1. **Project Title**
   The Cancer Experience Registry®: *An Online Survey Research Study to Understand the Experiences of Those Impacted By a Cancer Diagnosis*

2. **PRINCIPAL INVESTIGATOR**
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4. **ESTIMATED DURATION OF STUDY**
   Ongoing

5. **OBJECTIVE**
   Cancer Support Community's (CSC) Cancer Experience Registry (CER) is a research study on the emotional, physical, practical, and financial impact of cancer among patients, survivors, and caregivers using online research surveys. The CER's web-based platform collects longitudinal data, as well as patient and caregiver data that can be linked to understand how their experiences impact each other. Survey questions are designed to identify critical unmet needs of all individuals affected by cancer, regardless of a specific cancer diagnosis and across various stages in the cancer continuum from diagnosis through survivorship. Findings contribute toward enhancing care for patients, survivors, and caregivers via education, programming, and policy initiatives.

6. **SPECIFIC AIMS**
   The CER arose out of a need for local and national surveillance data that could provide information about the psychosocial and emotional impact of cancer, health-related quality of life, lifestyle behaviors, treatment decision-making, adherence, and survivorship care. Guided by a Cognitive Social Health Information Processing model, cancer patient and caregiver attitudes, emotional status, and coping strategies can influence treatment decision-making, adaptation to a cancer diagnosis and survivorship, and adherence to recommended health behaviors. The goal of this research initiative is to capture a broad population of cancer patients, survivors, and caregivers and to engage them over time to track cross-sectional, longitudinal, and dyadic trends. These findings bring awareness to persisting unmet needs for individuals impacted by cancer in a rapidly evolving cancer landscape ensuring that patient and caregiver voices help shape the future of cancer care. The project aims include:

   - To assess the psychosocial experiences and needs of people who have been impacted by cancer, including patients, survivors, and caregivers;

- To use the findings to develop and disseminate tailored (data-guided) educational materials and support programs and services and strengthen healthcare policies;
- To provide collaborating research sites (e.g., hospitals/health networks/CSC affiliates/state coalitions) with aggregated reports in support of institutions' research-based quality improvements and needs assessments.

7. BACKGROUND

The Institute of Medicine (IOM) Report, *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs* (2008), declares that psychosocial support is an essential part of cancer care. The IOM has further indicated that care for cancer patients ought to be patient-centered, and that patient-centered care is a marker of high quality. Yet, to date, proper measurement and understanding of the psychosocial experience and related markers of quality care are lacking in the cancer field.

The Cancer Support Community, via its Research & Training Institute (RTI), seeks to fill this gap through its online Cancer Experience Registry.

The Cancer Experience Registry

Built on a web-based platform, the CER is designed to engage individuals impacted by cancer, and, via online surveys, identify trends and track psychosocial needs over time to raise awareness of the collective experience.

The Cancer Experience Registry is based upon the successful research model developed and implemented by CSC in 2009 for women with breast cancer: The Cancer Survivor Registry: The Breast Cancer M.A.P. (Mind Affects the Physical) Project. This project, funded by the Breast Cancer Fund of National Philanthropic Trust, examined the emotional and social needs of individuals diagnosed with breast cancer and tracked how their needs changed throughout their cancer experience. Based on the success of the M.A.P. Project, CSC launched the CER in March 2013 to engage a more diverse population of individuals living with any type of cancer, and in 2015 launched a Caregiver CER including surveys for cancer caregivers.

The CER is now available to anyone who has ever been diagnosed with cancer regardless of the time point in their cancer trajectory, including survivorship. The CER is also open to caregivers who provide any form of assistance to a relative or friend with cancer.

8. RESEARCH DESIGN AND METHODS

The research design is an observational, self-report study with opportunities for cross-sectional, longitudinal, and dyadic data collection. All CER surveys are housed and operate through the secure online survey platform, Voxco.

