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GROUPS: Measuring Success of an Educational Video About Saving Medical Records After a Cancer Diagnosis

THESIS

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MASTER OF SCIENCE

in Genetic Counseling

by

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DEDICATION

For

Maggie Torgerson

my forever friend, lover of biology, who taught me to not sweat the small things
and how life-saving this information could be

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ABSTRACT OF THE THESIS

GROUPS: Measuring Success of an Educational Video About
Saving Medical Records After a Cancer Diagnosis

by

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Family medical history from previous generations often goes unpreserved, and critical records either lost or discarded. Historically, cancer survivors received information in a Survivorship Care Plan (SCP). However, SCPs are not always provided; when they are, usefulness varies when pieces are missing, such as genetic test results and updated family history. Certain medical records after a cancer diagnosis should be saved as they allow other providers to accurately assess cancer risk and provide appropriate screening recommendations for individuals with cancer and their family members.

Participants viewed a 5-minute educational, animated video (available in English and Spanish) that included an acronym checklist (GROUPS/GRUPOS) to teach which medical documents should be collected after a cancer diagnosis, why they are important to keep, and how to save them for subsequent generations. Identical questions were asked before and after the video to measure knowledge gained from the educational tool.

Statistically significant results were observed for the difference between the overall pre and post scores ($p<0.001$), all four domains: knowledge of medical records to keep after a cancer diagnosis, how to locate these records, awareness of the importance to save them, and confidence in saving them ($p<0.001$), and 14 of 16 individual survey questions ($p\leq0.001$). Data showed improvements in "Knowledge that saving medical records is helpful" ($p=0.006$) and "Knowledge of 'S'" (Surgical histories) in the list of GROUPS records ($p=0.002$), but statistical significance was not observed for these pre and post score differences. Two categorical variables were statistically significant: sex for knowing "R" (Relatives with cancer) ($p<0.001$); females knew more than men about their relatives with cancer and age at time of survey for overall score ($p=0.001$); participants 50 years or older showed greater overall improvement than those younger than 50; indicating these variables did influence participants' scores.

An overall score improvement of 14.2% was observed across study participants. The largest improvement (38%) was confidence in knowing which records to save after a cancer diagnosis. Participants felt the video was helpful (89%), the GROUPS checklist was useful (89%), and 92% felt motivated to find and save the recommended documents.

I. INTRODUCTION

1.1 Importance of an accurate family cancer history

The presence of a family cancer history can impact an individual in a myriad of ways. Depending on factors such as family structure and age at diagnosis, a cancer diagnosis could affect one's psychological and physical health, challenge personal finances, and impact familial and personal relationships. Along with the emotional, financial, and social effects, another critical aspect of a cancer diagnosis is understanding, documenting, and preserving an accurate family cancer history as it may impact other individual family members as well. Comprehending and having access to an accurate family cancer history can influence one's cancer screening and genetic testing recommendations and may be instrumental in future medical care (Kelly et al., 2015 and Johnatty et al., 2017).

A family cancer history consists of specific information such as which family members have received cancer diagnoses, the location(s) of cancer(s), age(s) at diagnosis, completed surgeries and/or treatments, as well as any genetic testing and/or other laboratory results. A self-reported family history is the main tool providers use for cancer screening and prevention strategies, and it also helps providers develop genetic testing recommendations for people with and without cancer. The majority of cancers are not hereditary and occur due to sporadic events which allow body's cells to grow uncontrollably and potentially spread to other parts of the body. In these instances, the cause of cancer is explained as multifactorial, due to a combination of one's genes and environment (thousands of exposures that occur during one's lifetime). As cells in the body age and encounter environmental exposures (i.e., individual diet,

medications, chemicals, toxins), the chance for them to grow out of control and into cancer also increases. A much smaller portion of cancers, approximately 5-10%, are hereditary (American Cancer Society, 2020). In this situation, one is born with a genetic predisposition for cells to grow into a cancer. Hereditary cancers tend to follow specific patterns that we can trace through a family's history. Most are inherited in an autosomal dominant fashion, in which a single copy of the disease-associated mutation is enough to significantly increase the risk for cancer. In these hereditary cancer syndromes, an affected person's first-degree relatives (parents, siblings, and children) have a 50% chance of also having the mutation themselves. Fewer cancer syndromes are inherited in an autosomal recessive pattern of inheritance, in which both copies of the gene (or in some case more than one gene) in each cell have mutations for a particular cancer syndrome. Importantly, in contrast to sporadic cancers, hereditary cancer syndromes require long-term care and management as well as recommended increased screening procedures to detect cancers at an earlier stage, or to prevent their occurrence through surgery, such as a colectomy for those with Familial Adenomatous Polyposis (FAP) or oophorectomy for those with Hereditary Breast and Ovarian Cancer Syndrome (HBOC) (Rahner et al., 2008).

An accurate estimate of an individual's risk for cancer is greatly influenced by the self-reported family history: histories suggestive of a possible hereditary cancer syndrome or those of certain types of cancers or earlier ages of diagnosis are typically classified as high risk for developing cancer within the lifetime (Murff et al., 2004). An inaccurate family cancer history can result in either missed screening opportunities in the case of a false negative report, or create unnecessary precautions, concern, and worry in a false positive report. In both

situations, reporting an accurate family cancer history arms an individual and treating providers with information to correctly recommend appropriate screening and prevention measures, and potentially future treatment.

1.2 Family history for risk calculation models

An accurate family history, cancer type, and age at diagnosis are factors providers use to refer a patient for genetic counseling and/or recommend genetic testing. This information is also critical for individuals to be aware of when using risk calculators. Cancer risk calculators can determine a person's risk for either the probability of having a hereditary cancer syndrome or the risk of developing a specific type of cancer in their lifetime. These algorithms create individualized predictions with the use of one's personal health history, family history, and current genomic advancements (Freedman et al., 2005). Both healthcare providers and patients use risk calculators such as the Gail model, Tyrer-Cuzick, BRCAPANCPRO, and PREMM5, to assess risk for breast, ovarian, colorectal, endometrial, melanoma, lung, pancreatic and prostate cancers (Blackford et al., 2021; Usher-Smith et al., 2014; Usher-Smith et al., 2015). The Tyrer-Cuzick model, for example, estimates the likelihood of a woman developing breast cancer in the next 10 years and over her lifetime; its use as a screening tool at the time of a mammogram has influenced women to meet with a genetic counselor and determine genetic testing eligibility. The American Cancer Society (ACS) and the National Comprehensive Cancer Network (NCCN) recommend MRI screening in women with a lifetime risk of breast cancer ≥20% as estimated by the Tyrer-Cuzick model. While the Tyrer-Cuzick model overestimated risk for most women in a cohort study by Bretnall et al. (2018), the study still found, when used in conjunction with breast imaging, it remained a valid long-term predictor of a woman's risk to

develop breast cancer. Another study utilizing the Tyrer-Cuzick model overestimated breast cancer risk for women with atypical hyperplasia and lobular carcinoma in situ (LCIS) (Boughey et al., 2010 and Valero et al., 2020). Despite some level of predictive inaccuracy, these studies remain a good reminder to users of these validated cancer risk models: it is essential to weigh any potential weaknesses of a risk model to predict an individual's unique risk for cancer.

These risk models are likely to incorporate scientific advances to improve predictions of future cancer risk. A recently developed software, PanelPRO, claims it can evolve with future scientific advances made for genes associated with an individual's increased risk for cancer. Current models focus on genes that have been well established through scientific discovery as being associated with one or several types of related types of cancer (i.e. BRCA1 and BRCA2 to model risk of pancreatic, breast, and ovarian cancer in the BRCAPANCPRO model) (Blackford et al., 2021). PanelPRO seeks to incorporate a larger number of gene mutations and adapt as new discoveries are made in cancer genetics, to calculate carrier probabilities accurately and comprehensively for a wide array of cancer susceptibility genes as well as future cancer risk (Jacobs, 2021). One crucial piece of PanelPRO's software is that it calculates these individual risks using detailed information from one's family history.

If the presence of a family cancer history is suspicious of a hereditary cancer syndrome, details about one's personal and family history are often crucial in deciding whether genetic counseling and testing is recommended (Mai et al., 2011). Currently, for an unaffected individual with a family history suggestive of a cancer predisposition syndrome, a specific risk calculator can be used to determine if genetic testing could be beneficial (Domchek et al., 2003; Kauff and Offit, 2007; Lindor et al., 2007). Depending on the type(s) of cancer(s) present in a

family cancer history, genetic testing is recommended by NCCN if the risk model has predicted a high enough risk. For instance, testing is indicated when a risk model (e.g. Tyrer-Cuzick or CanRisk) has a predicted probability of >5% for a BRCA1/2 pathogenic variant (NCCN Guidelines Version 2.2022 High-Risk Breast, Ovarian, and Pancreatic). Lynch Syndrome (LS) is the most common hereditary cause of colorectal cancer, accounting for approximately 3% of all colorectal cancers and up to 2% of endometrial cancers (Biller et al., 2019). The PREMM5 model is an evidence-based calculator to aid providers in assessing those at risk for LS. Three family cancer history data elements are required for computing a risk:

1. A personal or family history of colorectal cancer, endometrial (uterine) cancer, or other LS-associated cancers
2. Types of cancer and ages at diagnosis of first-degree relatives from the affected side of the family (parents, siblings, children)
3. Types of cancer and ages at diagnosis of second-degree relatives from the affected side of the family (grandparents, grandchildren, aunts, uncles, nieces, nephews)

A referral to a genetic counselor is recommended when the PREMM5 model-predicted risk is 2.5% or higher to have a mutation in one of the genes associated with LS: MLH1, MSH2, MSH6, PMS2 or EPCAM (Kastrinos et al., 2017 and NCCN Guidelines Version 2.2021 High-Risk Colorectal Cancer). However, Pande et al. (2019) found patient self-reported family cancer history was suboptimal for estimation of LS risk, and therefore, would impact a referral to see a genetic counselor. Further, only 20.9% of study participants who reported a family history of cancer were able to provide all three family history cancer data elements required for running PREMM5. For those reporting any data element of family cancer history, less than a quarter (21.7%) listed an age at diagnosis for their relatives' cancers. For most cancer types, a younger

age of diagnosis than expected is a critical component in evaluating a possible hereditary predisposition. In addition, the age of diagnosis is often a crucial requirement to meet NCCN Guidelines for genetic testing. In this example, for someone seeking an individualized risk for LS, they would not be able to calculate the PREMM5 model-predicted risk without age of diagnosis information and they may have further difficulty fulfilling requirements put forth by NCCN for genetic testing to evaluate for LS.

Prior to 2021, without a personal history of cancer, recommendations for genetic testing for LS by NCCN required one of the following (NCCN Guidelines Version 3.2019 High-Risk Colorectal Cancer):

1. A known LS pathogenic variant in the family
2. At least one 1st degree relative diagnosed with a colorectal or endometrial cancer before the age of 50
3. At least one 1st degree relative diagnosed with a colorectal or endometrial cancer and a synchronous or metachronous LS-related cancer (regardless of age)
4. At least two 1st degree or 2nd degree relatives with LS-related cancers (including at least one diagnosed before the age of 50)
5. At least three 1st degree or 2nd degree relatives with LS-related cancers (regardless of age)
6. A 5.0% or greater risk calculation from PREMM5 predictive model

In May 2021, the NCCN reduced the PREMM5 score threshold from ≥5% to ≥2.5% (NCCN Guidelines Version 1.2021 High-Risk Colorectal Cancer) and testing was recommended based on this lower PREMM5 score threshold and providers' clinical judgment. Mittendorf et al. (2021) recently published a paper demonstrating their adaptation of the provider-focused PREMM5 model into an electronic tool for patients to use. PREMM5 was originally designed to help

healthcare providers obtain a streamlined family history to identify individuals who should undergo genetic evaluation for LS. Early implementation has begun for PREMM5 to be utilized instead by patients to assess risk for LS.

Family history is an important factor for assessing one's own risk of cancer but, sometimes family dynamics result in poor accuracy due to factors such as the degree of relatedness, level of education, type(s) of cancer(s), and the complexity of the diagnoses (Qureshi et al., 2007). Often, reported family histories are not based on written documentation and instead rely on communication between family members that is verbally passed between generations. Therefore, there may be less accurate histories reported that will then result in inaccurate risk assessments for a hereditary predisposition to cancer. Furthermore, research has shown that under-reporting is far more common than over-reporting, with sensitivities ranging from less than 50% to as high as 98% depending on the cancer site and several types of cancer may not be accurately reported because they tend to cause confusion (i.e., reproductive tract cancers and those of similar organs, such as rectal or small intestine) (Murff et al., 2004).

Case control studies have compared the accuracy of family cancer histories and amount of over or underreporting for those affected and unaffected by cancer. Chang et al. (2006) observed lymphoma patients were more likely than case controls to accurately report any family history of cancer, regardless of cancer site. However, other studies have found no consistent difference in the accuracy of family cancer histories between affected and unaffected individuals (Mitchell et al., 2004 and Soegaard et al., 2008). A consistent finding among researchers is that individuals tend to have a more accurate knowledge of family cancer history for those who are more closely related (King et al., 2002 and Ziogas et al., 2003). A study

by Ozanne et al. (2012) found underreported family cancer histories were proportional to the higher degree of relatedness to the proband. This consistent pattern implies these histories are more likely due to a looser connection with more distant relatives rather than a lack of knowledge about their cancer diagnoses.

A recent study published in 2021 (Liu et al.), investigated the influence of the presence of a family cancer history on breast cancer characteristics (i.e. stage of tumor, lymph node involvement, ER/PR and HER2 status) at the time of diagnosis. Researchers separated people with breast cancer into three groups: family history of breast or ovarian cancer (FHBO), family history of other cancer (FHO) and no family history of cancer (non-FH). Results showed 19.2% (N=1484) of those with no family history of cancer (non-FH) had a significantly high proportion of stage III cancer compared to those with a family history of breast, ovarian, or any other type of cancer. These data suggest individuals with a family history of cancer may be diagnosed at a lower stage of cancer than compared to individuals with no family history of cancer.

1.3 Medical Records: Barriers to saving and locating necessary records

Cancer diagnosis details are recorded in a patient's medical record and typically hold valuable information both for the person diagnosed with cancer and their family members. This information can be helpful for the diagnosis, prognosis, treatment options, and recommendations for follow up care (Bariani et al., 2019). Furthermore, if there is information suggesting a possible hereditary cancer syndrome, this information is extremely beneficial to family members and may potentially affect recommendations for their own screening and care. However, this wealth of information after a cancer diagnosis and treatment is often poorly

understood, misplaced, or discarded by the patient and/or family. Patients and family members may feel overwhelmed and frustrated to be faced with having to know what is important to keep and to organize it in a meaningful and useful way.

Unruh and Pratt et al. (2008) completed a qualitative study to assess obstacles cancer patients faced when organizing the vast amount of health information accrued over a cancer diagnosis and management of care. This study revealed four main areas as barriers for one's individual health information: emotional, scalable, temporal, and functional.

> "Emotional: Cancer survivors may face emotional responses to this information, having survived an insurmountable cancer diagnosis and treatment."
>
> "Scalable: The task of organizing a large amount of data, often from multiple specialists and offices, may be deemed too difficult or overwhelming of a task."
>
> "Temporal: Over time, a once effective organization strategy may no longer work with the accrual of more medical records. Or, due to being ill and unable to keep up with paperwork amidst appointments and treatments, there may be medical records and information a cancer survivor does not remember or understand the importance of."
>
> "Functional: survivors may simply not understand or know how best to use the various pieces of medical information. For example, from the perspective of records being helpful to understand family members' risk for cancer, a survivor's genetic test results or pathology results may be best kept separately from insurance documents or billing statements."

Medical records and related information can be kept electronically or on paper, and often, most institutions use a combination of these. Depending on where the records are kept, state laws in the United States vary on medical records retention (Table A-7. State Medical Record Laws: Minimum Medical Record Retention Periods for Records Held by Medical Doctors and Hospitals. (2008)). This poses two upfront challenges for patients and family members to obtain a copy of these valuable medical records: some information may be missing between

electronic and paper copies and between providers and offices; and, if these documents aren't separately preserved by a patient/family in a timely manner, they may be difficult or impossible to track down years later.

1.4 Survivorship Care Plan: Challenges with implementation and delivery

In 2006 the Institute of Medicine (IOM) stated, "once they complete their primary cancer care, every cancer survivor should have a comprehensive care summary and follow-up plan that reflects their treatment and addresses a myriad of post-treatment needs to improve their health and quality of life." (Lost in Transition, 2006) This was the genesis of the Survivorship Care Plan (SCP). The purpose of the SCP is to provide the survivor with an individualized care plan and create a smooth transition from oncology to follow-up care (Chaput, 2018). The SCP contains a comprehensive summary of cancer history, treatments, and follow-up recommendations. The intent of the SCP is simple, but implementation is challenging and any shortfalls lead cancer survivors and their family members to either receive an incomplete SCP or no SCP at all. Seven years following the IOM's 2006 recommendation, only 20% of cancer care providers reported "always or almost always providing SCPs to patients" (Forsythe et al., 2013) and, despite the numerous benefits of receiving an SCP and recommendations by the Institute of Medicine and American College of Surgeons Commission on Cancer (CoC) that all cancer survivors receive one, most healthcare centers are not consistently providing them to patients (Blanch-Hartigan et al., 2014).

In a recent survey, the majority of oncologists perceived SCPs to be valuable and endorsed their creation for patients. However, this study also found a small proportion (3-20%)

of the oncologists surveyed believed that no component of the SCP was useful to either a primary care physician (PCP) or to a patient (Haggstrom et al., 2021). This finding suggests that there is still reservation to complete them per the IOM's 2006 recommendation. From this data, future efforts to simplify the SCP for efficiency and usefulness to all providers and patients may help to alleviate any existing resistance from providers to complete them.

One of the most prominent challenges to SCPs being delivered to all cancer patients is the time and resources required to make these plans. Average time spent on creating one plan in a study by Dulko et al. (2013) was 53.9 minutes. This study surveyed providers in Vermont from both an urban academic medical center and rural community academic cancer center. Another survey conducted by the ACS reported providers of CoC-accredited hospitals were spending anywhere from 45 to 120 minutes to gather data and prepare the SCP (Santiago, 2017). In a qualitative study, Hewitt, et al. (2007) found that while physicians providing oncology care *believed* in the value of providing SCPs to patients, they were still less-inclined to create and provide them because of the lack of resources and time available; doing so would detract from their ability to complete other required reports and meet necessary commitments.

Beyond the time required to create an SCP, cancer specialists cite insufficient organizational resources, lack of training, reimbursement, and templates as additional barriers to SCP development (Birken et al., 2013 and Merport et al., 2012). Online organizations, such as Livestrong and American Society of Clinical Oncology (ASCO), created templates as early as 2011 to enhance the effectiveness of SCPs. After several consortiums and through provider feedback regarding the barriers to creating SCPs, Livestrong achieved consensus on a list of 20

essential elements to include in a survivorship care plan and included them in their online template ("Survivorship Care Planning Template", 2014).

At the Essential Elements of Survivorship Care Meeting held September 15-16, 2011, it was decided "genetic testing would not be an essential element to the Livestrong SCP template until more progress is made in genomic science" (Rechis et al., 2011). Other institutions and providers have developed and continually revised their own templates over the past decade for use within their patient populations and have adjusted these templates to include items such as genetic testing, in line with following updated genomic discoveries in cancer genetics. Having a standardized template was a barrier cited by providers as they implemented these plans – and while some have adapted their own template, there is still no one standardized SCP template for all providers to use; hence, resulting in another challenge for survivors to consistently receive a plan and have it contain the same helpful summary of their care to have for their records and for their families.When SCPs are provided to cancer survivors, their usefulness varies as there is no "standard" delineating which information an SCP should contain such as genetic test results and updated family history (Birken et al. 2019 and Daudt et al. 2014). While this flexibility allows for institutions and providers to continually improve and personalize the plans they give to their patients, there may be critical elements missing from the plans entirely.

1.5 SCPs: Inequality among SCP recipients

Beyond the barrier of resources required to create these plans for cancer survivors, studies reveal inequalities among those who receive an SCP. Factors affecting a receipt of an SCP include medically underserved populations, type of cancer, and social determinants (Benci

et al., 2019; Tawfik et al., 2021; Timsina et al., 2021). Medically underserved populations are at a risk of inadequate follow up care after cancer treatments. By sheer definition, these patients have a lack of access to personal health services. Without a summary of care following cancer treatment, they are at an even greater disadvantage to be lost to follow-up care, understand what is recommended for medical management, and/or be able to communicate their medical history to their family members. A recent study published by Tawfik, et al. (2021) at the University of New Mexico Comprehensive Cancer Center (UNM CCC) recounted their success in creating SCPs for cancer survivors in rural communities outside Albuquerque, New Mexico. This patient population has a low socioeconomic status (just under 20% poverty rate), and ethnic minorities include Native American and Hispanic (10% and 48%, respectively). The team was able to complete SCPs for this medically underserved patient population and sent plans to survivors' primary care physicians. However, the study team was discouraged to find receipt and integration of the SCP at the primary care setting was extremely poor; the research team from UNM CCC sent 77% of SCPs for their cancer survivors to a provider's office, but only 8% were confirmed as having been received and a mere 5% were implemented into the practice and care for the cancer survivor.

Rural patients are less likely to receive an SCP and may face obstacles such as limited access to resources and a lower socioeconomic status in comparison to those in urban settings (Tawfik et al., 2021 and Rowe et al., 2020). Another study by Ko et al. (2020) narrowed in on a population of Latina breast cancer survivors in a rural US-Mexico border region and was consistent the aforementioned study. To remedy this at a local level, a team of social workers, public health experts, and clinical psychologist researchers from San Diego State University and

University of California, San Diego conducted a qualitative research study to develop an SCP program for rural Latina breast cancer survivors. They used SCP templates modeled from ASCO and Journey Forward and collected survivors' preferences and opinions to improve plans given to this population living near the United States/Mexico border. Results from the study provided insight for providers on how SCPs may be tailored to fulfill its intended educational role for this specific population of cancer survivors. Data revealed several challenges these patients faced: a lack of knowledge of treatment information, lack of proactive health behavior, gaps in information for care coordination, psychological distress, and difficulty retaining health information. An SCP could directly help in at least two of these areas: improving knowledge of treatment information and easing the retention of health information.

A similar study (Burg et al., 2009) led focus group discussions with breast cancer patients recruited from members of the "Sisters Network" (a national African American organization with regional breast cancer support groups) and urban public health department outpatient clinics serving many minority patients. They reviewed the ASCO SCP template to obtain participants' feedback on the utility of the tool for their use. It was viewed as important, but too technical, and did not contain enough helpful information on side-effects and resources for self-care. One participant shared her perspective on what she would have hoped to have been told and included in her SCP. She desired a more personalized summary, written in a more easily understood fashion, and one that would have addressed her concerns and anxiety:

> *"Much of my anxiety started once I stopped treatment because it was like, now what am I doing? I'm a sitting duck. As long as I was having treatment I was doing something about my cancer. I would have liked for them to talk to me about symptoms of metastases to be aware of. I would have liked to know about genetic counseling because I have kids*

and I was anxious for them. Talk to me about further imaging, blood tests, and scans. Don't tell me no, talk to me about the pros and cons." (Burg 2009)

Timsina et al. (2021) published statistically significant evidence for social determinant factors that influenced which survivors were likely to receive an SCP. Survivors were more likely to receive a plan if they were married or cohabitating; had received at least one college degree; and had medical insurance. Survivors who were widowed, divorced, or separated were 0.72 times less likely to report having received an SCP than those who were married or cohabitating. Of survivors who were widowed, divorced, or separated, 33% reported receipt of an SCP compared to 41% of those who were married or cohabitating. Twenty-six percent of survivors without medical insurance received an SCP compared to 39% of those who had medical insurance. It could be argued that survivors in these groups (unmarried or living alone, lower educational achievement, and/or without medical insurance) would likely receive more benefit from receiving an SCP. Lower education status has historically been associated with health inequality and increased mortality rates (Zajacova et al., 2018). Despite this argument that an SCP would be valuable and improve these survivors' own healthcare and medical management, these social determinant factors have no predictive value in whether a survivor has other family members and subsequent generations who would rely on this information and could benefit from understanding and having it to use for themselves in the future.

Beyond ethnicity and gender, another factor that affects whether a patient is likely to receive an SCP is the location of cancer. A convenience sample study was done at the University of Pennsylvania on 46,408 SCPs generated between 2007 and 2016 using an internet-based survivorship resource. It effectively asked nationwide survivors of 15 different

types of cancer if they had received an SCP and modeled predictive demographic and treatment factors associated with receipt of an SCP. The three top predicting factors for whether a survivor received an SCP were: type of cancer, type of healthcare provider, and geographical region of the United States. Of the study population, 60% of lung and prostate cancer survivors received a care plan and 62% of breast cancer survivors received one. In contrast, pancreatic and liver cancer survivors were among the least likely to receive a plan as less than 45% in each survivor group received one. Similarly, fewer than 40% of melanoma survivors reported receiving a plan. The study also found that of those who received a plan, they were equally cared for by either an oncologist or PCP (44% and 43% respectively), however, when both an oncologist and PCP were involved, 63% of survivors reported they received a care plan from their team of health care providers. Survivors were similarly distributed in the United States and divided into four regions: Northeast, South, Midwest, and West. Those in the Northeast were least likely to report receiving an SCP (45%) while those in the Midwest (55%) and West (57%) were most likely to receive one. Cancer survivors living in the Southern region of the United States were equally divided in having received an SCP; 50% reported having received one and 50% did not (Benci et al., 2019).

Two years earlier, researchers looked at a similar predictive model of SCP receipt and focused only on survivors of skin cancer. They found SCP plans were received at a higher rate for skin cancer survivors than in the 2019 study: almost half with melanoma (47%) and nonmelanoma (52%) skin cancer reported receiving a plan. Interestingly, one of the largest predictive factors they found to influence one's receipt of a plan was the survivor's current age: survivors who were 70+ years were more likely to have received one than those who were

either younger than 35 or those between the ages of 35 and 70 years old (Benci, 2017). For those older than 70 years of age, 70% received a care plan versus 40% in the younger two age groups. This finding differs from several other studies that found younger survivors were more likely to receive an SCP. In Timsina et al. (2021), when bucketed age groups are comparable to Benci's findings (2017) associated with age and receipt of an SCP, 48% of those younger than 35 years old and 42% of those between the ages of 35 and 64 received a plan. The oldest group, those 65+ were the least likely (33%) to receive an SCP. One possible reason for this discrepancy is the definition of age as the time of diagnosis vs the time of the study. However, age is an important factor in SCP receipt because if younger cancer survivors are less likely to receive a plan, this may result in a snowball effect of the next generation lack of knowledge of their family cancer history. In addition, cancer diagnoses at younger ages are more often associated with the presence of a hereditary cancer syndrome in the family. Regardless of age, if an individual with cancer dies before treatment is finished or they decide not to proceed with treatment, an SCP is never created nor received; leaving family members without these records and faced with the challenge to locate them after their loved one has passed.

1.6 SCPs: Plans are received, but some are incomplete

In some instances, plans are received as intended, but portions are either incomplete or missing entirely from the comprehensive plan. A chart review of breast cancer cases completed at five Chicago federally qualified health centers (FHQCs) and done within five years of cancer diagnosis, revealed missing elements to SCPs. In 2014, at the time of the chart review, American College of Medical Genetics and Genomics (ACMG) guidelines for HBOC syndrome stated the following regarding genetic testing: "Referral should be considered for any individual with a

personal history of or first-degree relative with breast cancer diagnosed at or before age 50" (Hampel 2015). Thirty percent of the charts met criteria for genetic testing. Family history information was included in only 26 of the charts and genetic testing recommendations in two of them. Across these records, documentation of family history and genetic counseling referrals were absent from 76% and 98% of the charts, respectively (Hamlish et al., 2020). Genetic counseling notes were absent in 70% of SCPs analyzed by Daudt et al. (2014). Those that did mention genetic counseling advised the cancer survivor to seek it (without a referral), one noted a referral was given at the discharge meeting, and one mentioned genetic counseling in the record of care. If charts do not include essential information for a survivor to pursue appropriate follow up care and ACMG guidelines for genetic testing, then it is unlikely they, and any family members, would meet with a genetic counselor and be appropriately evaluated for genetic testing options and recommendations.

An SCP may be incomplete because there is no standard designation of who is ultimately responsible to complete the plans, as they are meant to be comprehensive and require input from many different providers and specialists. Forsythe et al conducted a survey in 2013 and found 20.2% of oncologists reported always or almost always providing SCPs while 13.4% of PCPs reported always/almost always receiving them. There is not only a discrepancy between these self-reported claims, but more importantly, these low percentages effectively confirm two things: first, plans are not being shared among physicians; second, patients are not receiving the benefit of having a summary of their cancer care. In addition, literature suggests there is a lack of communication between physicians with respect to goals for the patient and appropriate roles in follow up care. PCPs and oncologists were surveyed and asked what their expected roles

were in the following situations: follow-up for primary cancer recurrence, screening for other cancers, general preventive health care, and treatment of other medical problems. In 65% of the cases, both PCPs and oncologists felt they were solely and mainly responsible for recurrence of the primary cancer. In 23% of cases, both PCPs and oncologists felt strongly they should play a significant role in screening for other cancers (Cheung et al., 2009). Communication and collaboration by physicians ultimately have an impact on the comprehensive care of a survivor. In Benci's study (2017) of skin cancer survivors: those who were treated by a combination of both an oncologist and a PCP were almost twice as likely to receive an SCP in comparison to those treated by either an oncologist or a PCP alone (Benci et al., 2017).

Requirements for creating an SCP have drastically changed since the IOM originally outlined its recommendation for all cancer survivors to receive a written summary of their care in 2006. In 2010, all NCI-designated cancer centers (N=53) were surveyed on their perceived readiness to meet IOM's recommendation. Forty three percent of the NCI-designated cancer centers provided SCPs for cancer survivors of breast and/or colon cancer. Of these, however, none of them delivered SCPs that included all components recommended by IOM. "SCPs rarely included information about legal and financial resources, genetic testing, screening for relatives, even though these components were recommended in IOM's report" (Salz et al., 2013). Half of those who reported not delivering SCPs to their breast and/or colon cancer survivors confirmed they were planning to do it in the future. The majority of cancer programs began using an SCP because of professional societies' recommendations (Birken et al., 2013). In 2012, the CoC required all accredited programs to provide an SCP for all eligible patients and created percentage thresholds to be met: 25% of eligible patients by the end of 2016, 50% by 2017 and

75% by 2018. In early 2014, the CoC surveyed members on their readiness to implement SCPs and found that only 21% already had a SCP process in place for implementation and another 37% of programs were confident they could be ready by early 2019 to fulfill the requirement for every eligible cancer survivor to receive a plan. In 2020, CoC removed this requirement, but still encourages the creation of SCPs. Rather than requiring each person to have a written plan, an emphasis is placed on the process of survivorship care given to patients by a robust team of health professionals. Three services per year are required for the patient to receive and one of these can be an SCP (2020 CoC Standards of Care and Blaes et al., 2020). In a study published in February 2019, 37% of cancer survivors reported having received a written SCP. Unfortunately, this finding is consistent among other studies that measured the utilization of SCPs for cancer survivors across the United States (Faul et al., 2014 and Shay et al., 2018).

As of 2016, providing SCPs at the end of treatment were not considered standard of clinical practice in Australia (Pratt et al., 2016). However, in the United States, it is typically developed after the completion of one's treatment. Recent studies investigated alternate timelines for creating these plans. In 2019, a study proposed to make breast cancer survivors an initial care plan, another plan at 5 years, and a third one at 10 years (allowing for mid-hormone and completion of hormone treatment, respectively) (Boehm et al., 2019). It was pilot tested, successfully integrated at Tufts Medical Center, and allowed for updates to family histories, advancements in genetics, as well as evolving treatments and recommended screenings to be edited to each revision of the plan. A study at Johns Hopkins was completed in May 2022, evaluating three delivery models for SCPs (sending care plan to patients at home, giving care plan to patients during a clinic visit, or giving care plan during a clinic visit and

following up on the plan at another clinic visit 6 months later). The study compared how often follow up care recommendations were received for each model. They found the three SCP delivery groups did not differ significantly in the proportion of patients who received recommended follow-up care within 18 months. The percent of patients who received follow-up care ranged from 42 to 51% (Smith, 2022). The type of SCP delivery model did not affect the follow-up care received. All patients did receive an SCP, thus providing evidence for how useful information contained in an SCP can be for cancer survivors and helpful in encouraging their follow-up care.

Lastly, a summary of an individual's cancer care and treatment may never be made if they choose to not receive or do not complete their scheduled treatment(s). Therefore, a summary of genetic test results, surgeries, treatments, pathology reports, and other information kept in one's medical record may not be shared with family members, who could potentially benefit from proactive cancer screening based on their family member's history.

1.7 Overview and purpose of the study

Saving essential medical records after a cancer diagnosis is difficult because there may be barriers to finding them, barriers to receiving them, and/or a patient may not have an understanding of what is important to keep. Possible reasons why individuals do not receive an SCP include: a patient dies from their cancer and an SCP is never created; a survivor may not receive an SCP at all based on the time and resources available; or a survivor does receive an SCP but its contents may be incomplete and/or lack critical information. Each of these scenarios could affect subsequent generations and may prevent essential family cancer history from

being preserved that could be beneficial for family members' cancer screenings, testing recommendations, and future care. In addition to the challenges cancer survivors and their families face to find and save these valuable medical records, those who die from their cancer must not be overlooked. In this situation, when an individual passes away from the cancer, it may be arguably more imperative for family members to understand and preserve family cancer history. Therefore, this study focuses on improving the education and awareness for cancer survivors and family members of any person who has or had cancer; specifically in understanding which medical records should be preserved, why these are important to keep, and ideas on how to store them safely for years and subsequent generations to use.

The study's purpose is to measure the success of an educational video and simplified acronym checklist explaining which medical records should be saved after a cancer diagnosis for subsequent generations to use. Educational videos have proven to be effective teaching tools and outcomes have been measured in different fields of study and among various subjects. Like the purpose of this study, a pilot study measured change in knowledge and self-efficacy in a cancer setting after watching an educational video. Results from Wolf et al. (2019) showed the video was well accepted among oncology team members and it improved their knowledge and self-efficacy of malnutrition assessment.

The use of educational videos for the purpose of improving patients' knowledge and understanding have also previously been studied and measured in the cancer setting. In an undereducated population of breast cancer patients (the majority had less than a high school education), implementation of an educational video significantly improved understanding of breast cancer concepts involving treatment and management options (Bouton et al., 2011).

Improvements were also shown in a study for colon cancer patients who were selected to be in an educational video intervention study group. These participants showed significant improvement in knowledge of risk factors for colorectal cancer, age of risk, warning symptoms, 5-year prognosis, and were more compliant for colorectal cancer screenings (Gimeno-Garcia et al., 2009).

The main objective of this study is to provide education, using an animated video, to individuals with cancer and their spouses/partners/family members so other family members may benefit from having accurate histories to provide additional screening recommendations or genetic testing and counseling. The hypothesis is overall knowledge will increase, reflected by at least a 10% increase in comprehensive and/or domain scores after watching the educational video. A future aim of the study is to use this video for people with cancer and their families in a quality improvement study to measure continued increase in knowledge and awareness.

II. METHODS

2.1 IRB approval

The study was determined as exempt by the University of California, Irvine Institutional Review Board (IRB) Self Determination Tool. The IRB application was approved through the online Kuali system on October 4, 2021. Due to the patient population involving participants with cancer or potentially at risk for cancer, three additional boards reviewed the study protocol to grant CFCCC's approval for the study to be conducted. These boards are required to review and approve all human studies involving participants with cancer, at risk for cancer, any active intervention (e.g., behavioral or pharmacological) involving cancer or pre-cancerous participants, or participants of a study involving a specific cancer focus (e.g. program evaluations, quality of life survey health education etc.). A Disease-Oriented Team (DOT) at UC Irvine is a multidisciplinary group of basic, translational, clinical, and population health investigators who collaborate on a specific cancer area to further the translation of CFCCC discoveries through the pipeline towards interventional clinical trials. As the first component of the CFCCC's two-step clinical research review process, the focus of the DOTs is to ensure rigorous internal scientific review of protocols, curate the clinical trial portfolio, and drive innovation. The Gastrointestinal Oncology DOT reviewed the proposed protocol on Tuesday, September 28, 2021, and approved it.

UC Irvine's Cancer Center Protocol Review and Monitoring Committee (PRMC) reviews all human studies involving participants with cancer, at risk for cancer, any active intervention (e.g., behavioral or pharmacological) involving cancer or pre-cancerous participants, or

participants of a study involving a specific cancer focus (e.g., program evaluations, quality of life survey health education, etc.) The CFCCC's Protocol Review and Monitoring Committee (PRMC) is the second step in the review process for new cancer-related clinical research studies. The PRMC evaluates new studies for scientific merit, feasibility, overall portfolio balance, and potential to accrue populations that are underrepresented in clinical trials. The PRMC also monitors the progress and continued relevance of studies that are open to enrollment. PRMC conducted an initial review of the protocol on September 1, 2021 and approved the protocol on October 6, 2021. The CFCCC Data and Safety Monitoring Board (DSMB) is an independent body responsible for the safety of study subjects as well as the data integrity of the protocol. DSMB's review followed PRMC's approval of the protocol. The DSMB met on November 15, 2021, and approval was granted on November 17, 2021.

2.2 Video design

A five-minute animated video was created using Vyond animation software. It was created in both English and Spanish with closed caption. The video was translated to Spanish by Dr. Fabiola Quintero-Rivera, MD, FACMG and narrated in Spanish by Alex Palacios, MS, LCGC. Animation was provided by Vyond, and graphics were used by both Vyond and Canva software.

The video explained six medical records recommended to save after a cancer diagnosis and used an acronym in both English and Spanish as a tool to help educate participants and allow them to have better recall following the educational intervention tool. In English, the acronym is GROUPS, in Spanish, GRUPOS. G: genetic test results/ resultados de la prueba genética, R: relatives with cancer/recolectar informacion en canceres en sus familiares, O:

oncology note/ nota de Oncología, U: urine, blood, or biopsy result of a tumor/ubicar los resultados de la prueba de tumore(es), orina y sangre, P: pathology report/ informe de Patología, S: surgical history/someterse a cirugías. To maintain the acronym for both English and Spanish the "O" and "U" documents are switched in the order presented in the video and on the checklist. (Appendix A: GROUPS and GRUPOS checklists presented in educational video)

The importance of each individual document was discussed in the video:

> Genetic test results can assist a healthcare provider in either knowing which familial mutation is present in a family or which additional testing options may be recommended.
>
> Relatives with cancer is instrumental for providers to have an accurate family cancer history. Family history provides a wealth of information to determine one's risk for a hereditary predisposition to cancer and whether genetic testing is recommended.
>
> Oncology note is a helpful document that summarizes one's cancer treatment. It can provide a healthcare provider with previous or current treatments and their success, as well as details about the cancer itself.
>
> Urine/blood/biopsy of a tumor may have detailed information about the cancer and how it was diagnosed.
>
> Pathology report is a thorough report from the pathologist that contains details about the cancer diagnosis made from looking at the cancer cells under a microscope. This information about the cancer's level of invasiveness, size, shape, and stage can be insightful to another healthcare provider.
>
> Surgical history refers to saving records for surgeries the person with cancer had; these may be both surgeries done to remove the cancer as well as surgeries to prevent the potential growth or spread of a cancer.

2.3 Survey design

The survey was created using UCI's Qualtrics XM system and opened to participants on November 24, 2021. The survey consisted of a total of 47 questions; 27 of these questions were asked before participants watched the study's educational intervention (animated video) and

the remaining 20 questions were asked following the video. Ten of the 27 questions asked prior to the video gathered information about the survey participant's characteristics and cancer history information about the person(s) with cancer. Sixteen questions were asked before and after the video to collect participants' pre and post level knowledge and understanding of the GROUPS records. The final four questions of the survey asked for participants' feedback on the video as well as gauging how many GROUPS records they had previously collected. On December 10th, 2021, 16 days after the survey was initially opened, one question was added asking participants how/where they learned about the study. Of the 174 completed and valid responses used in the analysis, 42 participants answered this question about how they had learned about the study. A response was forced for all questions, but an open entry field or "I do not know/do not want to report" option was always available. The survey was available in both English and Spanish. It was designed by the research team, translated to Spanish by Dr. Fabiola Quintero-Rivera, MD, FACMG and Alex Palacios, MS, LCGC.

Pre-educational intervention survey questions included multiple choice demographic questions (sex, current age, ethnicity, education level, and number of children), questions about type of cancer diagnosed, number of primary cancers diagnosed, age at diagnosis, and genetic test results. Participants answered these questions for themselves as a cancer survivor, having a spouse/partner with cancer, and/or a 1st or 2nd degree relative with cancer. For participants who had more than one 1st or 2nd degree family member with cancer, they were asked to choose one family member and answer all questions about one particular family member with cancer. Branching logic was incorporated into the study design to allow

participants to answer all applicable questions and to prevent participants from being presented with questions that did not apply.

Branching logic was used to allow a participant to bypass any questions related to a cancer diagnosis for which they either did not have a cancer diagnosis themselves, have a partner/spouse with cancer, or have a 1st or 2nd degree family member with cancer. If any of these populations did not apply to the participant, the survey skipped to the next possible category for someone with a cancer diagnosis. Participants who did not have a connection to one of any of these three categories connected to a cancer diagnosis were not eligible to participate in the study. If genetic testing was not done, a follow up question asking about the results of the genetic test (i.e., negative result or a variant found for a hereditary cancer syndrome) was automatically skipped.

Participants were asked the same 16 questions before and after the educational intervention to measure the impact of the video upon study participants. These were categorized into four domains: knowledge of medical records to keep after a cancer diagnosis, how to locate these records, awareness of the importance to save them, and confidence in saving them. One 4-point Likert-scale question asked a participant's familiarity of each of the six recommended documents to keep after a cancer diagnosis and a second 4-point Likert-scale question asked a participant's level of confidence in knowing how to find each of these six documents. Four 5-point Likert-scale questions were asked about how helpful it is to know an accurate family cancer history, how helpful it is to save medical records, participants' confidence in knowing which records to keep and confidence in knowing how to save them. A maximum score of 16 reflected a full understanding of knowledge and awareness about the

documents and a high level of confidence in knowing how to save them. Additionally, after watching the video, an additional four questions were asked: participants selected “yes” for each of the GROUPS records they had already saved, and three 5-point Likert-scale questions asking for their assessment on the helpfulness of the video and checklist. These included a response for how helpful they felt the video was, how motivated they were to find these documents, and how likely they felt they would use the checklist to do this.

The 4-point Likert-scale question for assessing knowledge of the GROUPS documents included the following possible responses: “I don’t know what this means”, “I have seen this before but don’t know what this means”, “I probably know what this means”, and “I know this well and understand what this means”. The 4-point Likert-scale question for assessing confidence in learning how or where to locate records included the following responses: “I don’t know what this is”, “I have no idea who to ask or where to find this information”, “I might know who to ask or where to find this information”, and “I definitely know who to ask or where to find this information”. The 5-point Likert-scale questions asking about helpfulness of knowing one’s family cancer history, having records saved, and confidence in how to save them included the following possible responses: strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, strongly disagree. To compute difference in pre and post educational tool scores, Likert-scale questions were adjusted to a 1.00-point scale. The 4-point Likert-scale question values were 0.00, 0.33, 0.67, and 1.00. The 5-point Likert-scale questions were valued at 0.00, 0.25, 0.50, 0.75, 1.00. In both 4-point and 5-point Likert-scale questions, a higher value reflected a higher knowledge, confidence level, or level of agreement with the statement.

Participants had the option to enter a lottery for one of 100 $5 Amazon.com gift cards by providing their email address. Participants had the opportunity to enter this drawing by clicking a link on the initial study consent form before beginning the survey or at the final survey page after completing the study. Email addresses were collected and stored separately from survey responses and were used to distribute compensation.

2.4 Inclusion criteria and data collection

Inclusion criteria for the study: adults who have/had cancer, have a partner/spouse who has/had cancer, and/or have a 1st or 2nd degree family member (sibling, parent, aunt/uncle, niece/nephew, grandchild, or grandparent) who has/had cancer. Participants were instructed to pick one 1st or 2nd degree family member and answer all survey questions in regard to this one family member.

A total of 342 individuals began the English survey between November 24, 2021, and March 1, 2022. The entire English survey was completed by 254 participants. A total of 85 responses were marked as incomplete, meaning the participant never reached the completion page of the survey. Responses were automatically marked as incomplete after two weeks of inactivity. Partially completed and incomplete responses were excluded from the analysis. Of the completed responses, 87 were marked as fraudulent or bot-generated and were excluded from data analysis. Responses were determined to be fraudulent or bot-generated if any of the following conditions were met: nonsensical or irrelevant answers were provided for the free response question, identical survey responses were identified, multiple responses were submitted in rapid succession with similar answer patterns, answer choices conflicted or

contradicted other responses to survey questions. A total of 170 English responses were included in the final statistical analysis. A total of 8 participants attempted the Spanish version of the survey; 4 of these were considered complete and added to the final statistical analysis. Together, the statistical analysis included 174 valid and complete responses (170 in English and 4 in Spanish).

2.5 Recruitment

A flyer advertising the study was posted to the lead researcher's private social media pages on Facebook and Instagram on November 24, 2021. An amendment was made to the IRB protocol on November 30, 2021, to allow cancer survivor support groups to advertise the research study on their own private Facebook pages and social media outlets. Some cancer support groups required approval by administrators and the principal researcher provided all required documentation to meet these requirements. A reminder was posted on each of these social media pages on January 6, 2022. Flyers were physically handed out in high-risk UCI cancer clinics between November 24, 2021, and March 1, 2022. These clinics included: breast, pancreatic, and GI oncology clinics, as well as cancer genetics counseling clinic.

Emails with a brief description of the survey, a link to the survey, and the recruitment flyer were sent to 44 cancer support groups and contacts. Six cancer support groups required additional information to ensure research validity and agreed to post the flyer on their social media pages. The National Society of Genetic Counselors (NSGC) listserv for student research projects electronically advertised the study to all NSGC members on November 30, 2021, and a 2nd e-mail reminder was sent on December 8, 2021.

2.6 Consent

Individuals could access the survey either through a website link or QR code and could select either English or Spanish to proceed to the survey in the desired language. They were redirected to a study information sheet in the selected language before any survey questions were presented. The information sheet included contact information for the lead researcher and faculty sponsor, the purpose of the study, eligibility requirements, data storage information, optional Amazon.com gift card lottery procedures, and contact information for the UCI IRB. Participants were asked to verify that they met the eligibility criteria and consented to participate in the voluntary study.

2.7 Protection of participant privacy

Participants were asked to complete an anonymous online survey. Participants were able to access the survey via electronic devices with Internet access, such as mobile phones and computers. Participants' responses were protected throughout the entirety of the data collection process. Data was stored securely (through password and 2nd verification) and confidentially on the lead researcher's private UCI Qualtrics account. Data (with no identifiers) was also stored electronically on the lead researcher's personal computer. Data was password protected and maintained in an encrypted format upon completion of the study. Email addresses collected for the gift card drawing were stored separately from the survey responses and were destroyed after compensation distribution.

2.8 Data analysis

The lead researcher used the IBM Statistical Package for the Social Sciences (SPSS) Statistics version 28 to run the statistical data analysis. Counts and percentages were used for categorical variables: participants' demographics as well as information collected about the cancer diagnosis (type of cancer, number of primary cancers, age at diagnosis, treatments completed, and genetic testing results). Descriptive analyses of means and standard deviations were used for the pre and post test scores. To measure the success of the educational intervention, 21 mean comparisons (comprehensive score, four domains, and 16 individual questions) were calculated using Wilcoxon Signed Rank Tests in SPSS. This test was chosen because the data does not follow a normal curve, as determined by the Kolmogorov-Smirnov test of normalcy. Statistical significance of changes in test scores among the categorical variables were measured using the Kruskall Wallis independent test. Bonferroni correction was made for multiple comparisons; p-values <0.002 were considered statistically significant. An ANOVA was run on an additional analysis for the difference in pre score between those reporting children and a family member with cancer; p-values <0.05 were considered statistically significant for this additional analysis.

III. RESULTS

3.1 Demographics of survey responses

The demographic characteristics of the 174 participants are shown in Table 1, which displays the respondents' sex, language preference, education level, race or ethnicity, age at time of survey, their relationship to the person(s) affected by cancer, and number of children. Race or ethnicity was self-reported by study participants, and race or ethnic categories were defined by the principal researcher based on the US Office of Management and Budget's Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Flanagin et al., 2021). In this study, 10 participants (6%) self-reported as "more than one race or ethnicity", which included four (2%) identifying as Asian and White or Caucasian, four (2%) as Hispanic, Latino or Spanish origin and White or Caucasian, and one (<1%) as Middle Eastern or North African and White or Caucasian.

Most respondents were female (83%), had an education level of at least a college degree (82%), and were White or Caucasian (76%). Almost half of the study population (N=84, 48%) represented all three of these characteristics: female, had at least a college degree, and reported White or Caucasian ethnicity. The largest represented age group was 40-49 years old (28%), and the second largest represented age group was 50-59 years old (25%).

Table 1: Number and percent of demographic characteristics

Sex	**N**	**%**
Female	125	72

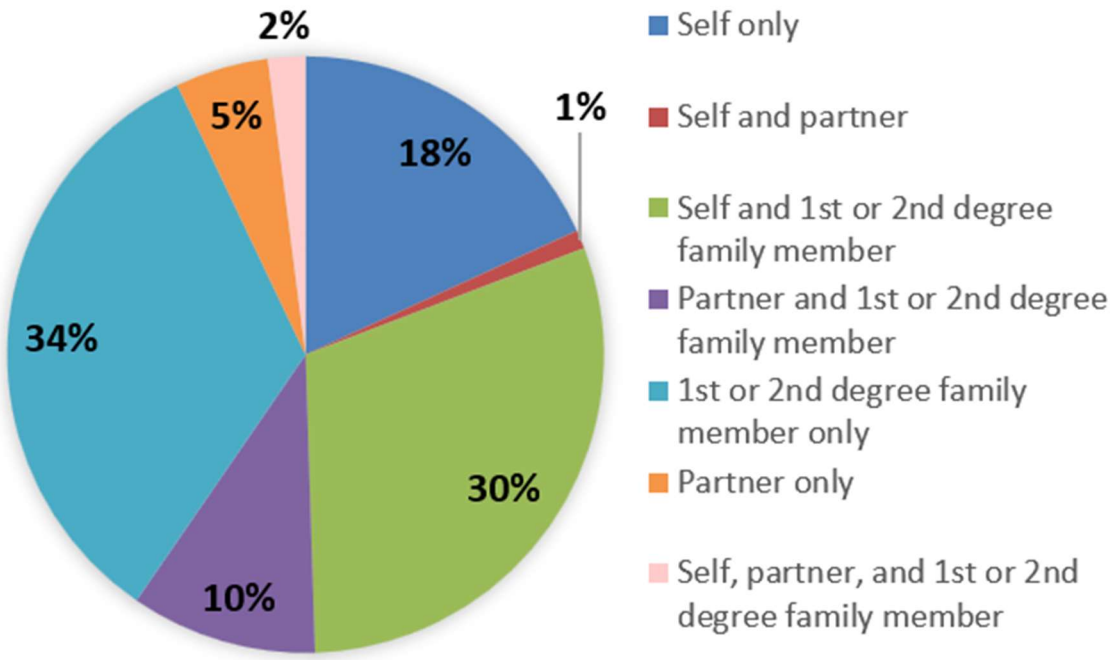
Male	48	27
Non-binary	1	1
Education Level	**N**	**%**
Trade/technical/vocational training	1	1
Some high school	2	1
High school graduate (diploma or GED)	28	16
College degree or higher	143	82
Race or Ethnicity	**N**	**%**
American Indian or Alaska Native	1	1
Black or African American	6	3
More than one race or ethnicity	10	6
Asian	11	6
Hispanic, Latino or Spanish origin	13	7
White or Caucasian	133	76
Age	**N**	**%**
18-29	14	8
30-39	40	23
40-49	48	28
50-59	44	25
60+	28	16
Person(s) with cancer	**N**	**%**

Self only	32	18
1st or 2nd degree relative only	57	34
Self and partner	1	1
Self and 1st or 2nd degree relative	53	30
Partner and 1st or 2nd degree relative	18	10
Self, partner, and 1st or 2nd degree relative	4	2
Partner only	9	5
Children	**N**	**%**
None	42	24
1	30	17
2	70	40
3	19	11
4 or more	13	7
Language choice for survey	**N**	**%**
English	170	98
Spanish	4	2%

Of the 174 participants, just over half have been diagnosed with cancer (52%, N=90). Fifty-three (30%) of all survey participants were cancer survivors who also had a 1st or 2nd degree family member with cancer. Fifty-eight (64%) completed the survey for themselves as well as a partner and/or a 1st or 2nd degree family member; 53 of these cancer survivors reported cancer in a 1st or 2nd degree family member, four in a partner and a 1st or 2nd degree

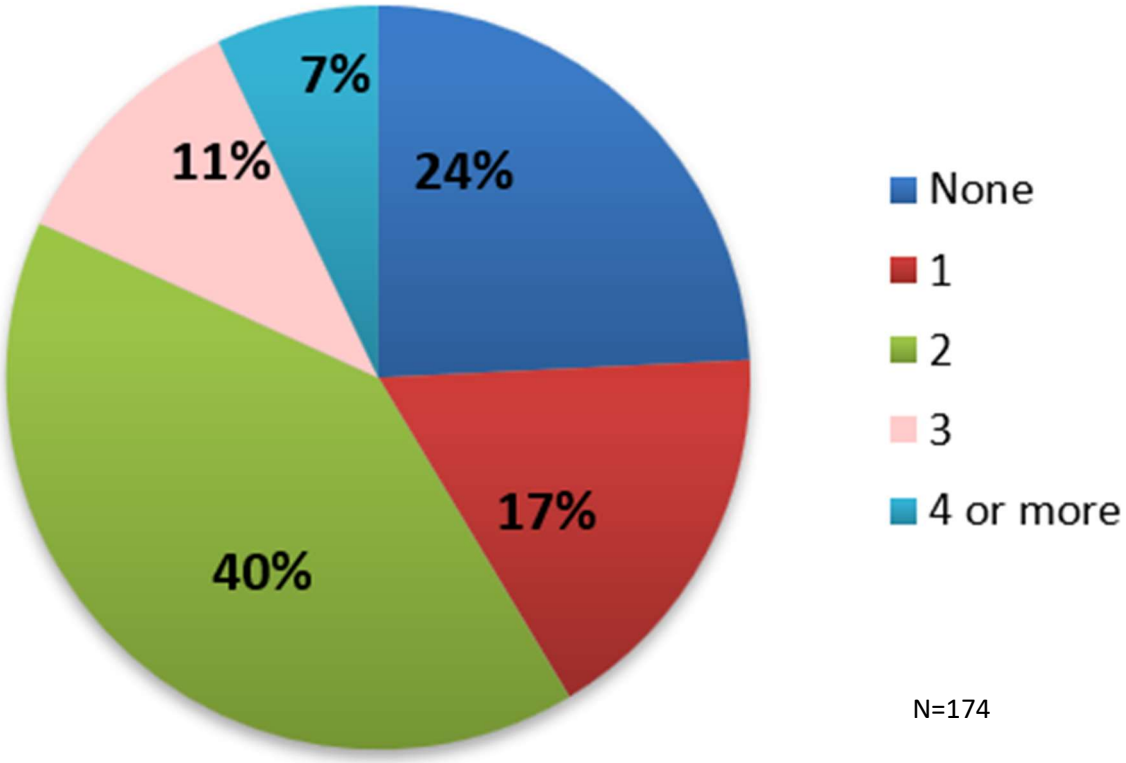
family member and one had a partner with cancer but no other family members with cancer. Fifty-seven (34%) of the study participants reported cancer in only a 1st or 2nd degree family member, 9 (<1%) reported only a partner with cancer, and 18 (10%) reported having both a partner and a 1st or 2nd degree family member with cancer. The largest group of survey participants (N=57, 34%) reported having only a 1st or 2nd degree family member with cancer. Figure 1 shows the percent of person(s) with cancer, grouped by their relationship to the study participant and Figure 2 shows the number of children reported.

Figure 1: Distribution of relationship of person(s) with cancer to survey participant. 174 participants in the study reported a cancer diagnosis in self, partner, and/or 1st or 2nd degree family member.



N=174

Figure 2. Distribution of number of children for study participants. The number of children a study participant reported was categorized for all 174 study participants. The largest percent of participants reported having two children (40%), while 24% had no children.



3.2 Cancer diagnosis information for person(s) with cancer

Study participants could enter information about a cancer diagnosis for themselves, a partner, and/or a 1st or 2nd degree family member. A total of 254 person(s) were reported as having cancer by the study's 174 participants. Table 2 shows the original site of cancer for all persons with cancer, listed in descending order of frequency. The two most common cancer sites were breast (N=81, 32%) and colon (N=44, 17%).

Table 2. Number and percent of original cancer site for all person(s) with cancer

Original site of cancer	N	%
Breast	81	32
Colon	44	17
Lung	15	6
Stomach	15	6
Prostate	14	6
Rectal	9	4
Uterine	9	4
Brain	7	3
Thyroid	7	3
Kidney	6	2
Skin	6	2
Ovarian	5	2
Cervical	5	2
Other, not specified	5	2
Bladder	4	2
Pancreatic	4	2
Testicular	3	1
Esophageal	2	1
Bone	2	1

Leukemia	2	1
Bile duct	1	<1
Hodgkin's Lymphoma	1	<1
Non-Hodgkin's Lymphoma	1	<1
Eye	1	<1
Head/Neck	1	<1
Throat	1	<1
Liver	1	<1
Peritoneal	1	<1
Small intestine	1	<1
Total	**254**	**100**

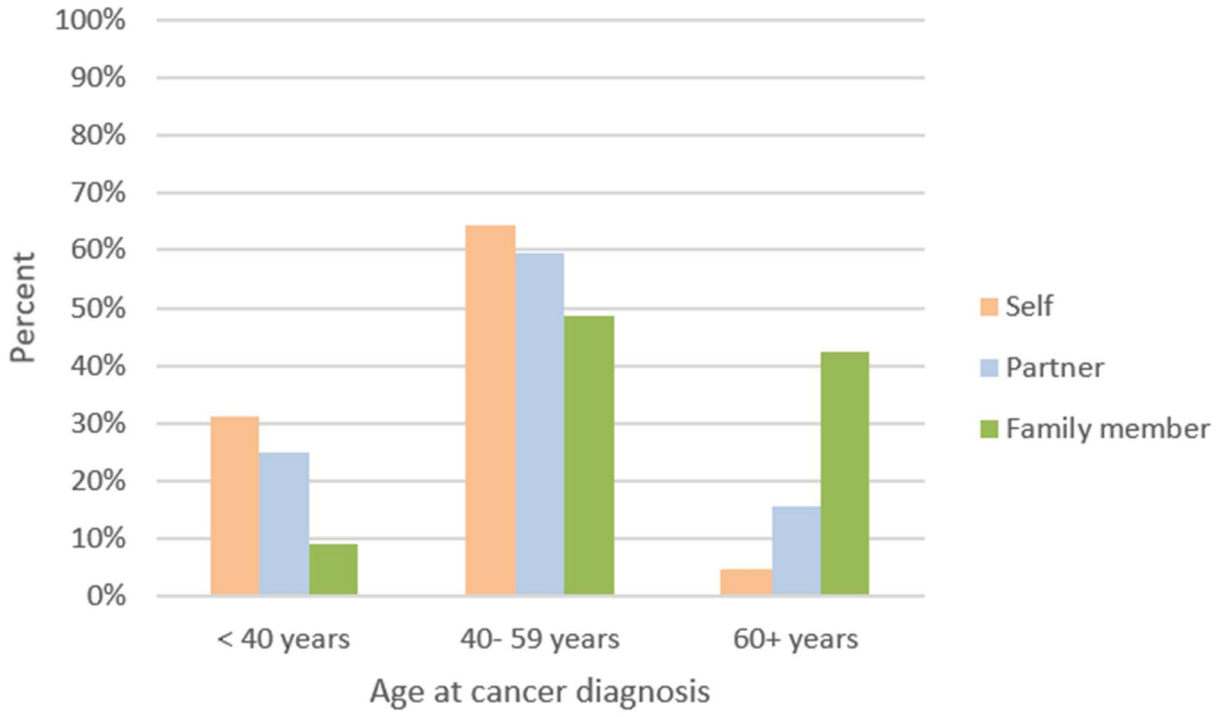
The distribution of age at cancer diagnosis for all persons with cancer is shown in Table 3 and Figure 3. Regardless of relationship to the survey participant, most individuals were diagnosed between the ages of 40 to 59 years old. Cancer survivors tended to be younger at the time of diagnosis; 31% of cancer survivors were diagnosed before the age of 40, compared to 25% of partners and 9% of family members. The vast majority (N=206; 81%) of cancer diagnoses for all persons with cancer occurred at 40 years of age or older.

Table 3. Number and percent of age at diagnosis for all person(s) with cancer

Age at cancer diagnosis	**N**	**%**
Under 18	2	<1

18-29	8	3
30-39	38	15
40-49	67	26
50-59	74	29
60+	65	26
Total	**254**	**100**

Figure 3. Distribution of age at cancer diagnosis by relationship to study participant. Age at cancer diagnosis was analyzed by age group and relationship to study participant; cancer survivors had a higher proportion of diagnoses before 40 and family members a higher proportion at 60 or older.



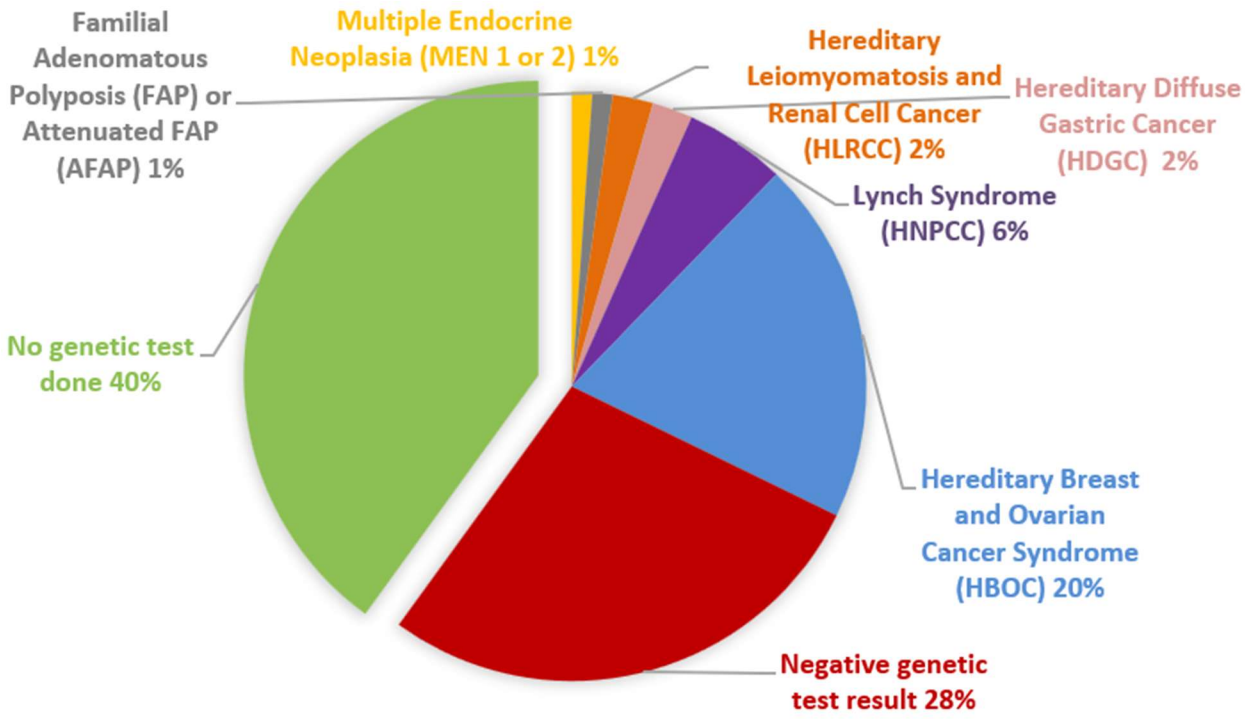
3.3 Genetic testing

Survey respondents reported genetic testing was done for 34% of persons with cancer (N=83). Distribution of genetic test results are shown in Figure 4A, B, and C. Sixty percent of cancer survivors received genetic testing (N=54), while 28% of partners had genetic testing (N=9), and 15% of family members (N=20). Positive genetic test results diagnosed a hereditary cancer syndrome in 32% of cancer survivors (N=29). Hereditary cancer syndromes were less common in partners (N=7, 22%) and family members (N=9, 7%).

Figure 4: Percent of Genetic Test Results by Relationship to Survey Participant

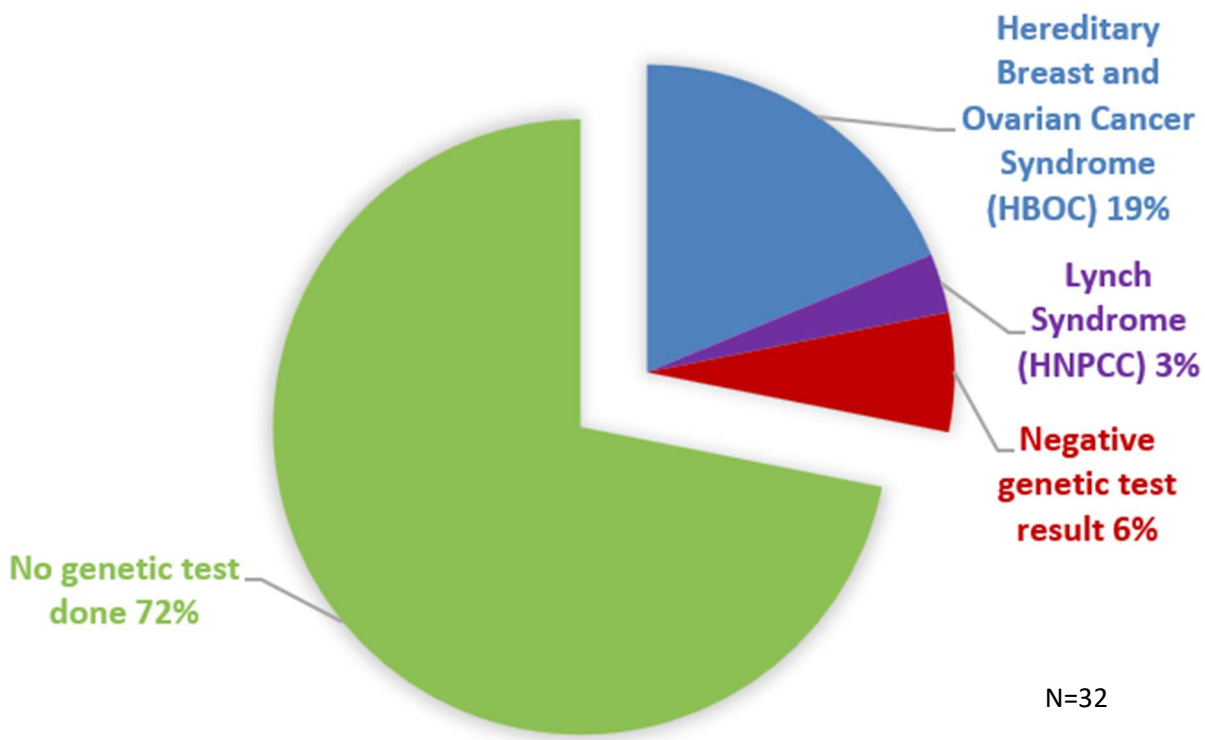
Genetic test results (or absence of testing) were categorized for the 90 cancer survivors (A), 32 partners (B), and 132 family members (C) in the study.

A: Genetic Test Results in Cancer Survivors



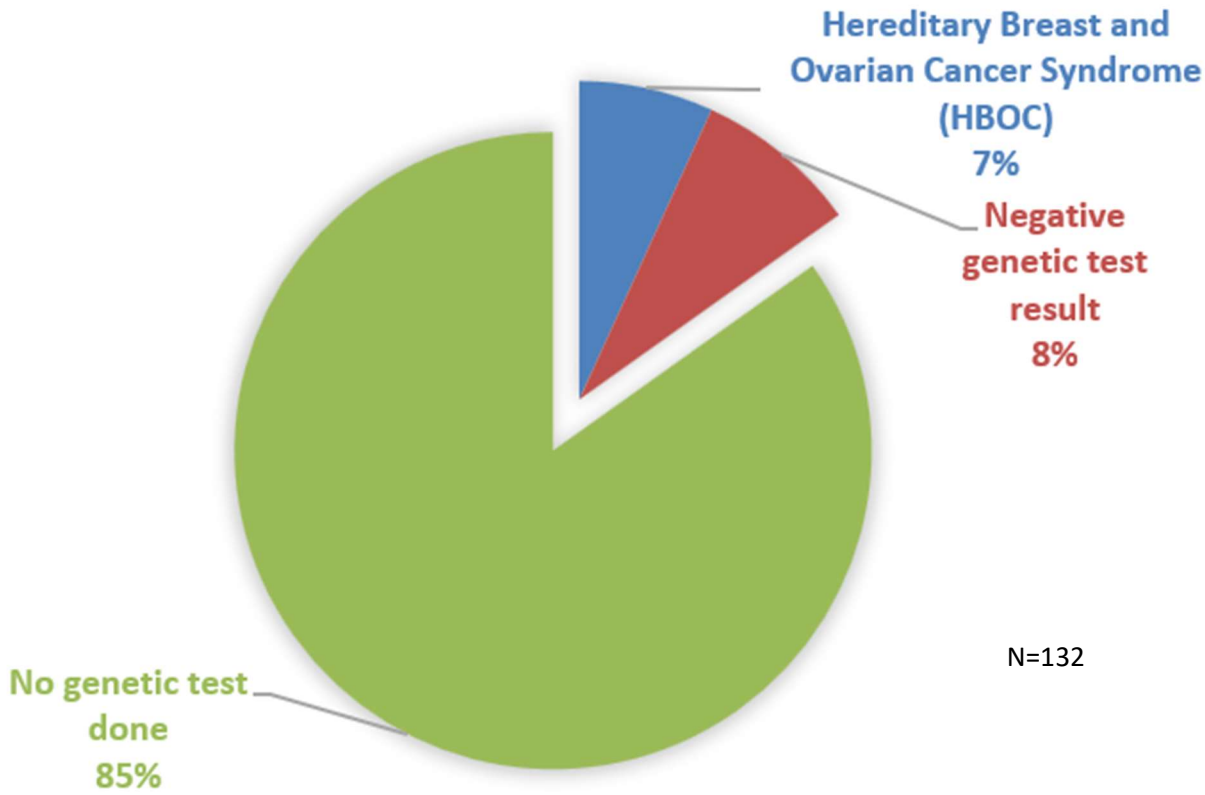
N=90

B: Genetic Test Results in Partners with Cancer



N=32

C: Genetic Test Results in 1st or 2nd degree Family Members with Cancer

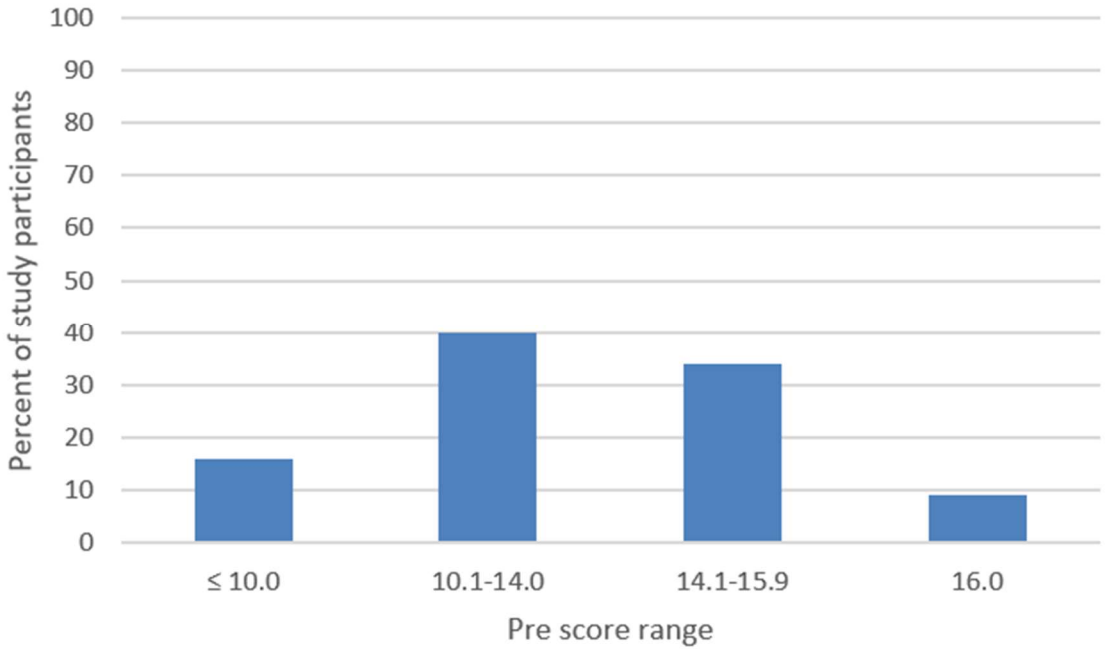


N=132

3.4 Success of video measured by differences between pre and post scores

When assessing and analyzing improvement by difference in pre and post scores, it is essential to note participants' pre scores before watching the video to indicate how much improvement was possible. Figure 5 shows the distribution of pre scores (≤10.0, 10.1-14.0, 14.1-15.9, and 16.0). Sixteen of the 174 participants (9%) had pre and post scores of 16, showing full knowledge before the educational video and thus no opportunity for improvement. Seventy-one participants (40%) had a pre score of 10.1-14, 59 (34%) had a pre score of 14.1-15.9, and 28 (16%) started with a pre score of 10 or less. Of the 28 who started with the lowest pre score range (10 or less), over half, 60% (N=17) were cancer survivors. Within this group of cancer survivors, seven (41%) reported they had undergone genetic testing, two of whom had a Hereditary Breast and Ovarian Cancer (HBOC) variant.

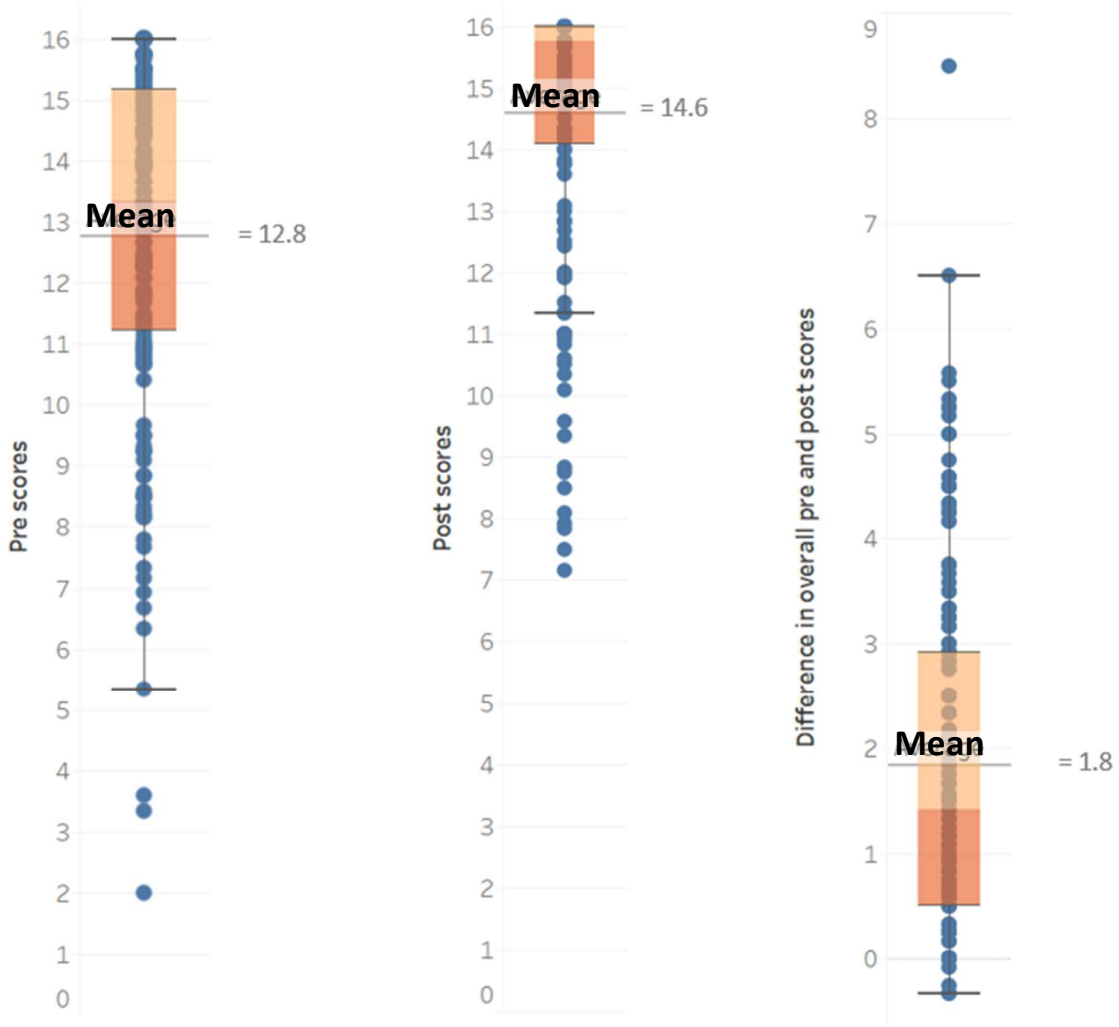
Figure 5: Distribution of pre-video scores. Pre score knowledge and understanding of GROUPS records was collected to use as a baseline measure before watching the video. The largest group of study participants (40%) had a pre score within the 10.1-14.0 range; 9% of study participants (N=16) started the survey with full knowledge and understanding before watching the video.



Differences between pre and post scores were analyzed and used to measure the success of the educational video in three ways: as one comprehensive overall score for all knowledge questions, as four scores grouped by domains addressing the hypothesis and aim of the study, and as sixteen individual scores for each of the survey questions. Six questions measured knowledge of what each of the GROUPS records meant and six measured participants' understanding of how to find each record. Four additional individual questions assessed four domains: how helpful it is to know an accurate family cancer history, how helpful it is to save medical records, how confident are you in knowing which records to keep and how confident are you in knowing how to save them.

For the overall comprehensive score, all pre and post test score differences were analyzed and displayed in Figure 6. The mean pre score for all participants was 12.8 (SD=2.3), mean post score was 14.6 (SD=1.7) and mean difference between pre and post scores for all participants was 1.8 (SD=1.4). Figure 6 shows the means and distribution of pre scores, post scores, and differences in these scores. Before the educational video, 50% of the survey participants had a pre score of 13.3 or greater and 75% had a pre score of 11.2 or greater. After watching the video and learning about the GROUPS checklist, 50% of the survey participants had a score of 15.8 or greater and 75% had 14.1 or greater. Fifty percent of survey participants showed an increase of 1.42 or more points between the pre and post score and 75% showed an increase of at least 0.5 points. Of the 174 participants, 18 (10%) showed an improvement of 4.5 to 8.5 between pre and post scores. Four (2%) participants' scores decreased after watching the video.

Figure 6: Overall comprehensive pre, post, and difference between these scores across the entire study population. Statistically significant differences ($p<0.001$) were observed for participants' change in mean pre score (12.8) and post score (14.6). Overall percent improvement was 14.1%.



Analysis of data from the individual 16 questions indicates the educational video significantly improved participants' knowledge, awareness, and confidence in saving appropriate medical records. Statistically significant differences between pre and post scores were observed in 14 of the 16 questions. Table 4 shows the improvement in knowledge and understanding of each of the 16 questions after watching the video. Statistically significant differences were observed for all questions except the knowledge of "S"/Surgical history

(p=0.002) and the knowledge of saving medical records is important (p=0.006). Because a Bonferroni correction was made for multiple comparisons, p-values <0.002 were considered statistically significant for this analysis.

Table 4: Mean pre, post, and difference between pre and post scores for the 16 individual questions

	Mean pre score (SD)	Mean post score (SD)	Mean difference (SD)	p-value
G – Knowledge*	0.83 (0.25)	0.91 (0.21)	0.08 (0.15)	<0.001
G – How to find*	0.80 (0.27)	0.90 (0.20)	0.10 (0.17)	<0.001
R – Knowledge*	0.88 (0.24)	0.94 (0.16)	0.06 (0.11)	<0.001
R – How to find*	0.81 (0.25)	0.90 (0.20)	0.09 (0.15)	<0.001
O- Knowledge*	0.67 (0.36)	0.89 (0.22)	0.22 (0.25)	<0.001
O – How to find*	0.68 (0.32)	0.88 (0.20)	0.20 (0.21)	<0.001
U- Knowledge*	0.83 (0.26)	0.94 (0.17)	0.11 (0.16)	<0.001
U – How to find*	0.82 (0.26)	0.92 (0.17)	0.10 (0.16)	<0.001
P – Knowledge*	0.85 (0.24)	0.94 (0.16)	0.09 (0.13)	<0.001
P – How to find*	0.83 (0.24)	0.92 (0.17)	0.08 (0.13)	<0.001
S - Knowledge	0.88 (0.22)	0.93 (0.16)	0.05 (0.11)	0.002
S – How to find*	0.83 (0.22)	0.92 (0.16)	0.09 (0.14)	<0.001
Accurate family history*	0.94 (0.17)	0.97 (0.10)	0.03 (0.07)	0.001
Save medical records	0.94 (0.15)	0.96 (0.11)	0.02 (0.06)	0.006
Confidence in which to keep*	0.70 (0.26)	0.94 (0.12)	0.24 (0.19)	<0.001
Confidence in how to save*	0.66 (0.28)	0.93 (0.14)	0.27 (0.22)	<0.001

*= Observed differences were statistically significant. Bonferroni correction adjusted statistically significant p-value is p<0.002

The differences between pre and post scores for the four domains are shown in Figure 7A and 7B. Figure 7A shows the differences between these scores for each survey participant (in order of the difference) and the overall improvement for each domain. The domain with the largest improvement (38%) was for confidence of knowing which records to save. The domain

with the smallest improvement (3%) was for knowing why the records are important to save, but the mean pre score baseline for this domain was very high (0.94/1.00). Figure 7B shows the mean pre and post scores for each domain, as well as the difference between these scores by each of the four domains across all study participants.

Figure 7A. Overall percent of improvement in each domain displayed by ascending amount of individual change in pre and post scores. Red bars indicate study participants' knowledge/confidence decreased; blue bars indicate participants' knowledge/confidence increased within each domain.

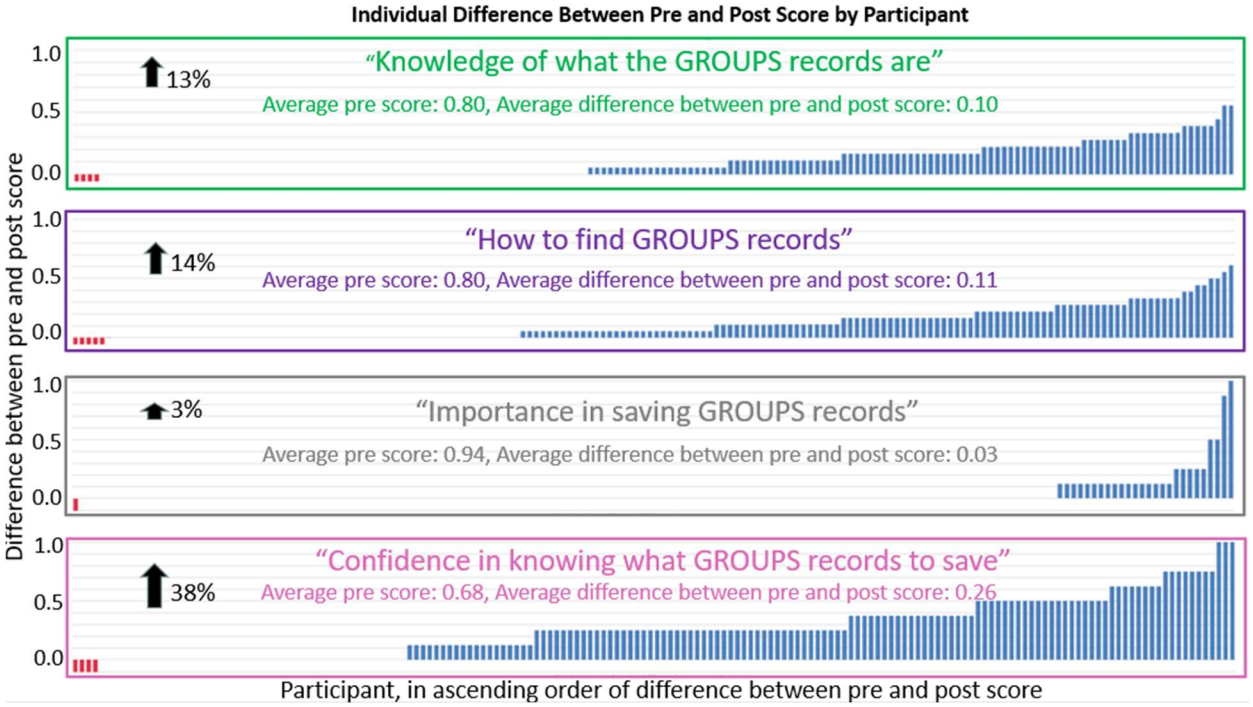
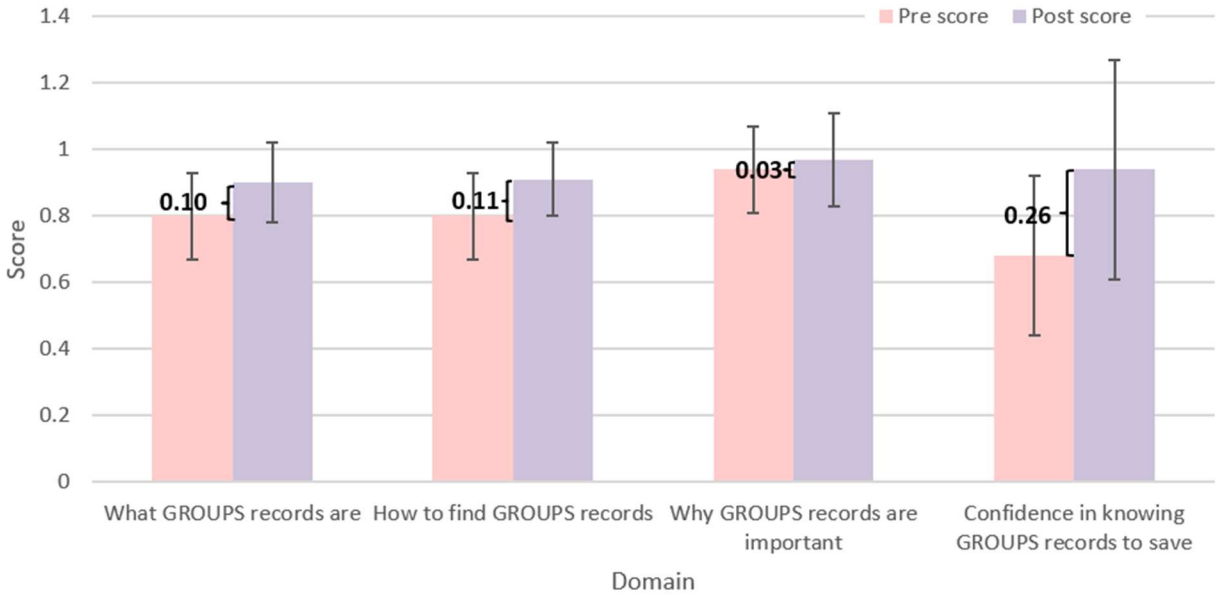


Figure 7B. Improvement in mean score for each domain for all study participants after watching the video. Statistically significant differences ($p<0.001$) were observed for difference in pre and post scores for all four domains. The largest improvement (38%) was in confidence of knowing which records to save**.**

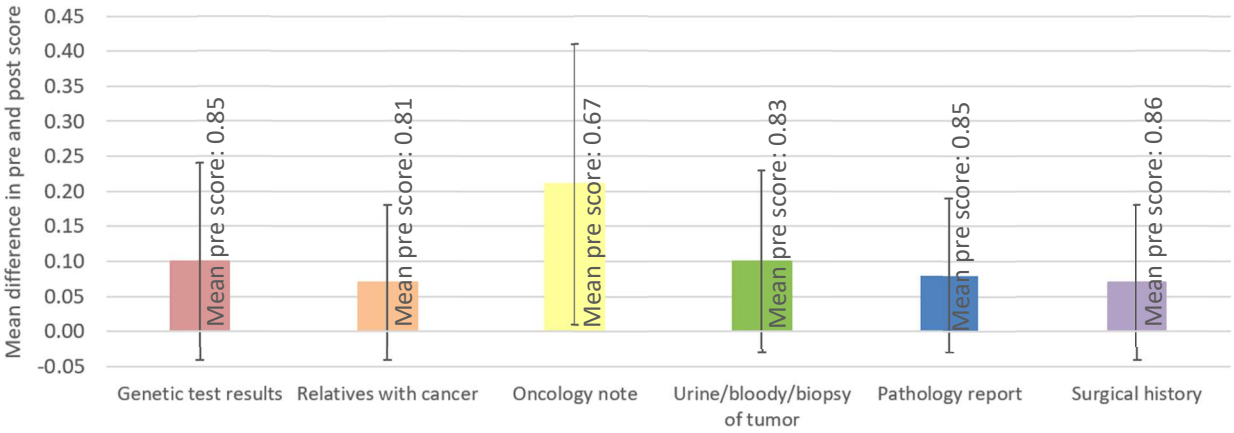


3.5 Pre and post score comparison for each of the GROUPS records

A comparison of pre and post knowledge for each of the six GROUPS documents was made for each participant. The differences in pre and post scores for each participant's knowledge of what each document is and how to find it were summed and the mean of these differences for all 174 participants was compared for each of the GROUPS records. Full understanding of this knowledge is equal to 1.0. Mean pre scores ranged from 0.67 to 0.86; the lowest mean pre score was for Oncology note (0.67) and the highest mean pre score was for Surgical history (0.86). Mean pre score and improvement between pre and post scores for each of the GROUPS documents are shown in Figure 8. The GROUPS record with the greatest

improvement between pre and post score was Oncology note (M=0.21) and the least amount of improvement (M=0.07) was observed for Surgical history.

Figure 8. Improvement in knowledge of what each individual GROUPS record is and where to find it. Lowest baseline knowledge was for Oncology note (0.67), greatest baseline knowledge was for Surgical history (0.86). Participants showed greatest amount of improvement (0.21) in learning what an Oncology note is and how to find it.



Following the video, participants were asked to report which GROUPS records they had already saved prior to participating in the study. Table 5 shows the number and percent of study participants who reported having previously saved each of the recommended medical records from the GROUPS checklist.

Table 5. Number and percent of study participants who reported previously saved GROUPS records.

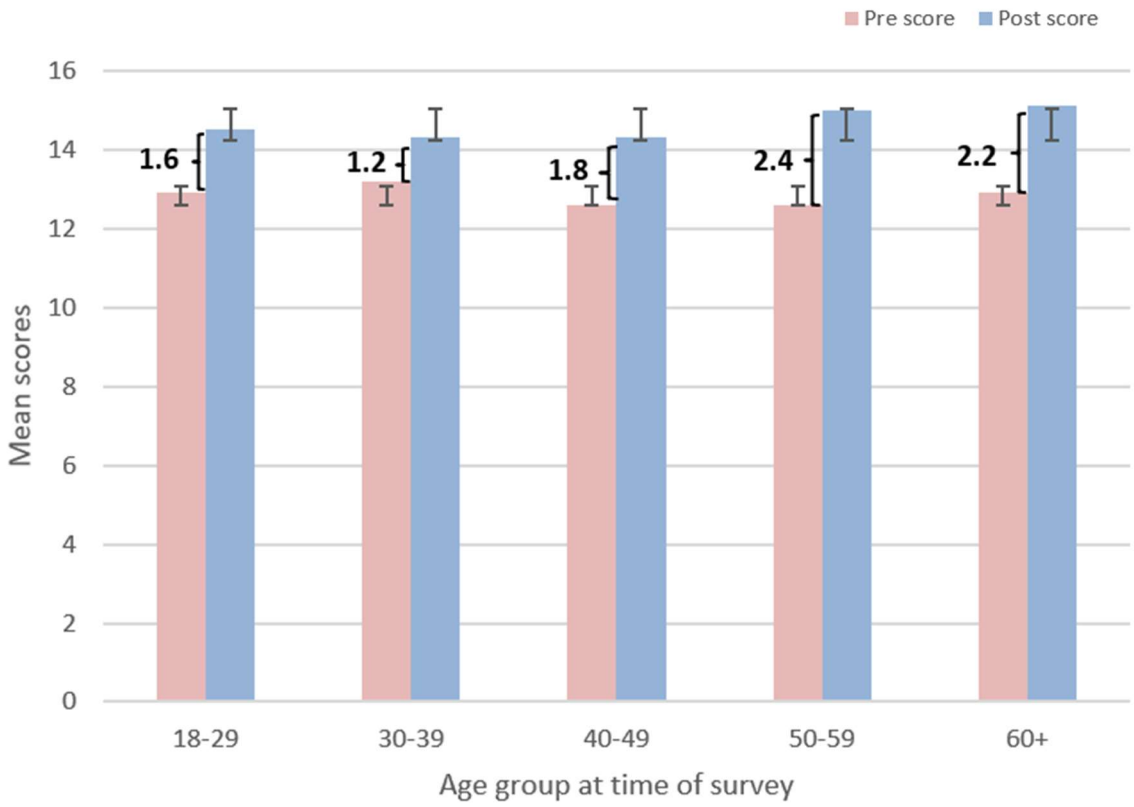
GROUPS Records	N	%
Genetic test results	96	55
Relatives with cancer	96	55
Oncology note	67	39

Urine/blood/biopsy of tumor	92	53
Pathology report	102	59
Surgical history	100	57

3.6 Categorical variables influencing difference in pre and post scores

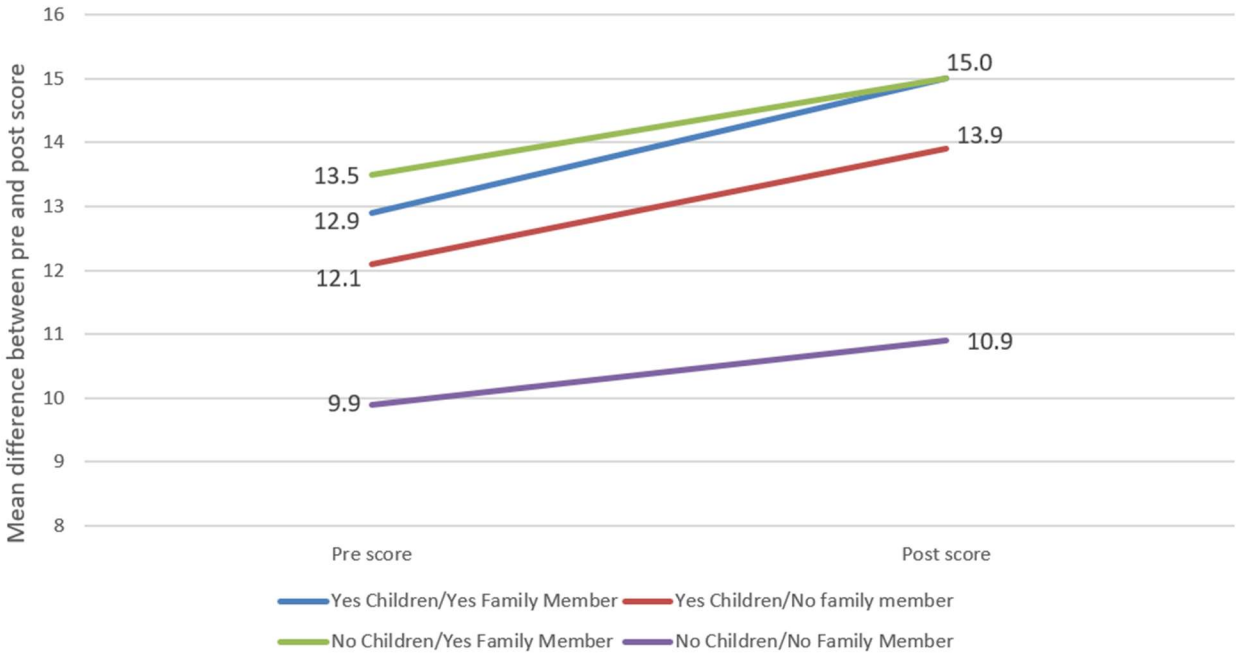
Various categorical variables (sex, education level, race or ethnicity, age at time of survey, number of children, type/relationship of person(s) with cancer) were analyzed to see if the difference in pre and post scores for these groups in the 21 tests (overall score, four domains, and 16 individual questions) were found to be statistically significant at the 0.05 level after adjusting for multiple comparisons using the Bonferroni method. Kruskal Wallis analysis confirmed differences in pre and post scores to be statistically significant for sex and knowledge of Relatives with cancer ($p<0.001$) and age at time of survey and comprehensive overall score ($p=0.001$). When males and females were combined, the mean difference in pre and post scores for increase in knowledge of Relatives with cancer was 0.06; however, the average difference for males was 0.13 and 0.03 for females. Participants who were older than 50 years showed a larger improvement compared to those younger than 50. Figure 9 shows the mean pre and post comprehensive scores, as well as the difference between these, by age group at time of survey. The mean difference in pre and post comprehensive scores for participants between 50-59 was 2.4 (SD=1.8) and for those 60+ it was 2.2 (SD=1.6). Pre scores for these groups were 12.6 and 12.9, respectively, which were comparable to the pre scores for the other age groups (ranged from 12.6 to 13.2).

Figure 9. Mean pre and post scores and difference between these scores by age at time of survey. Statistically significant differences ($p<0.001$) were observed for the improvement in study participants 30-39 and 50-59 years old. The greatest improvement in overall score was seen for those who were 50-59 years old at the time of the survey. Results indicate participants over the age of 50 received the greatest amount of benefit from the video.



Participants' pre scores were significantly higher if they reported having children and/or a family member with cancer. Those with neither children nor a family member with cancer had a pre score of 9.9, compared to a pre score of 12.9 for those with children and a family member with cancer. Participants who reported having a family member with cancer had higher pre scores (12.9 with children and 13.5 without children) compared to those who did not have a family member with cancer (12.1 with children and 9.9 without children). Differences between and pre and post scores for these dichotomous variables are shown in Figure 10.

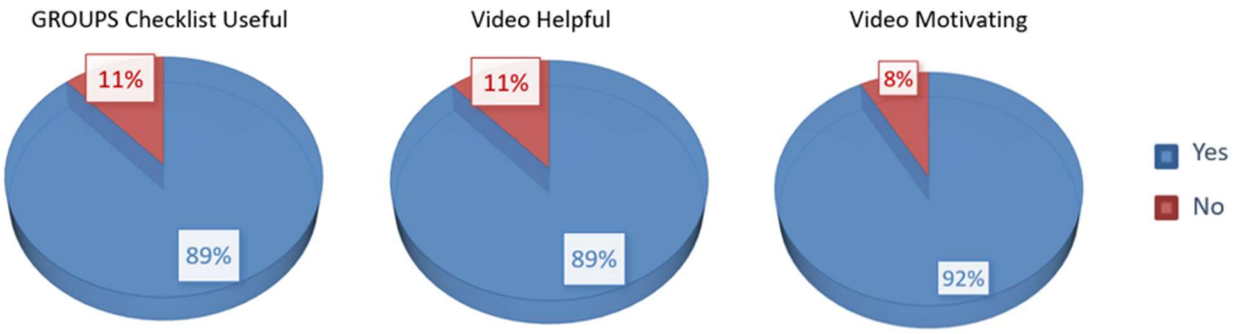
Figure 10. Impact of having children and a family member with cancer on pre and post scores for study participants. Pre scores were significantly lower (p=0.044) for those reporting no children and having no family member with cancer (starting point of purple line). Pre scores were also significantly lower (p<0.002) for those having no family member with cancer compared to those who do (red and purple compare to blue and green).



3.7 Self-reported impact of video and checklist

At the end of the survey participants were asked to rate the usefulness of the GROUPS checklist, helpfulness of the video, and how motivating the video was to inspire them to find and save the medical records from the GROUPS checklist. Of the 174 participants, 89% felt the GROUPS checklist was “definitely” (N=109) or “probably” (N=45) useful. Eighty-nine percent agreed the video was either “extremely” (N=90) or “very” (N=65) helpful and 92% felt the video either “definitely” (N=120) or “probably” (N=40) motivated them to find and save the GROUPS medical records.

Figure 11. Percent of study participants reporting the GROUPS checklist was useful, the video was helpful, and the video was motivating to save medical records.



IV. DISCUSSION

This study aimed to provide cancer survivors and their family members with information to educate them on which documents should be kept after a cancer diagnosis, why these are important, and information and strategies to increase participants' confidence to save them. An educational video and checklist were created and knowledge/confidence in this information was scored before and after the video intervention. Pre and post scores were analyzed to assess if the video and checklist would be worthwhile to pursue on a larger scale and whether a quality improvement study at local cancer clinics at UC Irvine would be beneficial. Analysis also included any other statistically significant evidence or trends of how categorical variables, such as: sex, education level, race or ethnicity, age at time of survey, number of children, and type/relationship of person(s) with cancer, may have influenced participants' change in pre and post scores after watching the video.

The content of the study was unique in the creation of the GROUPS video and checklist; both were created for this study and the research question was formed to collect pilot data on both tools. Prior studies have been completed on the use of an educational video to increase knowledge about cancer (Bouton et al., 2011 and Gimeno-Garcia et al., 2009) and previous research on use of acronyms to increase learning and retention (Putnim et al., 2015 and Stalder, 2005). This study was aimed at doing both; while making the information useful and adaptable for individuals to learn and retain the information, and available to primary language speakers of either English or Spanish.

4.1 Effect of educational intervention on overall score

The hypothesis of the study was that the average overall comprehensive score would increase by 10% between participants' pre and post scores. Improvement in pre and post scores exceeded this hypothesis by showing an overall average improvement of 14%. The video and GROUPS checklist provided information to study participants and a statistically significant difference was found between participants' pre and post scores after watching the video and learning about the checklist. The differences in pre and post scores for the overall comprehensive score was statistically significant at the 0.05 level after using the Bonferroni method for multiple comparisons. This measured improvement indicates the educational video resulted in a significant increase in knowledge, awareness, and confidence in saving appropriate medical records after a cancer diagnosis.

Because this study focused on the measuring of one's improvement between pre and post scores, it is important to consider the level of prior knowledge participants may have had before watching the educational video. Results of the survey showed 9% (N=16) of the 174 survey participants began the study having full understanding and knowledge of the GROUPS documents, where to find them, and confidence in saving them. Recruitment for the study included the primary researcher's personal social media account and it is likely there were individuals who participated in the study who work or previously worked in healthcare. Providers and students were eligible to complete the study if they were affected by cancer and they likely had a more extensive pre-existing knowledge of cancer and health literacy, which may have skewed the data as well. Therefore, this was a limitation to the study and may not be reflective of the population of UCI Chao Cancer patients or the nationwide population. Four

participants (2%) commented in free text that they each had previous healthcare knowledge coming into the study. Furthermore, over half of the study participants were cancer survivors; they should have at least some experience and familiarity with these records. Therefore, it is not unlikely they may have begun the survey with a relatively high level of knowledge about the topic.

Almost half of the study participants (N=75; 43%) had a pre score of 14.1 or greater. With a score of 16 being equivalent to full knowledge and understanding, having a prior knowledge between 14.1 and 16 was a high starting point for these 75 participants before watching the educational video.

Twenty-eight participants (16%) had a prescore of 10 or less. Race and education level for this group of 28 in the lowest pre score range followed the biased numbers seen in the study population: 68% (N=19) vs 76% (N=133) Caucasian participants in the study population; 75% (N=21) vs 82% (N=143) college degree or higher in the study population. This relatively large percent of higher education level in this group shows it is possible education level was not as influential as one's occupation or level of healthcare knowledge in providing participants with a higher pre score. Sex was slightly biased in more females (N=16, 57%) than males in this lowest pre score group, which would be expected given the female bias of the entire study population; though it is closer to the 50/50 split one would expect to be representative of a larger population outside the sample population. This variation toward a more even 50/50 split of sex indicates more men may have a lower base knowledge about records to save after a cancer diagnosis. The video may have an even larger overall improvement for those with a

lower level of health literacy or knowledge about medical records to keep after a cancer diagnosis and this would be a target population for future studies.

The categorical variable of age at time of survey was found to be statistically significant at a 0.05 level for the mean overall comprehensive difference between pre and post scores. The pairwise comparison between the group of 30–39-year-old participants was significantly different than those in the 50-59 age range ($p<0.001$). The mean comprehensive pre and post score difference was 1.18 (SD=1.48) for individuals in their 30s compared to 2.37 (SD=1.84) for those in their 50s. Participants in their 30s started with the highest mean pre score of all the age groups (M=13.1). Mean pre score for those in their 50s and their 40s was the lowest among the age groups (M=12.6). Participants in their 50s had the largest improvement between pre and post scores, slightly greater than those 60 and older (M=2.17, SD=1.56). The baseline mean pre score for individuals who were 60 and older (M=12.9) was slightly higher compared to those in their 50s; similarly, mean post score followed a similar trend as those 60 and older had a slightly higher mean post score (M=15.1) compared to those in their 50s (M=15.0). One possible explanation is that people who are 50+ may have witnessed a greater number of loved ones receive cancer diagnoses, or experienced loss of family and friends more than those in their 30s or even 40s. It may be that this life experience makes them more open to understanding the importance of learning about documents to save, why they are important, and how to save them.

4.2 Effect of educational intervention on improvement of individual scores

Participants showed a positive improvement in all 16 individual questions: 12 were specific to the GROUPS records and where to find them and four assessed understanding on a broader scale: saving medical records is helpful, importance of knowing family medical history, knowing what records to keep after a cancer diagnosis, and how to save them. The overall improvement in all 16 questions indicates the educational video and checklist did positively influence participants' knowledge of the GROUPS documents and overall understanding and awareness about the importance of saving medical records after a cancer diagnosis. Differences between pre and post scores for 14 of the 16 questions were all statistically significant at the 0.05 level ($p<0.002$) after using the Bonferroni correction for multiple comparisons. One of the two questions specifically targeted at understanding of the GROUPS records not found to have a statistically significant difference between pre and post scores was "knowledge about Surgical history"; participants' scores on this question still improved from pre to post scores, but the prior knowledge of this record was high (0.89/1.0) and the average improvement of 0.05 was marginally not statistically significant ($p=0.002$). This makes sense, though, as understanding what one's surgical history is, how to find it, and why it would be important to know and save, is likely to be a concept understood by most individuals.

A statistically significant increase in pre to post score was not observed for one of the four questions that assessed understanding on a broader scale: "Saving medical records is helpful." The mean score across all participants improved from pre to post but this change was not statistically significant. Similar to knowing what one's surgical history is, "Knowing medical

records can be helpful" is an intuitive concept that is likely to be understood by many, despite learning this in the educational video of the research study.

4.3 Effect of educational intervention on improvement of four domains

As a whole, study participants showed a positive improvement in all four domains: knowledge of what the GROUPS records are, how to find them, the importance in saving them, and confidence in knowing what to save; indicating the educational video and checklist did positively influence their change in knowledge, understanding, and awareness across these four domains. Differences between pre and post scores within the grouped domains were all statistically significant at the 0.05 level after using the Bonferroni correction for multiple comparisons. A lower post score was observed by a few individual study participants in each domain.

As expected, the smallest amount of gain between pre and post scores was for the domain reflecting participants' awareness of importance in saving medical records. This coincides with the relatively high pre score of 0.94/1.00 participants had before watching the video and the knowledge that it is well-known and widely accepted that medical records do provide useful information to a person with cancer, a healthcare provider, and family members (Gravis et al., 2011). The largest amount of gain was evidenced by a 38% positive change in average pre and post scores (0.68 vs 0.94) across all participants for the domain of confidence to save GROUPS records.

The main aim of the study was to increase knowledge, awareness, and confidence; with the goal to inspire, motivate, and teach participants how to save these documents for

themselves and for subsequent generations in the future. This finding illustrates that the video was a powerful tool in increasing participants' confidence in knowing what records to save and how to save them. This domain not only showed the greatest improvement among the four, but it had the lowest pre score of 0.68 and ended up with the second highest post score of 0.94, just second to the post score of 0.97 for the domain of knowing medical records are important to keep. The domains of knowledge surrounding what the GROUPS documents are and knowing where to find them both showed a statistically significant difference between pre and post scores, increasing by 13% and 14%, respectively. These improvements paralleled the overall 14% improvement seen by participants in the comprehensive score.

4.4 Characteristics of survey participants recruited for the study

Reported primary cancer site did vary, but the largest tumor type among study participants was breast cancer (N=81, 32%). This is not surprising as the most common type of cancer for females is breast cancer (National Cancer Institute, 2020). Furthermore, more than half the study participants were cancer survivors (N=90, 52%) and female (N=125, 72%). In addition, the UCI Breast Cancer clinic was one of the main two clinics who participated in actively handing out flyers to UCI cancer patients as part of the study recruitment. The next two most reported cancers by study participants were colorectal (N=44, 17%) and lung (N=15, 6%). This is also not surprising because lung is the second most common cancer among people in the world, followed by colorectal cancer (National Cancer Institute, 2020). The UCI GI Cancer clinic was the main clinic used to hand out flyers and inform patients and family members about the study during clinical appointments. Therefore, this could explain why the number of colorectal cancers reported is larger than the number of lung cancers. This may also explain

why there are more gastrointestinal cancers reported by study participants (i.e., stomach, esophageal, pancreatic, and liver; N=22, 9%) than would otherwise be expected based on non-colorectal gastrointestinal cancers being among cancers that are less commonly diagnosed (stomach: 0.8%, esophageal: 0.5%, pancreatic: 1.7%, liver: 1.1%) (National Cancer Institute, 2019).

Characteristics of the study participants were compared to two populations: patients seen at UC Irvine's Chao Cancer Center and nationwide, to assess potential success in implementing the use of the video and checklist for future use in these populations. Planned future quality improvement studies will take place at Chao Cancer Center and there is interest from support groups and research centers from across the nation to utilize the video and checklist for their patients and families. The racial and ethnic demographics of patients at the Chao Cancer Center were compared to those who participated in this pilot study. Several discrepancies were observed: the percent of females in the GROUPS study (72%) was much higher than those at UC Irvine's Chao Cancer Center (47%) (Tumor Registry Data, 2018). A direct comparison of Hispanic and Latino ethnicity was not possible due to the way in which race and ethnicity were asked between the Tumor Registry and the GROUPS study. However, of all cancer cases at Chao Cancer Center, 19% individuals reported a Hispanic or Latino ethnicity (Tumor Registry Data, 2018). This is a much higher percent compared to the 7% in the GROUPS study who reported having a Hispanic, Latino, or Spanish origin (7%). The percent of Caucasian individuals was the same between the two populations; both reported 76% of the population as Caucasian (Tumor Registry Data, 2018).

The US Census Bureau asks two separate questions: one for race and one for Hispanic or Latino origin. For the first time, in 2020, respondents were prompted to write in origins or ethnicities for all racial groups (Noe-Bustamante et al., 2021). According to the U.S. Census Bureau, (2020), 20% (N=12,579,626) of Hispanics selected White as their race, 42% (N=26,225,882) of Hispanics marked their race as "some other race" without marking any other response.

It is not possible to accurately compare the percent of racial and ethnic groups represented between the GROUPS study, Chao Cancer center (Tumor Registry, 2018) and nationwide (U.S. Census, 2020) because the GROUPS study treated Hispanic or Latino as its own individual category rather than asking all individuals to report a Hispanic or Latino origin separate from other options as a race. However, based on the Bureau's analysis of race for those identifying with a Hispanic or Latino origin, it is likely individuals in this research study who identified as Asian were under represented (6% vs 17%) in comparison to the Chao Cancer patient population at UC Irvine but reflective of the nationwide numbers (6% vs 7%); Black or African American study participants were reflective of the Chao Cancer patient population (3% vs 2%) but under represented compared to the nation (3% vs 15%); and the percent of American Indian or Alaskan Native individuals was comparable across all three groups (study: 1%, Chao Cancer Center: 0%, nationwide: <1%). A substantial percent of individuals who identified as Hispanic on the 2020 Census selected race group of White, "Some other race", or "Two or more races". Therefore, it cannot be accurately assessed as to how the percentages of these three groups of racial and ethnic classification compare between the study, Chao Cancer Center, and nationwide. Despite this discrepancy, it is very likely individuals reporting as

Hispanic or Latino are underrepresented in the study population in comparison to those at UCI Chao's Cancer Center and across the nation, as only 7% (N=13) of the study's participants selected Hispanic or Latino and the percentages reporting Hispanic or Latino ethnicity or origin are much larger for both the patient population at Chao Cancer Center and nationwide (19% and 18%, respectively).

The survey participants were biased in sex, as 72% of study participants were female compared to 47% at Chao Cancer Center (Chao Cancer Center Tumor Registry 2018) and 51% nationwide (U.S. Census Bureau, 2019). Also, individuals who completed the survey were well educated; 82% (N=143) had a college degree or higher. Education level for patients at Chao Cancer Center is not available; however, according to the 2019 Educational Attainment in the United States, 33% of individuals in the United States held a college degree or higher (U.S. Census Bureau, 2019), indicating the percent of study participants with a college degree or higher is much greater than those nationwide.

4.5 Trends of categorical variables: number of children and family members with cancer

Statistically significant differences were observed in the mean pre scores for participants based on whether they reported having children and/or a family member with cancer. Pre scores for those with neither children nor a family member with cancer were significantly lower than those who reported having either children, a family member with cancer, or both. Additionally, there was a statistically significant difference in the mean pre score for participants who had a family member with cancer; those who reported a family member with cancer had a higher mean pre score, despite whether they have children. A likely explanation

for this difference is in the prior knowledge one gains through the experience of supporting a family member through a cancer diagnosis.

Improvements from mean pre to post score were made for all group comparisons; despite reporting children and/or having a family member with cancer. However, the data showed the video provided the greatest amount of improvement for those who reported having both children and a family member with cancer. This result may be due to the video's focus to inform participants about the importance of keeping GROUPS documents and saving them for subsequent generations to use. This concept may have been more tangible, resonating more with study participants who had children and/or family members affected by cancer. Two participants noted in the survey's open comments they did not have children nor family members; therefore, they felt the information was less meaningful to them. In contrast, eight comments admitted to not having realized the impact of these records being saved for their children and family members and were inspired and motivated to find and save these records for them to have. These comments suggest an educational opportunity to better inform individuals about the importance and impact of saving these records; both for subsequent generations as well as for oneself as a cancer survivor. These records provide helpful information for subsequent generations; however, for those without children, understanding and saving records from one's previous cancer is also important for the cancer survivor. Future providers who are not familiar with a survivor's cancer history will find these records helpful to best provide accurate, continued surveillance recommendations and overall medical care. If cancer reoccurs, they could potentially provide information for beneficial treatment options. Future educational opportunities should reinforce the importance of saving these records for

oneself as well as for family members and doing this sooner versus later to avoid challenges of not being able to locate the records.

4.6 Genetic testing results

Eighteen percent of study participants (and/or their partners or family members) reported a positive genetic test result for a hereditary cancer syndrome. This is two to three times the expected percent; as discussed earlier, hereditary cancer syndromes affect 5-10% of the general population (American Cancer Society, 2020). The inflated percent of those in the study with a hereditary cancer syndrome may be due to several reasons. First, the study recruited patients from high-risk cancer clinics (i.e., those with young age cancer diagnoses, more rare cancers that may more likely associated with a hereditary cancer syndrome, or those with a strong family cancer history). Second, individuals who are aware of their increased predisposition to have cancer may be more likely to volunteer for a research study and be motivated to learn about which records are important to keep and how to save them. The inflated percent of study participants with hereditary cancer syndromes may be explained by the recruitment method; but also provides further support for the study's poor external validity. Those with hereditary cancer syndromes began the study with a pre knowledge level above the mean of the entire study population (M=13.8) and while they did show improvement between pre and post scores; this was a smaller amount of improvement (M=1.4) compared to the mean change of the entire study population.

4.7 Implications for use

Participants' feedback on the helpfulness and usefulness of the video and checklist, as well as the level of motivation the video provided for them to save records, confirmed participants did gain knowledge and improve their understanding of GROUPS documents, how to find them, and why they are important to save. Further, it illustrates participants found subjective value in the video as an educational tool and checklist to assist in ensuring these documents are found and safely stored for future use.

Survey questions specifically asking about the knowledge gained in what the specific GROUPS records are and where to find them have provided insight to an opportunity to provide further education to people with cancer and their family members. Of the six documents, an oncology note had the lowest pre score (indicating lowest prior knowledge about what an oncology note is and where to find it). It also had the greatest magnitude of change among all study participants; increasing by 0.21 from a pre score of 0.67 to a post score of 0.88. In addition, of all six GROUPS records, the least reported saved record was an oncology note (N=67, 39%). Over half of study participants reported having already saved all the other GROUPS records; indicating there is a need and use for people with cancer and their families to learn about what an oncology note contains, where to find it, and why it is important to save. This finding also further illustrates the high baseline knowledge many participants had coming into the study before watching the video.

As discussed previously, Unruh & Pratt (2008) identified four major barriers to cancer survivors keeping and organizing their medical records (emotional, scalable, temporal, and

functional). Data from this study supports cancer survivors (and their families) used the educational video and checklist to overcome three of these four barriers. Scalable: participants identified the use of the checklist as a convenient way to simplify the types of records necessary to save. In the open comments, six participants explicitly stated the simplicity and helpfulness of the GROUPS acronym made it easier to identify what records should be saved. In addition, 89% of the study participants reported the GROUPS acronym checklist was useful. Temporal: participants increased their understanding of the importance of these medical records. Data revealed an overall improvement in participants' understanding of why it is important to save the GROUPS records. Free text comments provided further support for overcoming this barrier: three participants commented on having not remembered the importance of these records around the time of diagnosis and treatment, and eight discussed having not fully understood the importance of saving them altogether until having watched the video. Functional: participants learned how best to use this information and how to save the GROUPS records together, in a safe place, and away from other documents. The largest domain of improvement in overall score change for all participants was their confidence in knowing which records to save and how to save them. The "Emotional" barrier was not addressed or supported with the pilot study data; however, a future research question to investigate is whether the video could be useful during initial stages of a cancer diagnosis and beneficial for creating a simplified way for those experiencing the emotional barrier to efficiently collect records.

4.8 Unexpected results

The study results supported the hypothesis that the average overall comprehensive score would increase by 10% between participants' pre and post scores. However, along with this overall evidence of improvement in the data, there were two unexpected results. One, some individuals' scores reflected a loss of knowledge or understanding on a question after watching the video. It would not be expected the video would cause someone to lose knowledge, awareness, or confidence; rather data would show an improvement or no change. A possible explanation for why this occurred is because responses were on a Likert scale (either 4-point or 5-point, depending on the question), and participants may have waffled between two responses on a question before watching the video (pre score) and then forgotten this selection and chose a response after the video (post question) that resulted in a "loss" of knowledge, understanding, or awareness.

A second unexpected result was a large statistically significant difference found for the knowledge of "R" (Relatives with cancer) between pre and post scores for sex ($p<0.001$). The mean difference for males was 0.13 (SD=0.03) and females was 0.03 (SD=0.06). One participant reported sex as non-binary but the pre and post score for this individual was the same, demonstrating no change for this question. There is scientific literature evidence demonstrating paternal family cancer histories are significantly less accurate than maternal histories (Ozanne et al., 2012 and Quillin et al., 2006), and data from this study mirrors these findings as well. This may be an important piece of information for healthcare providers to be aware of; paternal family cancer histories may not only be underreported but also less accurate than maternal family cancer histories.

Another surprising finding was the large percentage of study participants claiming to have already saved each of the GROUPS records. Again, this may be due to the limitation of self-reporting; when asked if a task has already been done, individuals may "over report" or inflate this to be higher than the true number because it is perceived to be a more socially desirable behavior (Lavrakas, 2008), and additionally could be due to the nature of the study population (overall more educated than expected and a higher proportion of individuals with a hereditary cancer syndrome). This finding provides more evidence for conducting a quality improvement study that measures the collection of GROUPS records; a researcher would measure how many records were saved prior to the video and how many are collected after a short period of time, to be defined by the study protocol.

4.9 Limitations

Overall study limitations due to the method of ascertainment through social media included biased characteristics of sex, race or ethnicity, primary language, level of health literacy and education level. Individuals who completed surveys were not representative of nationwide characteristics of sex, race or ethnicity, occupation, education level, and health literacy; therefore, these pilot study results may not accurately reflect the potential impact of the information provided in the GROUPS educational video and checklist to those outside the study. Participants who elected to complete the survey may have had a greater baseline knowledge of the information than the general population. Therefore, their pre scores may have been elevated and data may have shown a smaller improvement between pre and post scores.

The source of recruitment was not recorded for all study participants, and therefore, was a limitation to this study because it is unknown how many individuals learned about the survey link or QR code from social media, a UCI cancer clinic appointment, a support group, or through a friend sharing the survey link/QR code. A question was added to the survey on December 10, 2021, after data collection began, and at a point when 76% of study participants had already completed the survey. From December 10, 2021, through the completion of the study on March 1, 2022, 42 (24%) study participants reported how they learned about the study. Of these 42 participants, 67% (N=28) discovered the survey by support groups, 14% (N=6) through a UC Irvine cancer clinic appointment, 12% (N=5) via email from a friend or colleague, 5% (N=2) through social media, and 2% (N=1) chose not to share the source. Because this question was not added at the beginning of data collection, it cannot be inferred where the overwhelming majority of the study participants learned about the study, nor any of their associated characteristics that may have been helpful to know based on how they were recruited.

The educational video and survey were translated to Spanish to recruit and additionally measure the success of the video and checklist for participants who speak Spanish as a primary language. Unfortunately, the study did not successfully recruit a substantial number of primary Spanish speaking patients. The survey was sent out via social media and four cancer support groups specifically for primary Spanish speakers, but only four participants completed the study in Spanish. There are a few explanations for why the response rate for the Spanish survey was lower than expected: fewer than 10% of patients seen at the UCI Breast Cancer and Gastrointestinal clinics speak Spanish as a primary language; surveys were completed at home

and not on site, and non-English speakers may be of a lower socio-economic status and more challenged to complete the electronic survey at home; Atske and Perrin (2021) suggests Hispanic adults are less likely to own a computer or have high-speed internet at home (67% Hispanic vs 80% White adults). A similar study in 2016 surveyed 1500 Hispanic adults on their reported mobile internet use based on language dominance. Of 679 Hispanic adults who considered themselves to be Spanish-dominant, 71% reported using mobile internet compared to 86% of those who classified themselves as English-dominant (Brown et al., 2016).

The electronic format of the study may have limited populations of people from participating and allowed for an increase in self-reporting bias. Though the study was translated to Spanish, it was not available in any other non-English language; therefore, there was also a limitation of linguistic fluency to other individuals who may have been able to participate in a language other than English or Spanish.

Support groups and local cancer clinics agreed to recruit participants for the study; but some support groups are geared toward survivors of certain types of cancer. Similarly, only three UCI cancer clinics (breast, gastrointestinal, and high-risk genetics) were approached and agreed to actively participate in the recruitment for the pilot study. Therefore, there was not an equal comparison of types of cancer within UCI cancer clinics.

A logistical study limitation was the inability for patients and family members at in-person UCI clinic appointments to complete the survey while they waited to see the provider. The initial research plan was to have the survey and video available in person to those attending a UCI cancer clinic appointment and to complete the study while waiting to see a

provider. Due to logistics around time in the waiting room and COVID-19 precautions to ensure headphones and tablets were not shared and/or were disinfected properly, it was decided potential study participants would learn about the study and handed a flyer to take home with the study link and QR code to complete at home.

4.10 Previous research and future studies

The GROUPS video and checklist were created for this pilot study, so there is no direct previous research that has been completed specifically on these tools. However, as discussed earlier, previous educational research does support the use of acronyms to enhance learning and educational videos have shown to have a positive effect in others' understanding and retention of information (Bouton et al., 2011; Gimeno-Garcia et al., 2009; Putnim et al., 2015). As a pilot study, it was successful in collecting and measuring differences in participants' pre and post scores as well as their feedback on the content of the video and checklist. The data collected has provided guidance for follow up quality improvement studies at UC Irvine's cancer clinics. A next step is to work with clinics to provide a physical copy of the GROUPS checklist and collect data on GROUPS records that are saved for participants and their family members. Research has shown learners felt it was easier to remember the information when acronyms were provided to them on a review sheet after receiving instructional content (Stalder, 2005). Therefore, the strategy of providing instructional content from the video along with a physical copy of the checklist (or a link to download one), may be a future idea to help increase the likelihood participants would retain and recall the information from the video.

Additional pilot data should be collected for individuals who speak Spanish as their primary language. Future pilot data results from primary Spanish speakers may not emulate the results observed in this initial study population which contained mostly English-speaking, well educated, Caucasian females. Pending continued successful pilot data results from Spanish speaking individuals, a future goal will be to increase the utilization of the video and checklist for those who speak Spanish as their primary language.

UC Irvine is home to a diverse population and individuals residing in neighboring counties speak other languages besides English in the home. Fifty-seven percent of families in Los Angeles County speak a non-English primary language, and this is true for 46% of households in Orange County and 38% of households in Riverside County. In all three of these neighboring counties, Spanish is the most common non-English language spoken (Los Angeles: 39%, Orange County: 26%, Riverside: 35%). If additional translations for the video and checklist are done in the future for the Chao Cancer Center patient population, the next most common spoken primary languages in these three counties are Vietnamese, Mandarin, Cantonese, and Tagalog; though these are all less than 10% of the total county population (Data USA, 2019).

The findings of this study illustrate the need for and potential to improve knowledge and understanding of saving certain medical records after a cancer diagnosis. As discussed earlier, challenges exist for people to receive this information: inconsistency of SCP delivery and medical records being stored in various places for varying amounts of time. Individuals with cancer and their family members may not have the level of health literacy and awareness as they encounter a cancer diagnosis and proceed through treatment. Receiving this information

through an educational video may provide them with knowledge that was not otherwise communicated while undergoing treatment and coping with a cancer diagnosis.

4.11 Suggestions from open comments for survey improvement

At the final survey question, participants were welcome to comment and make suggestions to the overall study, checklist, and video. A few of the suggestions highlighted areas on the survey that may have caused confusion for participants and, if measured again in a different population, should be changed and improved. Participants were asked if each of the GROUPS records had already been saved; options were strictly yes or no. An additional option should have been included for "not applicable", especially in the case of genetic test results. A participant who did not qualify for genetic testing would not have this record available; thus, a yes or no does not adequately reflect the fact that this record is not applicable to their collection of GROUPS records. There was also no option available if a participant received a Variant of Uncertain Significance (VUS) result; the only options to select were "no genetic testing done", "positive result", "negative result", or "I am not sure". Additionally, as previously discussed, several participants indicated their previous knowledge of cancer and healthcare. The suggestion was made to capture occupation and work setting in the survey to account for providers beginning the survey with full knowledge of the video content.

4.12 Conclusions

This original study collected and measured pilot data for an educational video, providing evidence it is useful to teach people about the importance of saving certain medical records after a cancer diagnosis. Data revealed study participants believed the checklist was useful,

and the video was both helpful and provided motivation for them to save the GROUPS records discussed in the video. Even though an overall improvement was made after watching the video, many participants began the study with a relatively high pre knowledge about the topic. This indicates, even with the overall improvement after the video, there may be an opportunity for greater knowledge and understanding gained for those with an average or lower level of awareness about the topic. Specifically, participants had the lowest level of prior knowledge regarding what an oncology note is and where to find it; this was also the record that showed the greatest amount of growth in knowledge and understanding after the video. This finding suggests there may be a gap in education and an opportunity to teach people about what an oncology note is, what it provides, and its importance in saving this record for oneself and subsequent generations. Participants who were 50 years or older demonstrated a greater increase in knowledge and awareness after watching the video than those younger than 50, indicating people of this age group may be more inclined or interested in learning about the information. Overall, the greatest area of improvement was made in participants' confidence in learning what GROUPS documents should be saved and how to save them, illustrating there is potential for individuals with cancer and their families to benefit from this information, gain confidence, and be motivated to save records for subsequent generations to use in the future. Limitations for the study include participants' occupational healthcare bias and/or background knowledge of healthcare, as evidenced by more than 75% of the study having a relatively high pre score as well as more than half the participants indicating they have already saved specific GROUPS medical records. A future quality improvement study is planned to place the video and checklist on the website for the high-risk cancer clinics at UC Irvine. An additional follow up

study should target primary Spanish speaking patients to obtain pilot data on this specific population before expanding its utilization. Future use of this video and checklist should target individuals with a lower health literacy as this population has the greatest potential for educational gain and benefit from the GROUPS video and checklist.

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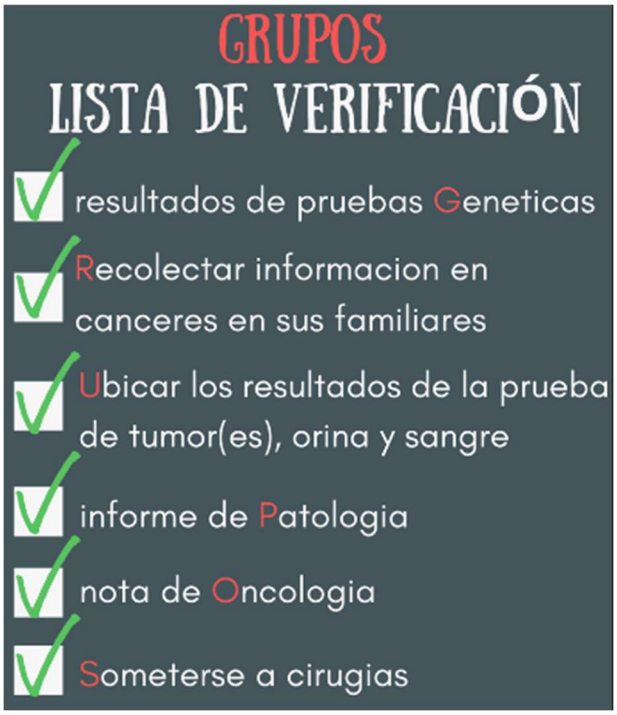
Appendix A: GROUPS and GRUPOS Checklists presented in educational video



Appendix B: Open ended survey comments, in order of time survey was taken

“Very helpful.”

“I think the video is helpful for patients but less helpful for family members. As my family member with cancer has passed and I do not have a relationship with their next of kin, I do not have any way to access any records.”

“Helpful to understand family history and collect detailed medical records for future use.”

“Very helpful.”

“I am a genetic counselor, so was already familiar with most of this. I think the video will be a great tool for my patients!”

“It’s not always possible to obtain records for cancer diagnosis that was a long time ago, which the video touched on. is there a way to be reassuring about that or to give other options for people whose loved ones had cancer 10+ years ago? are there any options?”

“Did not add significant information to what I already have (context: I work in healthcare)”

“This would be a helpful resource to someone more naive to cancer genetics than I am.”

“It let me know how important it is to keep these materials, with multiple post-treatments it can provide a lot of help and time.”

“Learned that knowing a person's family history can be helpful in the future. Didn’t realize how much this was true.”

“It is an easy way to remember the important stuff to save.”

“Some individual scenes are "busy", distracting, move very quickly. Might need to be viewed multiple times to glean info?”

“Maybe adjust survey to capture education and work setting. I’m a provider so I knew all of this.”

“As a 48 year long cancer survivor now dealing with late effects, I am fortunate to have all my old records but my original surgery notes (although I do have the summary). I have found paper records to be the most helpful to keep over the decades, as electronic record systems change, software changes, passwords get lost, but paper records can travel with you easily. I strongly recommend all survivors print out their important records, especially surgery notes, pathology reports, chemo types and regimen, radiation type, dose, regimen, and targeted location map, as well as records of any secondary cancers, side effects, and atypical testing. All scans should be saved for future comparison.”

“Most helpful to me was knowing that medical records are only kept for a certain number of years. I saved everything from my initial cancer diagnosis which was over 25 years ago and I’m so glad that I did.”

“It may be helpful for those who haven’t experienced cancer or been a caregiver or a parent to someone that has cancer.”

“A downloadable checklist to fill out at the end would be helpful.”

“Indicate if the reason records are not available is patient did not meet criteria for genetic testing. No, not yet does not adequately capture it. Also, I mistakenly interpreted knowing what the term means vs understanding the content.”

“The survey wasn't completely clear on how to answer if I (personally) have saved these documents vs if someone else in the family has. In my case, it's the latter, but I know where to get them if needed.”

“Great info! Especially like getting the information to each child I had not thought of that.”

“Very good survey and video.”

“Very helpful to know what records are important to save for the future.”

“This is great. The survey & video is very helpful. A link to where some apps can be found would help people use them.”

“Pause 2 seconds between each category so I can write them down.”

“Very helpful video.”

“I think it was very helpful to learn how to keep my records better.”

“I liked the acronym. Thank you.”

“Being able to save a copy of the checklist would be useful.”

“It's short and thorough. I like the visual of a video and the examples provided.”

“Provides a simple way to remember what to save.”

“Good acronym.”

“A written GROUPS list to copy would be helpful.”

“Some of the scenes (containing a lot of text) flashed by too quickly to read and register.”

“It was very helpful for me to know the importance of keeping these materials.”

“Sharing what not to save would be helpful as there are many records that one inherits after a relative has cancer.”

“Liked the groups acronym.”

“I think the content of this video is very complete and easy to understand, I think I have learned a lot, I think I will use this list to record and save.”

“As a breast cancer patient, I worry about the future health of my twin daughters who are 7. Saving important health documents now for them to read in the future will be at the top of my

priority list. Also their maternal grandma (my mom) had cancer and passed away at 71. I will be gathering those materials too."

"One of the items was labeled with an unfamiliar label ("Oncology Note"); the video clarified and confirmed that I do have that documentation. The video also reinforced my efforts to obtain and retain records. This project would be helpful if there were room to provide info on additional family members' cancers and decisions to undertake genetic testing. Overall, I felt it was a good, clear well-paced introduction to the issues."

"Very helpful."

"I need to figure out best place to store the docs."

"The video was very useful, now what should I do for my future and that of my brothers."

"I think this video is very helpful for me and I think I will use this list to record."

"There was no audio! When I stopped the video to read the CC, the words were covered. I'm a slow reader. This was way too difficult. Sound would make all the difference. A printed 1-page fact sheet with this content would also be helpful. Good idea. Not executed well."

"This is a good idea. My only thought is that pulling those specific records out of the mass of papers I have requires some effort, and time and effort are often in short supply after a diagnosis. It would be nice if there were some quicker way to do this - perhaps if online records had an option to print only those records designated under this category? Otherwise I think many of us will be lazy and just not get to this. I also wonder what makes sense for those of us who don't have children to do and share."

"I am very glad to participate in this survey, I think it is very helpful to me, I did not realize what I needed to record and save, but now I think it is very necessary, thank you very much."

"Never thought about this until the video. My father had cancer and I generally know his diagnosis and treatments but never thought about genetic testing or pathology reports. Just asked my mom for whatever documents she has before I even finished the survey! Thank you. Excellent information. Easy to understand and makes the data collection seem manageable."

"Good, useful information."

"Glad I could participate in this survey; it was helpful to me. I think I can keep a good record of my medical history."

"Video was very helpful in understanding the importance of keeping medical records. Narrative was very clear and concise and motivated me to gather information from my family that will be helpful in the future."

"I didn't understand at first why you were asking about my 1st degree relative's cancer treatment."

"I don't have any children, nieces or nephews, so it's not really applicable to me..."

“With extensive, evolving disease I have had a lot of biopsies/biomarker testing all which have had slight differences and a lot of surgery/treatments. Still unclear on which to keep and at what level. My online system refers to Oncology Report as clinic Note (it’s part of each clinic note).”

“Let's make it a little bit more intuitive.”

“This is a very good video, very productive, thank you very much.”

“Very helpful information to provide to my four children.”

“I knew I would use the GROUPS list to collect medical records.”

“It's very helpful! Reaching out to my dad and will share with our clients. Nicely done!”

“GROUPS acronym was very helpful!!”

“I'm glad I can do this survey. I know how to save the records, which is of great help to my family.”

“I think this video is very helpful to me. Thank you very much. I know how to record and save it”

“It allows us to know how at risk we are of developing cancer ourselves and to better prevent cancer”

“I am uncertain as to where I get the oncology report. From the oncologist, I assume.”

“Definitely think a PDF of the checklist would help, and also how to approach relatives about having this information without it seeming too insensitive or adding something to their plate while also experiencing the really tough road of hopefully treatment, recovering and healing”

“Amazing job!”

“I think GRUPOS is useful but perhaps the explanation in the presentation of what each letter means is difficult to memorize. I could only remember the first letter. “

“Very helpful. Unfortunately, I lost both of my parents to cancer more than 30 years ago and no records were saved and obviously there is no way to go back and recover the information.”

Appendix C: List of categorical variables collected

Age

Sex

Race or ethnicity

Education level

Number of children

Where found out about survey (for some participants; question added after data collection began)

Type of relationship of person with cancer to survey participant

- Age of cancer diagnosis
- Number of primary cancers
- Site of primary cancer
- Type of treatments
- Genetic testing done/results

Appendix D: IRB protocol

UCI Office of Research	**Institutional Review Board Human Research Protections** **Exempt Self-Determination Tool** **UPDATED!** *Version June 2021*

UC Irvine IRB review is required for *most* activities that constitute engagement in human subjects research, as federally defined.

At UCI, researchers, including undergraduate students proposing exempt human subject research as part of the Undergraduate Research Opportunities Program (UROP) are permitted to self-determination their exempt research without confirmation from the IRB.

IMPORTANT! Should the study sponsor require evidence of IRB review for a self-determination of exempt research, please provide the sponsor this letter.

INSTRUCTIONS:

1. **Review Parts A & B to determine if the research is eligible for exempt self-determination.**

2. **If the research is eligible for exempt self-determination, maintain a copy of the completedExempt Self-Determination Tool and any supporting documentation in your records.**
   a. **Sign the Lead Researcher (LR) Assurance statement at the end of the Exempt Self- Determination Tool. Obtain the Faculty Sponsor's signature as appropriate.**

   b. **IMPORTANT! Do NOT submit the Exempt Self-Determination Tool to the IRB.**

3. **If UCI IRB Review *is* required, please submit a New IRB Application for exempt, expedited, orfull committee review. For more information, please review: How To Submit Electronic IRB Applications for Review.**

If you have questions about completing the Exempt Self-Determination Tool or about the IRBprocess in general, contact the Human Research Protections staff.

COVID-19 IMPORTANT REMINDER! Refer to the Office of Research webpage on ResearchContinuity for details on what research is allowed at UCI.

PART A: VERIFY SELF-DETERMINIATION ELIGIBILITY

The activity is eligible for exempt self-determination *IF* all of the statements below are true.

IMPORTANT! If one or more statement below are not true then the research is not eligible for exempt self-determination and IRB review is required.

☒ **A. The research IS human subject research.**
Please review the Non-Human Subject Research Determination form. If your activity is non-human subject research, please complete the form and maintain it for your records.If your activity does not qualify as non-human subject research, please check the box tothe left and proceed to the next check box.
NOTE: Graduate student dissertation research involving humans is consideredhuman subject research – please check the box to the left.

☒ **B. This research is NOT Food and Drug Administration (FDA) regulated.**
An individual becomes a *human subject* for FDA purposes if their data or specimens are used as the recipient of the test article or control. For example, when retrospective data areused as the control, the individuals become human subjects. Likewise when an individual's blood sample is used to test an assay, the individual becomes a human subject. *Specimen* includes the use of leftover specimens **that are not individually identifiable** (e.g., a remnant of a human specimen collected for routine clinical care oranalysis that would otherwise have been discarded).

☒ **D. The research is NOT supported by the Department of Justice (DOJ).**
Research that is funded/supported by the Department of Justice (DOJ) is not eligible for exemption either by Self-Determination or through submission to the IRB. Submit a New IRB Application for expedited / full committee review. For more information, please review:How To Submit Electronic IRB Applications for Review.

☒ **E. The research does NOT include any of the following.**

1. The use or disclosure of UCI Protected Health Information (PHI)[1]
    a. *Use* is any sharing, employment, application, utilization, examination, or analysis within the entity
    b. *Disclosure* is any release, transfer, provision of access to, or divulging outside of entity
2. A targeted recruitment of children targeted recruitment of children
3. A targeted recruitment of adults (age 18 or older) who may not belegally/mentally/cognitively competent to consent
4. A targeted recruitment of prisoners (*may* include parolees)
5. A targeted recruitment of American Indian/Alaska Native tribes
6. A targeted recruitment of undocumented people
7. International Research
8. A request for UCI to serve as IRB of Record for non-UCI individuals engaged in humansubjects research.
    a. Note: To initiate a request for UCI to serve in this capacity, the LR must have a dual affiliation with the non-UCI entity and IRB review is required to formalize the reliance process.
9. A study team member has a Disclosable Financial Interest

IMPORTANT! IRB approval is required to enroll any of the above listed subject populations. Should the study team inadvertently encounter a potential subject that belongs to an excluded population above, this individual may NOT be enrolled in the study.

PART B: VERIFY EXEMPT CATEGORIES ELIGIBLE FOR SELF-DETERMINIATION

1. **Please review the following Exempt categories that are eligible for self-determination.**

2. **Check the category(ies) that apply to the research.**

IMPORTANT! If one or more category below are not applicable then the research is not eligible for exempt self-determination and IRB review is required.

[1] When PHI is communicated inside of a covered entity, this is called a ***use*** of the information. When PHI is communicated to another person or organization that is not part of the covered entity, this is called a ***disclosure***. HIPAA allows both use and disclosure of PHI forresearch purposes, but such uses and disclosures have to follow HIPAA guidance and have to be part of a research plan that is reviewed and approved by an Institutional Review Board (IRB).

Category 1: Education (the following criteria must be met)	
☐	Research, conducted in established or commonly accepted educational settings and specifically involves normal educational practices that are **NOT** likely to adversely impact students' opportunity tolearn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on theeffectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **IMPORTANT!** Research involving the secondary analysis of materials derived from normal educational practices is not eligible for Exempt Category 1 and must either be reviewed under ExemptCategory 4 or Expedited Category 5.
Category 2: Interactions (the following criteria must be met)	
☒	Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (includingvisual or auditory recording) [2] ***One of the following criteria must be met:*** ☒ 2i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects **CANNOT** readily be ascertained, directly or through identifiers linked to thesubjects ***OR*** 2ii) Any disclosure of the human subjects' responses outside the research would **NOT** reasonably[3] place the subjects at risk of criminal or civil liability or be damaging to the subjects'financial standing, employability, educational advancement, or reputation

	Category 3i: Behavioral Interventions *(All of the following criteria must be met)*	
☐	☐	The research involves behavioral interventions in conjunction with the collection of information from an**adult subject** through verbal or written responses (including data entry) or audiovisual recording if thesubject prospectively agrees to the intervention and information collection
☐	☐	The behavioral interventions are brief in duration[4], harmless, painless, not physically invasive, not likelyto have a significant adverse lasting impact on the subjects, and the investigator has no reason to thinkthe subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

[2] *Subpart D applicable only when involving educational tests or the observation of public behavior when the investigator(s) do NOTparticipate in the activities being observed.*

One of the following criteria must be met:	
☐	3iA)The information obtained is recorded by the investigator in such a manner that the identity ofthe human subjects **CANNOT** readily be ascertained, directly or through identifiers linked to thesubjects
	OR
☐	3iB) Any disclosure of the human subjects' responses outside the research would **NOT** reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects'financial standing, employability, educational advancement, or reputation
Category 4: Secondary research for which consent is not required:	

SECTION 1: STUDY INFORMATION

1. Specify Activity Title (if applicable).
Preserving Medical Records after a Cancer Diagnosis for Subsequent Generations to Use
2. Identify the funding source. *Check all that apply:*
Student project that will incur no costs.
☒ Department or campus funds (includes department support, unrestricted funds, start-upfunds, personal funds, campus program awards, etc.)

Grant/Subaward ***OR*** Contract/Subcontract

1. Provide details below:

   Prime Awardee(s): **Type Here**

   Sponsor Name(s): **Type Here**

   SPA Proposal or Award #(s): **Type Here**

2. **Maintain on file:** A copy of the human subjects portion of the grant.

Other; specify: **Type Here**

SECTION 2: PURPOSE OF THE RESEARCH

1. Provide a non-technical summary of the proposed research that can be understood individualswith varied research backgrounds, including non-scientists.

This summary should not exceed ½ of a page.

Family medical history from previous generations often goes unpreserved, and records with critical information are either lost or discarded. This becomes apparent when a patient presents years later, being evaluated for a possible hereditary cancer predisposition. The young patient may not be certain of the type of cancer, treatments completed, or genetic test results a parent orolder family member experienced. The goal of this project is to inform cancer patients and their families of the importance of preserving an accurate family history for their younger family members in subsequent generations, educate cancer patients and their families on which medicaldocuments to preserve, and provide instructions to preserve medical documents for future reference. The proposed research will provide cancer patients and their families a simple processthat teaches them which medical documents should be collected and how to preserve them. By preserving specific documents, subsequent generations will have an accurate family medical history and, hopefully, will be able to avoid a future situation of presenting years later for a health evaluation of a possible hereditary cancer predisposition without the critical information available.

2. Describe the purpose, specific aims or objectives.

Purpose of the study is to educate people with cancer and their families about which medical documents are important to save for subsequent generations. Specific aims: to increase knowledge of which medical records should be kept, increase the awareness of why keeping them is important, and increase confidence in where to find them and how to save them years and decades in the future. Success of the video intervention will be determined by a 10%+ increase in composite and/ordomain score changes between pre-and post-survey questions. Capturing baseline data will be important for a future study to maximize effects of behavioral changes of patients and improving their knowledge, awareness, and preservation of these medical documents.

3. Specify the hypotheses or research questions to be studied.

The purpose is to show a straightforward educational animated video and simplified checklist explaining which medical records should be preserved after a cancer diagnosis for subsequent generations to use. The main objective of the study is to provide education to individuals with cancer and their spouses/partners/family members so younger family members may benefit from having accurate histories to provide additional screening recommendations or genetic testing andcounseling.

Hypotheses for the study include:

- the educational video will increase knowledge of which medical records should bepreserved
- the educational video will increase confidence in where to find/who to ask for thesedocuments
- the educational video will increase the level of understanding of how to preserve thesedocuments

Research questions this study will ask:

- What is participants' baseline knowledge of these medical documents?
- How does this educational video intervention change the level of knowledge of thesedocuments?
- How does this educational video intervention change understanding for the importance ofpreserving these medical documents?

4. COVID-19: Does this research include a focus on SARS-CoV-2/COVID-19 (Coronavirus)?

☒ **NO**

YES: Please consider whether Ancillary Committees for COVID-19 Research apply.

5. If study team will recruit their own students and/or employees, specify the precautions taken toavoid compromised objectivity.

☒ Not applicable: Study team does not recruit their own students/employees.

Type Here

SECTION 3: STUDY TEAM

1. **A. UCI Study TeamList the Lead Researcher (LR), Co-Researchers (CR), and Research Personnel (RP) who will be engaged in human subject research.**

    - **CRs are faculty, staff, students and other academic appointees who the LR considers to be key personnel for conducting the research study. These individuals work closely withthe LR to design, conduct, and/or report on the research.**

2. **If there is a Faculty Sponsor (FS), they must be identified to provide oversight and guidance tothe LR. The FS should be designated as having access to the identifiable information and/or identifiable biospecimens.**

3. **Include additional rows for study team members, as needed.**

4. **For each individual, indicate all applicable research activities they will perform.**

    a. **Finalizing informed consent is reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent.**

IMPORTANT! Do not list non-UCI researchers below. To initiate a request for UCI to serve as the IRB of Record for non-UCI researchers, the LR must have a dual affiliation with the non-UCI entityand IRB review is required to formalize the reliance process.

LR Name & Degrees: Elise Glines, MA **Position/Title:** Genetic Counseling Graduate Student**Department:** Pediatrics

Affiliation: UCI Faculty UCI Staff ☒ UCI Grad Student UCI Undergrad
UCI Other: TypeHere

Duties: Screen/Recruit Subjects Finalize Informed Consent Translate ConsentAccess/Analyze Identifiable Information Access/Analyze Identifiable Biospecimens
Research Procedures; specify: **Recruit participants, design the research study methodology, create the educational video and pre- and post-survey questions, and analyze collected data.**

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience): **Elise will be responsible for creating the educational video and pre- and post-surveys for the participants to complete. She will also design the study methodology, collect and analyze the data, and present these findings in both oral and written presentations for her thesis project. She is qualified to complete these tasks as she has participated in IRB-approved research studies in her previous graduate program at UC Irvine and has held several employed research positions in her career.**

☒ **FS Required** **OR** ☐ **FS not Required**

FS Name & Degrees: Jason Zell, DO **Position/Title:** Vice Chief of Academic Affairs in the Division of Hematology/Oncology, Program Director of Hematology/Oncology Fellowship TrainingProgram, and Associate Professor at UCI School of Medicine **Department:** Epidemiology

Affiliation: ☒ UCI Faculty UCI Other: Type Here

Duties: ☒ Oversight of Research Screen/Recruit Subjects
Finalize Informed ConsentTranslate Consent
Access/Analyze Identifiable Information
Access/Analyze Identifiable Biospecimens Research Procedures; specify: Dr. Zell will oversee allof the study design and execution. He will also oversee the production of the educational video, pre- and post-surveys, and the dissemination of materials to recruit participants in high risk cancerclinics at UCI Medical Center. He will recommend edits to the written thesis dissertation.

List the research activities/procedures to be performed and the individual's relevant qualifications(training, experience): Dr. Zell is the cancer control and prevention liaison to the gastrointestinal committee within SWOG, a clinical trials organization of the National Clinical Trials Network.
Additionally, he is national principal investigator for SWOG clinical trial #S0820/PACES, a large multicenter randomized Phase III trial involving risk reduction among resected colon cancer patients, which is supported by the NIH National Cancer Institute-Division of Cancer Prevention. Heserves on two clinical trials-based committees within the NIH-NCI: The Cancer Prevention Steering
Committee and the Gastrointestinal Steering Committee's Rectal/Anal Task Force.

☒ **CR** **OR** **RP**

Name & Degrees: Kathryn Singh, MPH, MS **Position/Title:** HS Associate Clinical Professor**Department:** Pediatrics

Affiliation: ☒ UCI Faculty UCI Staff UCI Grad Student UCI Undergrad
UCI Other: TypeHere

Duties: ☒ Screen/Recruit Subjects Finalize Informed Consent Translate ConsentAccess/Analyze Identifiable Information Access/Analyze Identifiable Biospecimens
Research Procedures; specify: Provide guidance on the study design, help recruit participants, review and make recommendations for survey and educational video content, assist with statistical analysis, and edit written thesis dissertation.

List the research activities/procedures to be performed and the individual's relevant qualifications(training, experience): Kathryn has completed her own thesis to complete the Genetic Counseling

program at UC Irvine. She has vast experience with this study population and has held numerous positions in which she has interacted with cancer patients and their families. In addition, she has had roles and responsibilities in which she has been involved with conducting research protocols (study design, implementation, and statistical analysis).

☒ **CR** **OR** **RP**

Name & Degrees: Meghan Gillespie, MS **Position/Title:** HS Assistant Clinical Professor**Department:** Pediatrics

Affiliation: ☒ UCI Faculty ☐ UCI Staff ☐ UCI Grad Student ☐ UCI Undergrad ☐ UCI Other: TypeHere

Duties: ☒ Screen/Recruit Subjects ☐ Finalize Informed Consent ☐ Translate ConsentAccess/Analyze Identifiable Information ☐ Access/Analyze Identifiable Biospecimens ☐ Research Procedures; specify: Review and make recommendations for survey and educational video content, help with recruitment of participants, assist with statistical analysis, and edit written thesis dissertation.

List the research activities/procedures to be performed and the individual's relevant qualifications(training, experience): Meghan has completed her own thesis to complete the graduate coursework. Her project similarly created an educational intervention video and she analyzed theresults from her project. She has held numerous positions in which she has interacted with this study population and with conducting research protocols (study design, implementation, and statistical analysis).

☒ **CR** **OR** **RP**

Name & Degrees: Katherine Hall, MS **Position/Title:** Genetic Counselor **Department:**Pediatrics

Affiliation: ☒ UCI Faculty ☐ UCI Staff ☐ UCI Grad Student ☐ UCI Undergrad ☐ UCI Other: TypeHere

Duties: ☒ Screen/Recruit Subjects ☐ Finalize Informed Consent ☐ Translate ConsentAccess/Analyze Identifiable Information ☐ Access/Analyze Identifiable Biospecimens ☐ Research Procedures; specify: Review and make recommendations for survey and educational video content, help with recruitment of participants, assist with statistical analysis, and edit written thesis dissertation.

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience): Katherine has completed her own thesis to complete the Genetic Counseling program at UC Irvine. She has held numerous positions in which she has interacted with this study population and with conducting research protocols (study design, implementation, and statisticalanalysis).

SECTION 4: SUBJECT POPULATION(S) (INDIVIDUALS/RECORDS/BIOSPECIMENS)

A. Persons/Records/Biospecimens to be Enrolled

1. Complete the table below with each Category/Group documented on a separate row. Includeadditional rows for categories/groups, as needed.

2. Specify the maximum number of individual-level information and/or biospecimens to beaccessed/analyzed within each cohort and in total across all cohorts.

Category/Group (e.g., adults, parents, healthy controls)	**Age Range** (e.g., 18 or older)	**Maximum Number to be Consented or Reviewed/Collected** (include withdrawals and screen failures)	**Number Expected to Complete the Study or Neededto Address the Research Question**
adults	**18 or older**	**500 (max due to feasibility of analysis with time available)**	**100 is expected minimum**
As many participants as possible will be included. Estimate 100-500 based on projections of number of patients see in UC Irvine Cancer Genetics patients seenin clinic per week. Timeframe to collect data is mid-October 2021 through mid-January 2022.		**Total: 500**	

B. Overall Study Sample Size

If this is a multi-site study, provide the total number of subjects to be enrolled from all sites.

☒ Not applicable: This study will only take place at UCI, and does not involve other sites.

Specify total number of subjects across all sites: **Type Here**

C. Eligibility Criteria

1. Identify the criteria for inclusion and exclusion for each of the study populations. Include additional rows for categories/groups, as needed.

Category/Group (e.g., adults, parents)	**Inclusion Criteria:**	**Exclusion Criteria:**
Adults	**Currently have or had cancer**	**Younger than 18 years of age**

Adults	spouse/partner or 1st or 2nd degree relative of a person with cancer	Younger than 18 years of age

SECTION 5: PRE-SCREENING AND DETERMINING ELIGIBILITY WITHOUT INFORMED CONSENT

☒ Not applicable: Identifiable information will not be obtained for the purpose of screening, recruiting, or determining eligibility of prospective subjects. **Skip to Section 6.**

1. The 2018 Common Rule allows for pre-screening activities (i.e., determining if potential subjects may be eligible to participate in research) performed without the written informed consent of the prospective subject or legally authorized representative (LAR). This means that the IRB does notneed to grant a waiver of consent. **2. Provide a complete list of the data points, variables, and/or information that will be collectedduring pre-screening (i.e. data abstraction form).**
Check here if the list will be submitted as a separate document [i.e. case report form (CRF;eCRF)]. Variables or information required for pre-screening: **Type Here**
3. Indicate the methods of pre-screening. Check all that apply.
Study team will obtain information through oral or written communication with the prospectivesubject (i.e. self-report of medical information; medical records will not be screened).
Study team will screen student records. 1. **Check here** to confirm that the local school/district site has verified that signed permissionis not required to screen school records. 2. **Maintain on file:** Evidence of FERPA[5] compliance.
Other pre-screening: **Type Here**

4. **When contacting subjects prior to enrollment, use a pre-screening script that meets theminimum recruitment requirements.**

5. **In addition, the pre-screening process must adhere to the following guidelines:**

   a. **Privacy: The script must address the case where someone other than the potential subject receives the communication. Please be mindful of privacy considerations (i.e., do not disclose any private information). Limit phone contact / messages to no more than 5 attempts.**

   b. **Expertise: Study team member/s contacting potential subject must be knowledgeable and able to answer questions related to the screening and the main study.**

   c. **Specific Information: Include a description of the information that will be obtained for the purpose of screening, recruiting, or determining eligibility and the reasons for performing the screening tests.**

   d. **Confidentiality: Include a statement that informs the potential subject that if they are not eligible to participate in the study that the identifiable information will not be used for research purposes and will be destroyed at the earliest opportunity consistent with conduct of the research.**

☐ Not applicable: Subjects will not be contacted for eligibility or recruitment purposes.

Maintain on file: Pre-Screening Script which will follow the above guidelines.

SECTION 6: RECRUITMENT METHODS

☐ Not applicable: This study involves no direct contact with participants (i.e., passive observation of public behavior). **Skip to Section 7.**

Indicate all methods that will be used to recruit subjects for this study.

IMPORTANT! Recruitment materials must adhere to UCI Recruitment Guidelines. Varioustemplates are available here: Application and Forms → HRP → Recruitment Templates

Recruitment Method	Population	Recruitment

☒ Flyers/Brochures	☒ All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. Specify where posted: **High risk cancerclinics at UCI Medical Center** 3. Type of space: Public (i.e., site/media that allows openaccess to content) ☒ Private (i.e., site/media that allows control ofaccess to content)
Newspaper/Radio/ Television	All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. Specify where posted: **Type Here**
☒ Online/Social Media	☒ All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. Specify where posted: **Personal (Elise Glines') Facebook and Instagram page** 3. Type of space: ☒ Public (i.e., site/media that allows openaccess to content) Private (i.e., site/media that allows control ofaccess to content)
School of Social Ecology UCI HumanSubject Pool	All subjects **OR** specify cohort: **Type Here**	**Check here** to confirm that applicable consentdocuments will include reference to the use of SONA.
Individual/Group/ Class Presentation	All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. Specify where: **Type Here**
Email/Postal Mail/ Phone	All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. Specify how contact information will beobtained: **Type Here**

Study team will contact potential subjects who have given prior permissionto be contacted for research studies.	All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. Specify how these individuals granted permission: **Type Here** 3. HS#: **Type Here**
☒ Study team members will approach their ownpatients, students, employees.	☒ All subjects **OR** specify cohort: **Type Here**	1. ☒ **Check here** to confirm a statement attestingthe below will be included in applicable recruitment and/or consent documents. 2. ☒ **Check here** to confirm that subjects will be: b. Approached with the emphasis on the voluntary aspect of being on this study; and c. Informed that no matter their decision, itwill not affect: ✓ Their relationship with UCI ✓ How their doctor cares for them as a patient or their care at UC Health in general ✓ How their instructor grades their participation in the course
☒ Colleagues provide subjects with information about the research and how to contact investigators	☒ All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. ☒ **Check here** to confirm that colleagues may provide a copy of the consent and othermaterials but do not obtain subjects' consentfor the research or act as representatives of the investigators.

☒ Colleagues seek or obtain the subjects' permission for investigators to contact them	☒ All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment Materials 2. ☒ **Check here** to confirm that colleagues may provide a copy of the consent and othermaterials but do not obtain subjects' consentfor the research or act as representatives of the investigators.
Colleagues, who are treating physicians, will send UCI IRB approved recruitmentletter to their patients.	All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Recruitment letter to be signed by the treating physician. 2. **Check here** to confirm that colleagues do not obtain subjects' consent for the researchor act as representatives of the investigators.
☒ Other recruitment methods	☒ All subjects **OR** specify cohort: **Type Here**	Specify: **Email listserv through National Societyof Genetic Counselors (NSGC) to recruit participants who have been seen and counseled by other NSGC members, email cancer support groups to provide online study invitation to members of these support groups and their families**

SECTION 7: INFORMED CONSENT PROCESS

A. Methods of Informed Consent

Identify the consent or assent process as applicable for each participant population. Check all that apply.

Consent Process	Subjects	Required
No informed consent(no direct contact)	All subjects **OR** specify cohort: **Type Here**	
☒ Oral/Implied informed consent (no signature) ☐	☒ All subjects **OR** specify cohort: **Type Here**	1. **Develop and use:** Study Information Sheet 2. ☒ **Check here** for online consent and to confirm all of the following: ✓ A Study Info Sheet will be presentedprior to administering research procedures, ✓ Subjects verify they meet the eligibilitycriteria, ✓ Subjects indicate their willingness to participate in the research (e.g., click"Yes")
Paper-based signed Informed consent	All subjects **OR** specify cohort: **Type Here**	**Develop and use:** Adult Consent Form

Electronically signed informed consent (eIC)/assent ☐	All subjects **OR** specify cohort: **Type Here** ☐	1. **Develop and use:** Adult Consent Form 2. **Maintain on file:** All informational materials, including any videos and web-based presentations, which the subject will receiveand view during the eIC process. 3. **Maintain on file:** Any optional questions or methods used to gauge subject comprehension of key study elements. 4. **Check here** to confirm the eIC processadheres to the OHRP guidance: Use of Electronic Informed Consent: Questions and Answers

B. Circumstances of Consent

1. Indicate the location where the consent process will take place. Check all that apply.
Private room ