measured on the same patients at three time points; at baseline and 6 months, and 12 months after transition to the complex care team for each individual patient. We will use linear mixed models to estimate effects on change in scores. Through specification of fixed effects, the mixed model allows for control of confounding variables, and can account for sources of natural heterogeneity by adding random effects that are unique to a particular individual. We will test different covariance matrices for random effects and will choose the matrix yielding smallest Akaike information criterion or largest restricted maximum likelihood estimate. Residual analyses and plots will examine adequacy of the final model. We will use SAS Proc Mixed procedure for analysis. Retrospective data might be missing. If data are missing at random (MAR), a linear mixed regression model is appropriate to address the issues of repeated measures and missing data in longitudinal studies. If the missing data are not missing at random (NMAR), we will explore the missing data pattern and a technique such as pattern mixture model will be used to adjust for NMAR bias.

> **Power/sample size:** Assuming intra-subject correlation of 0.7 and minimum detectable standardized effect size of 0.25 (standardized effect size = effect size/standard deviation), we will need 402 patients to attain 80% power at α=0.05 using proposed mixed-effects linear regression analyses.

Aim 3: (Research Component) ***Conduct an intervention mixed-methods evaluation of implementation of care coordination strategies.*** This is especially important for system interventions implemented in the context of real world settings as proposed in this application to: (a) describe how the system-level strategies are implemented; (b) elucidate contextual factors affecting implementation at system and patient-levels; and (c) identify alternate explanations for observed effects on outcomes to generate counterfactual inference. Gathering qualitative and quantitative data before, during, and after implementation will enable us to assess the factors that influence implementation at system- and patient levels. Data collection methods include structured observations, complex care team surveys and provider interviews, patient surveys and interviews, and EMR extraction.

Structured observations - quiet observation of daily clinical work with opportunistic discussion with staff at the primary care clinics, Patient Access Center, and the complex care team- will describe usual care prior to and document how workflow changes after strategies are implemented. Adapted from anthropological participant observation, this method lends itself to multiple levels of observation and analysis Led by Dr. Lee, research staff will conduct 40 hours of structured observation prior to implementation and at 3 and 6 months post-implementation.

Patient surveys and interviews will assess experience of care coordination and its broader effects on health-related quality of life as well as the mediating and/or moderating effects of patient activation, attitudes toward follow-up cancer care, care quality, challenges of daily living (multiple low-wage jobs), competing demands/structural barriers to access (transportation, no paid time off), and health literacy. Administration of patient surveys is described in Aim 2 above. We will stratify across the two cancer types compared to a usual care sample of complex patients without cancer, and account for originating clinic. Interviewing across these groups will elucidate the experience of coordination for patients with multiple chronic conditions and enable us to see how cancer may create additional or different needs or perceptions. Additional patient interviews will be conducted to assess receipt of a care plan, survivor-level outcomes, experience with survivorship, and to understand the impact of COVID-19. These interviews will allow us to understand the patient experience throughout the cancer care continuum.

Interviewing providers and focus groups from primary clinics with high and low rates of survivors' referred to the complex care team will help identify "work-arounds" and protocols that impede or facilitate care coordination, e.g. primary and specialty physician communication. Providers (n=30), sampled based on their involvement in cancer survivor follow-up care and chronic disease management, will be invited to interviews which will assess perspectives on patient uptake and other perceived challenges and opportunities. The PIs will develop interview guides, train and supervise the team in conducting interviews. Focus groups (N=2) and additional provider interviews (N=10) will be conducted to understand provider perceptions and experience treating cardiovascular disease risk for cancer survivors.

Epic EMR data Extraction will be used to characterize: (1) visit patterns with the nurse coordinator; (2) the extent to which care coordination, disease management and referrals to specialty providers and receipt of referrals occur; (3) patients who do not receive appropriate follow-up services; (4) missed appointments or loss-to-follow-up; and (5) processes related to care coordination. A separate data extraction of 1000 non-cancer patients with multiple chronic conditions will allow us to analytically characterize the non-cancer comorbid patient population at baseline as a comparator. We will also recruit a small subsample of these for baseline pre-intervention surveys and interviews.

Aim 3 Data analyses: We will use *NVivo 9.0* (QSR International, AUS) to collate and analyze qualitative data. Use of this software makes the analytic process transparent so that investigators can track evolving analyses. Research staff will transcribe field notes from structured observations and gather existing protocols and documents relating to care of complex patients to enter into the database. We will develop flowcharts depicting complex care and primary care team members' relationships, roles, responsibilities, and behaviors in relation to practice change. Drs. Lee and Balasubramanian will work with research staff to organize these source documents and develop a codebook relating data to practice change, behavioral and organizational theories. We will triangulate across diverse data sources, to understand how providers adapt the strategies to suit the Parkland

context. Through monthly meetings, we will test emergent themes and interpretation against the knowledge base of our study team. We will review coding agreement and resolve discrepancies through consensus. Cross-analysis of qualitative data from all sources will enable integration across strategies and implementation processes to assess key steps and the interface of oncology and primary care. Using waves of surveys from Aim 1, we will explore whether changes in teamwork scores correlates with changes in primary outcomes in Aim 2.

4. Criteria for Inclusion of Subjects:
Patient sample: The study eligible patient population includes adult patients over 18 years of age diagnosed with AJCC Stage I-III incident breast or colorectal cancers AND with one or more of the following highly prevalent ambulatory-sensitive chronic conditions (diabetes, hypertension, chronic lung disease, chronic kidney disease, depression, or heart disease). We will exclude patients with in situ cancers (Stage 0) and those with metastatic disease (Stage IV).

Usual care pre-intervention sample: Our sample of 1000 non-cancer patients will include those with multiple chronic conditions (as above) and at least one doctor visit in the previous 12 months.

For patient cognitive interviews, surveys and semi-structured interviews (Aim 2), we will apply the following additional eligibility criteria: ability to comprehend English or Spanish, and communicate with voice (to participate in interviews and telephone surveys). Patients with and without eligible cancers are interview candidates.

Provider sample: Physicians and clinical staff (nurse practitioners, physician assistants, nurses, etc.) will be eligible if they have current clinical responsibilities in Parkland oncology clinics, involved in colorectal or breast cancer care; the Parkland complex care team; and Parkland Community-Oriented Primary Care Clinics (COPCS) who manage patients with multiple chronic conditions.

5. Criteria for Exclusion of Subjects:
Patients with impaired hearing or speech, inability to speak to English or Spanish, and refusal to consent (patient survey only) will be excluded from this study.

6. Sources of Research Material:
Data for this study will include:

1) Electronic Health Record (patient demographics, cancer and comorbidity diagnoses, appointments and dates, lab results and dates, screening procedures including results and dates, smoking history, medications, cancer treatment data). For the retrospective component of the study, we will request the EMR data from 01/01/2010- 12/31/2016. An additional sample of patients without cancer, but with 2 or more chronic conditions and a doctor visit in the last 12 months as a comparator group.
2) Patient survey data about patient experiences of care - validated measures
3) Audio-recordings of patient and provider interviews will collect qualitative data about patient experiences of care
4) Field notes of structured observations of clinic workflow

7. Recruitment Methods and Consenting Process:
To evaluate the system-level outcome, we will use EMR data collected on approximately 1000 patients from the Parkland system. We will ask the IRB for Waiver of Consent and Waiver of HIPAA

Authorization for EMR review and extraction of outcome data, and to conduct a confirmatory audit of 50 patient records identified by the EMR algorithm for individual chart review to confirm our ability to accurately capture all complex, Stage I-III breast, colorectal cancer patients completing active treatment.

To evaluate the patient-level outcome, we will use the EMR-generated patient list to randomly select ~866 complex cancer survivors in order to survey at least 402 after their transition to the complex care team. Based on our prior research experience with contacting Parkland cancer patients, patients are able and willing to complete telephone surveys. Further, we can expect 55% of those eligible will participate (n~480); 12% will actively refuse, 13% will have a non-working number, and 20% will be unreachable. We will also request a Waiver of HIPAA Authorization to identify and invite patients, and to compare, subsequently, demographics of non-respondents with participants to examine selection bias. All patients included in the system-level and patient-level outcomes are Parkland patients of the study investigators.

Cognitive Interviews. Working with the Cancer Center's *Spanish Language Translation/Validation Resource*, we will conduct 15 cognitive interviews in English or Spanish with a sample of Parkland cancer patients who were diagnosed with cancer in 2014 or earlier. These patients will not be included in the analyses for Aims 2 or 3. This sample will be recruited from the Parkland cancer registry or the Community Health Registry (STU 112010-061). We will ask the IRB for a waiver of documentation of consent and waiver of documentation of HIPAA Authorization for these participants. Trained, bilingual staff will recruit potential participants by telephone, explaining the goal of the interview, and schedule an on-site interview to be conducted at UT Southwestern. At the interview, staff will review session purpose, solicit informed consent, and conduct a half-hour cognitive interview to ensure the survey is understandable by individuals with low literacy skills and culturally appropriate. We will also evaluate whether the English and Spanish versions are conceptually equivalent. Cognitive interviews will be digitally audio-recorded; no HIPAA or other identifying information will be retained in the interview transcript. Gift card in the amount of $15 will be provided to interview participants as an acknowledgment of their time and effort.

Patient telephone surveys. Patients identified for telephone survey will be mailed an invitation letter on Parkland letterhead, as appropriate, requesting participation in a "project to improve patient satisfaction with continuing care for their existing medical conditions." The letter will provide a local telephone number parents can use to opt-out or ask questions. Letters will be in both English and Spanish. A few days after the mailing, patients who have not refused contact will be called by a bilingual research assistant (RA) who will explain the project, verify eligibility, obtain verbal informed consent and HIPAA authorization for EMR review, and conduct a 30-minute survey. Up to 6 attempts per month for 2 months (day and evening) will be made to reach patients. Token gift cards will be provided to survey participants as an acknowledgment of their time and effort, per IRB stipulations. Provision of incremental remuneration (gift cards of $10, $20, $40) will be provided in appreciation of the participant's time. Bilingual staff will invite a subset of survivors and usual care patients (n=90) for follow-up interviews (see below). We will also endeavor to sample an additional 10 patients for interviews from among those who did not respond to the surveys to explore selection bias.

Patients will complete surveys three times by phone – prior to their initial visit with the complex care team (baseline), and twice thereafter at 6 and 12 months. In addition to the primary measure, patients

will also be surveyed for key patient-reported confounding variables, potential mediators and moderators. Patients who have completed at least one survey will be invited to participate in an additional survey to assess the impact of COVID-19 on their overall health and well-being, including understand the effects of social distancing, patients' physical, emotional, and mental health, financial impact, and coping. Patients will receive a $20 gift card for their participation in the COVID-19 survey.

Structured observations and provider interviews and focus groups: For study procedures involving clinicians and staff, we will request a Waiver of Documentation of Consent from the IRB because signed consent forms would be the only written record of participation, observations and interviews will concern only professional roles and responsibilities and no personal personnel information will be collected. We plan to conduct approximately 40 hours of structured observation, to interview approximately 40 providers, and conduct 2 focus groups (10-20 providers). Providers will be sampled on the basis of their involvement in cancer treatment, primary care and morbidity management (diabetes, hypertension, depression, heart disease, asthma); they will be invited to interview by faculty investigators. We will describe study objectives and purpose of the interview then solicit oral informed consent. No PHI will be collected.

Patient semi-structured interviews: A subset of 90 survey responders, (plus 10 non-responders, n=100) patients will be invited to complete a telephone interview. Following the existing recruitment procedure, additional eligible patients who did not complete a survey will be identified using EHR data and will be invited directly to interviews. An additional subset of 40 patients will be invited to complete a telephone interview focused on their experience with COVID-19. Patients will receive a $40 gift card for their participation in the COVID-19 interviews.

An additional subset of 15 colorectal and breast cancer survivors identified from the retrospective cohort data will be invited to participate in semi-structured telephone interviews. Eligible participants will be mailed an invitation letter on Parkland letterhead requesting participation in a "project to improve satisfaction with cancer care" with a toll-free number to opt out or to ask questions. Bilingual staff members will contact patients by phone to 1) obtain informed consent and HIPAA authorization to review the patient's EMR; and 2) conduct the semi-structured interview in the patient's preferred language (English or Spanish). The interview will last about 45 minutes to 1 hour, and will be audio-recorded. All interviewers will be trained by Dr. Lee and supervised by Drs. Lee and Balasubramanian. Gift cards will be provided to interview participants as an acknowledgment of their time and effort, per IRB stipulations. All data will only be accessible to authorized study personnel and members of regulatory agencies.

8. Potential Risks:

This is a minimal-risk study. Main risks to patients are minimal because the proposed implementation of effective strategies to provide cancer patients with care coordination for multi-morbidities promotes appropriate medical care and follow-up. **The *system-level intervention combining three evidence-based care coordination strategies* will be implemented by Parkland clinicians under the direction of Parkland leadership and evaluated by the research team**.

Care coordination is recommended by the *Institute of Medicine* and *National Comprehensive Cancer Network*. We are studying care coordination for complex cancer survivors to understand how best to provide for complex survivors in safety-net settings generally and to inform Parkland system-wide

adoption of team-based care coordination for all patients with multiple chronic conditions in the future.

Patients: The main potential risk of participation is that patient confidentiality may be compromised, leading to a third party gaining access to personal health information. There is also a small psychological risk that collecting data about care coordination following cancer treatment may cause patients to worry about their care. Patients will be identified through the EMR and approached with the knowledge of their treating physician or clinic director. No personal identifying information will be collected during the qualitative interviews and transcripts will be reviewed and purged for personal identifiers by study staff. Methods for protecting against risks are described below. Patients who chose not to participate in surveys or interviews will continue to receive their usual care.

Physicians and Staff: Potential risks to participants include feelings of discomfort and concerns about continued employment, future promotion, or adverse evaluation resulting from their participation as well as privacy regarding the information they will provide in the interviews. However, the information solicited concerns only routine professional behaviors related to management of chronic conditions and cancer survivorship follow-up care**;** questions are not personal in nature. Data collection is analogous to routine quality improvement initiatives conducted at Parkland and all leading healthcare organizations. The oral informed consent process will explicitly seek their voluntary participation. Participants will be assured that names are not identified in transcripts or analysis, and that any information they might provide is confidential and will in no way be used in the evaluation of their professional roles. Methods for protecting against these risks are described below.

9. Subject Safety and Data Monitoring:
Our implementation study applies evidence-based care coordination strategies, as articulated by the IOM, NCCN, and AHRQ, to the clinical care of complex cancer survivors and anticipates the integration of patient-centered medical home models in safety-net settings. Monitoring will be conducted primarily by the Principal Investigators and through periodic review by the UT Southwestern IRB.

All data transactions will run through controlled, secure transactions to ensure the preservation of database integrity and privacy. The data will reside on a secure, password-protected SQL database accessible by approved study personnel only. All personal identifying information will be kept by the investigators in a secure place with IRB approval. All data management procedures and databases will be HIPAA compliant. Any study data maintained as paper documents will be stored under lock and key.

All study data will be backed up on a nightly, monthly, and biannual schedule; nightly backups are purged every 30 days. Monthly and biannual backups will be kept on static media throughout the duration of the study and up to 5 years after. The process of restoring data from a backup will be conducted to preserve as many data as possible, while ensuring that database integrity has been preserved.

10. Procedures to Maintain Confidentiality:
We will use rigorous data security procedures to protect subject confidentiality and comply with federal HIPAA requirements. All personal identifying information will be kept by the investigators in

a secure server with IRB approval. All data management procedures and databases will be HIPAA compliant. Any study data maintained as paper documents will be stored under lock and key in a secure filing cabinet in locked offices.

All interviews will be digitally voice-recorded and transcribed by a professional vendor under a Business Associates agreement to ensure confidentiality. All resulting transcripts, together with field notes from structured observations in the clinics, will be de-identified and stored on password-protected computers.

A systems administrator will monitor server hardware, operating system and database service performance. Workstations, laptops, and other devices will receive periodic back-up and maintenance to ensure high performance and secure operation.

All data protocols will be approved by the UT Southwestern Medical Center, UT School of Public Health, Institutional Review Board (Parkland uses the UTSW IRB). All protocols will follow University policies that confine all personal information on paper or only on password-protected computers that are not accessible through the web, as per University of Texas System interpretations of HIPAA regulations.

Finally, the study will proceed with the full knowledge and approval of Parkland leadership; we will ensure all research activities that take place in the Parkland system do not disrupt clinic operations. To execute this study protocol, we will work closely with our clinic partners and believe the steps we outline below are adequate to ensure patient privacy and overall data security for the course of the study. We will also work with Parkland to publicize results of the study to inform the patient community of the knowledge gained.

We will include cancer patients with chronic conditions at Parkland as a part of the initial database. We have requested waivers for these participants for retrospective and prospective data to accomplish recruitment and analysis goals. To conduct the system-level analysis, we will need to include all incident cancer patients with chronic conditions.

If we remove participants who decline to participate in these surveys/interviews from the total EMR cohort, we risk a significant percentage of cancer patients with chronic conditions treated at Parkland. Removing EMR data for these individuals would result in selection bias and also adversely impact our power to detect an effect as a result of our intervention. Inclusion/exclusion criteria (a finite number of eligible patients) eliminate our ability to replace patients who would decline to participate.

Therefore, we are requesting to consent participants for survey and interview participation, and maintain a full waiver of HIPAA authorization for eligible patients to conduct the system-level analysis.

11. Potential Benefits:

This research will inform future local, regional and national efforts to improve the quality of care and comprehensive management of complex cancer survivors in resource-limited settings, especially those caring for safety-net populations. There is prospect of direct benefit from the research, in that our implementation is designed to increase care coordination between oncology and primary care for patients completing active cancer treatment and to increase referrals and management for relevant

care of chronic conditions. However, there is no prospect of direct benefit for participation in surveys, interviews, or structured observation, save the possibility of increased awareness and attention to survivorship care in the context of multi-morbidities as a result of discussion in the course of data collection. We also expect indirect benefit from future quality improvement initiatives in the Parkland system that might flow from our findings.

The potential benefit of the quality of care information to improving care to Parkland patients and others receiving care through safety-net networks is significant and greatly outweighs the minimal risks.

12. Importance of the Knowledge to be Gained:
Despite increasing numbers of cancer survivors, survivorship care coordination and follow-up processes are suboptimal nationwide, particularly for survivors living with other chronic conditions. Because cancer survivors have risks related to surveillance, treatment effects and lifestyle behaviors, it is critically important to be able standardize the coordination of all complex (multi-morbidity) cancer patients ending initial cancer treatment, as well as to identify the barriers and facilitators of care coordination in the safety-net setting. This information will inform local, regional and national quality improvement initiatives. Examining effectiveness of care coordination for complex patients in a community-based, safety-net setting has important health policy and public health significance. Low-income, under- and uninsured minorities have higher rates of cancer and complicating chronic conditions, thus our focus on the effectiveness of care coordination among the vulnerable populations treated in the Parkland system offers great potential public health gains for the care of complex (multi-morbidity) cancer survivors. The proposed study's potential contributions to care coordination justify the minimal risks to patients.