Research Surveys

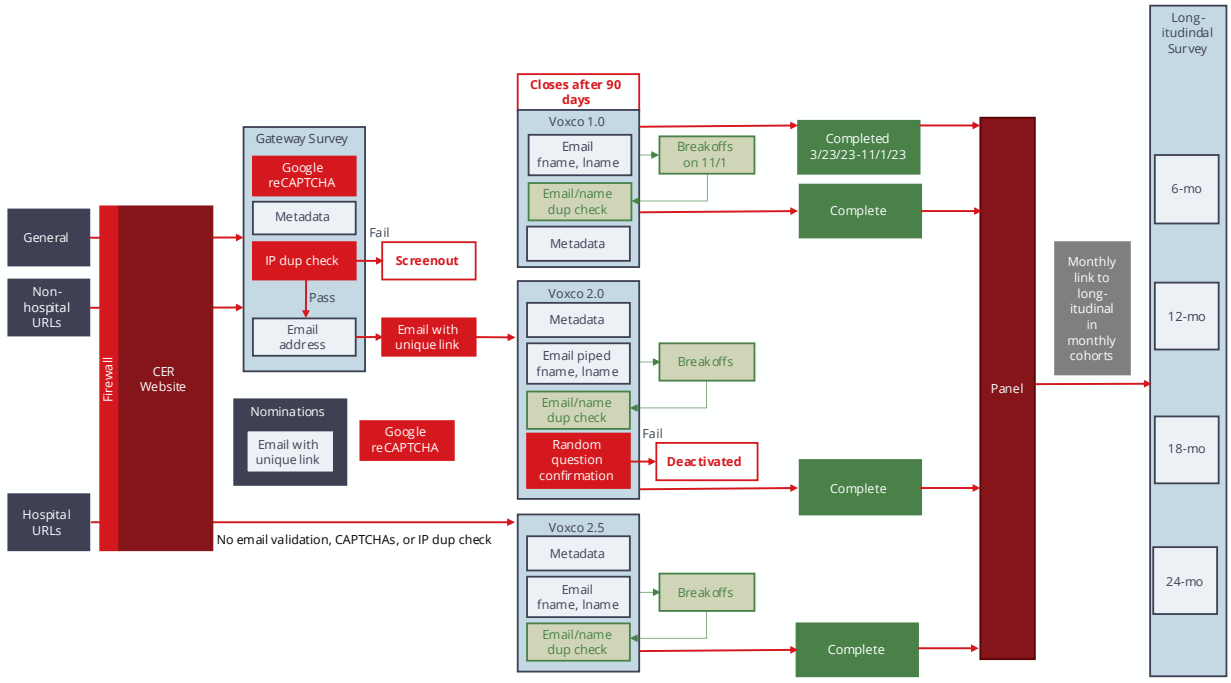
The CER consists of two distinct survey tracks: one for patients/survivors, and one for caregivers. Each track consists of a baseline survey and 6-, 12-, 18-, and 24-month follow-up surveys. Each track is also designed to house individual spotlight surveys that focus on a specific topic of interest (e.g., mental health). The baseline survey for patients/survivors consists of a core set of questions that are administered to all participants as well as additional diagnosis-specific questions for participants with that specific diagnosis (e.g., breast cancer, multiple myeloma, prostate cancer, etc.). These diagnosis-specific questions explore concerns that are uniquely related to a specific cancer diagnosis. Both the patient and caregiver baseline surveys take approximately 35 minutes to

complete; follow-up and spotlight surveys are shorter. The core (patient/survivor or caregiver) survey as well as the cancer-specific questions are developed with input from National Advisory Councils comprised of content experts in oncology, psychosocial research and behavioral practitioners, advocacy, policy, industry, as well as patients and caregivers (see Appendices I and J for surveys).

The survey is accessed via the Gateway Survey for participants using the General CER URL or any non-hospital or healthcare Unique CER URL (see Appendix K for the Gateway Survey questions and see Section 10 for more information on the various ways these can be accessed). The Gateway Survey asks participants to share their email address and collects metadata including IP address. The survey will flag any participants with the same IP address and who start the survey within 3 minutes of one another as spam and they will not be sent an invitation to start the CER Baseline Survey. All participants who pass the IP check will receive an email with a personalized link to begin the CER Baseline Survey (see Appendix H). Participants who access hospital or healthcare partners' Unique CER URLs will direct to the CER baseline survey immediately to prevent any complications of duplicate IP addresses during in-clinic recruitment. Please view Figure 1 below for additional details on this process.

Once potential participants navigate to the CER baseline survey, they are asked to provide their name, email address, and participant type (patient/survivor or caregiver). Participants then view the consent form and are asked if they provide consent to participate in the CER. Following consent, patients and caregivers complete their respective version of the baseline survey. After completing the survey with their initial selection, participants who identify as both a patient/survivor and a caregiver will be given the option to take the other survey. Participation is completely voluntary, and registrants may refrain from answering any question they do not wish to answer with the exception of a few mandatory questions including diagnosis, email, and date of birth. Responses to these items are required to ensure participant eligibility and functionality of the CER. In addition, once a participant begins a survey it remains open for 90 days, allowing participants to leave the website and return to complete their questions at a later time if they wish.

Figure 1.



Participant Support and Follow-up

Participants who reach the end of the survey will be redirected out of the Voxco platform to a Thank You page designed and hosted by CSC's digital team. This page contains a closing message and links to CSC resources. Participants who break off from the survey before completing it will immediately receive a pop-up message that includes the Cancer Support Helpline tollfree phone number. Once participants start the survey, they may become eligible to receive invitations for follow-up CER surveys including longitudinal surveys, spotlight surveys, and baseline update surveys. Eligible participants receive email invitations for these opportunities at the appropriate time (e.g., 6-, 12-, 18-, and 24-months post-baseline for follow-up surveys). These email communications contain unique links to access the follow-up survey and are generated and distributed from the Voxco platform. All follow-up surveys are optional, and participants can unsubscribe from emails at any time.

If a participant needs assistance before or while taking the survey, they can reach out to the research team by phone or email, and a research team member will provide technical assistance (see Appendix G) or support as needed to complete the survey. Once a respondent completes the consent form and provides their name, email, and patient/caregiver status on the first page, the applicable main survey will launch automatically. At the same time, an automated message will be sent to their email including their personalized unique survey link so they can access the survey again, picking up where they left off, should they break off or close the survey before finishing. Respondents will also be sent reminder emails should they not complete the survey within 30 days of starting (See Appendix H for email invitations and reminders).

Survey Security

To protect against bots and bad actors attempting to take the survey, CSC may implement some or all of the following security measures:

- **Implementation of Google ReCAPTCHA**
  - This would replace the existing custom captcha solution with one provided by Google.
- **Email/phone verification as part of the baseline survey**
  - Participants will be redirected to another survey where they will need to validate their code before continuing with the survey.
- **Input field validation**
  - Validating the initial screening process with a hidden input field that the research team would update on a regular basis.
- **Prevention of duplicate IP addresses on submissions**
  - Rather than blocking duplicate IP addresses outright, the research team may block duplicate IP addresses based on the time since a previous submission.
- **Other changes**
  - Move the capturing of Metadata to the beginning of the form to better assist in identifying bad actors/spam.
  - Adding reworded existing survey questions to a different section of the survey for additional verification checks against bots/bad actors

9. HUMAN SUBJECTS

Only eligible participants who agree to participate will be included in this study. Registrants (patients/survivors/caregivers) must provide online consent to participate in the CER survey. Eligibility criteria include: 1) anyone who has been diagnosed with cancer at any point in time in their life; or 2) anyone who is or has been a family caregiver or informal caregiver (i.e., relative or friend) for someone diagnosed with cancer; 3) 18 years of age or older; 4) ability to read and understand English; and 5) residence in the U.S., a U.S. Territory, or Canada.

10. RECRUITMENT

Cancer patients, survivors, and caregivers will be recruited to the CER through one of 5 ways:

1. **Organic Website Traffic:** Potential participants may access the CER webpage (www.cancersupportcommunity.org/registry) through the CSC website or search engine searches.
2. **General and Unique URL Advertisement:** CSC/CSC Partners will recruit participants through in-person and virtual networks and using the various recruitment materials provided in the attachments (See Appendices B-E) with the General URL (www.cancersupportcommunity.org/registry) or with a Unique URL (e.g., www.cancerexperienceregistry.org/join/CSCLA).
3. **Nominations:** Patients and caregivers can be nominated to participate in the CER by a counterpart in their patient/caregiver dyad (i.e., patients can nominate their caregivers, and caregivers can nominate their patients) (See Appendix H).
4. **Snowball Sampling:** Consented participants may refer new participants in their network to the CER (See Appendix H)

Organic Website Traffic

A link to access the Voxco CER landing page is available on CSC's CER webpage (www.cancersupportcommunity.org/registry). CSC's CER webpage is publicly available; therefore, anyone with internet access can find and access this link. As such, website traffic can result in organic recruitment to the CER.

General and Unique URL Advertisement

CSC and CSC Partners may recruit participants to the CER using a General URL or a Unique URL. A **CSC Partner** includes, but is not limited to, CSC Network Partners, advocacy organizations, hospital/healthcare partners, state coalitions, state health departments, and other research institutions. CSC uses a combination of the General URL and Unique URLs depending upon recruitment context and partnership. For example, a CSC Partner may choose to use a General URL if they are interested in receiving aggregated learnings about a specific-diagnosis, or they may choose to use a Unique URL if they are interested in receiving aggregated learnings about their specific community. Unique URLs are set up by CSC's digital team and used to track targeted recruitment efforts (e.g., a specific recruitment partner). A unique identifier will be embedded in each URL for identifying the source of recruitment. If potential participants utilize a unique URL to access CSC's CER webpage and chooses to access the survey (i.e., click a link to the Voxco CER landing page), the Voxco system will collect the unique identifier from the URL to determine the source of recruitment.

Outreach strategies include the **distribution of promotional materials** that include the General or Unique URL link, or QR code, for the CSC CER webpage. Outreach strategies may include outreach via email blasts, websites, newsletters, podcasts, webinars, online networks, and online patient and caregiver communities. This approach utilizes diverse promotional materials for the CER, including flyers, email messages, social media content, business cards, videos, and other materials (See Appendices B-E).CSC may also promote through other venues such as Internet search engine optimization and mass media. CSC and CSC Partners may tailor promotional materials to a targeted community. Tailoring may include specifying cancer type (e.g., bladder cancer), mentioning geographic location (e.g, Colorado), or identifying another characteristic (e.g., LGBTQ); CSC Partners may add their organization name in partnership with CSC, and/or add their logos.

CSC and CSC Partners may also recruit participants **at in-person settings** (e.g., healthcare facilities), during events or meetings, or **at virtual or hybrid events**. During these meetings, CSC and CSC Partners may use specialized promotional materials, explain the CER mission, discuss how to participate, provide information about local resources, and share the importance of participating in research. CSC and CSC Partners may provide incentives for those who attend an event or complete the survey. The proposed incentives (e.g., gas cards, hoodie sweatshirts, Starbucks gift cards) can vary but must not exceed $100 in value and may be provided to all attendees, to those who complete the survey, or awarded via a raffle. A member of the research team may follow up with interested participants who did not complete the survey (see Appendix C).

CSC and CSC Partners may support recruitment **by mailing** postcards, flyers, or letters to potential participants (See Appendices B & C). The mailing campaign will utilize the General URL or a Unique URL and take one of two approaches: 1) CSC Partners will provide the CSC team with mailing addresses to send postcards that invite recipients to join the study; or 2) the CSC team will provide CSC Partners with the promotional postcards and the CSC Partner will mail them directly to their constituents. The mailings may include an opportunity for the first participants (e.g., first 100 participants) who complete the survey using the unique URL provided to be entered into a raffle for an incentive worth up to $200. The winning participant will be notified by email.

Nominations

Patients and caregivers can be nominated to participate in the CER by a counterpart in their patient/caregiver dyad (i.e., patients can nominate their caregivers, and caregivers can nominate their patients). The nomination will prompt an email invitation. The email will include a link that will take participants directly to the CER survey. Each patient or caregiver will have a code embedded in the URL so that a dyadic dataset can be generated. Each numeric code will crosswalk to one patient or caregiver. CSC may also send reminder emails to nominated respondents (See Appendix H).

Snowball Sampling

To support an increased sample size, consented research participants will be asked via email to help recruit new participants for the Cancer Experience Registry. Participants who consented to the baseline survey will receive an email asking them to forward information about the Cancer Experience Registry (either the email text itself and/or an attached study flyer) to anyone they know who has been impacted by cancer. The research team will not collect names, email addresses, or any identifiers/other information on potential "snowball" participants; it will be up to the consented study participant to reach out to their own network as they see fit; additionally, it will be up to the future participants to contact the research team or sign up for the Registry on their own.

11. INFORMED CONSENT

Informed consent for the CER baseline survey will be provided electronically by checking an acceptance button prior to the respondent beginning the survey. See Appendix A for consent form. As part of this consent process, respondents agree to be recontacted for longitudinal and other follow-up CER surveys. Data from publicly available data sources may also be linked to participant responses. Any additional research opportunities in which CER participants are contacted about will require a separate informed consent process.

12. THERAPEUTIC ALTERNATIVES

As this is not a treatment study, there are no therapeutic alternatives.

13. POTENTIAL RISKS

There is minimal risk to taking part in the project. The questionnaire includes topics that can be of a sensitive nature that participants may feel uncomfortable answering. Participants are informed during the consent process that they do not have to volunteer information they do not want to share.

14. DATA MANAGEMENT PROCEDURES

The CER maintains procedural safeguards to protect information collected from participants who complete online surveys. Only trained members of the CSC research team will have access to study data. Responses from each survey will be stored electronically. All data will be stored on a password-protected computer server. Any data that is exported for analysis will be de-identified (i.e., will exclude any contact information) and analyzed on password-protected computers by trained research staff. Further detail on confidentiality is provided below. The CER system is hosted in a HIPAA-compliant infrastructure. In the case of a breach in confidentiality, an individual would be notified by CSC, and CSC would inform Salus of any such breaches.

15. CONFIDENTIALITY

Research records will be kept private according to all local, state, and federal laws. Trained members of the research team will be able to link contact information to the participant. This information will be kept secure and confidential. Names and identifying information will not be used in a way that anyone outside of the research team could identify participants, unless a participant has opted to be contacted about additional research, programmatic, or other relevant opportunities. Participants' email addresses will be used to invite participants to follow-up surveys and to provide them with updates about the CER and its findings. Participants may be sent reminders to complete their survey.

It is CSC's policy not to make Personal Information (i.e., individual information) available to anyone other than the CSC team involved in the CER. We will never share, sell, or rent participants' Personal Information without their prior permission or unless ordered by a court of law. Personal Information will only be made available to staff managing this information for purposes of contacting participants or sending emails based on participants' request for information. For the purpose of reporting to collaborating recruitment partners, we will provide aggregate findings but not individual data. Similarly, the results of this project may be published in scientific journals or presented at professional medical or psychological meetings; however, names or identifying information will not be used.

16. POTENTIAL BENEFITS

There may not be a direct benefit to study participants. Participation will be used to support greater understanding of the needs of cancer survivors and those living with the diagnosis, raise awareness about the challenges of people affected by cancer, and develop programs and services that will address the needs and improve the long-term quality of life of people impacted by cancer. Collective reports may be provided to collaborating and contracted organizations and sponsors to understand quality of care or member needs. Participants will also have access to summary reports and educational resources.

17. RISK/BENEFIT

It is possible that participants may find answering some of the questions upsetting. Participants do not have to answer questions that they do not want to answer. Participants can choose not to take part or leave the study at any time without penalty or loss of benefits to which they are entitled. In the event participants need social and/or emotional support, the Cancer Support Community has a toll-free helpline, which they can access over the phone at 888-793-9355, and free services, which can be accessed online at www.cancersupportcommunity.org. There is also a risk of loss of privacy.

18. EXPENSE TO SUBJECT

There will be no expense to participants as a result of their participation in this study.

19. PAYMENT FOR PARTICIPATION

There is no payment for participation in the baseline CER survey. There are a few exceptions related to special promotional activities listed under Section 10. Recruitment. Incentives do not exceed $200.

20. RESEARCH TEAM

Erica Fortune, PhD, is Vice President of Research at the Cancer Support Community's Research & Training Institute. She is the principal investigator of the Cancer Experience Registry (CER), an online

research study for cancer patients, survivors, and caregivers aimed to uncover the emotional, physical, practical, and financial impact of cancer. Dr. Fortune earned her Ph.D. in Cognitive and Experimental Psychology from the University of Georgia in 2013 where she was extensively trained on various research methodologies and psychometric approaches. Her research efforts in the past have focused on elements of judgment and decision-making as well as addiction. Her most recent research effort, prior to joining CSC, focused on how variations in medical decision-making, specifically how much patients trust their physicians and desire autonomy in their treatment choices, might be predicted by a combination of personality and behavioral traits.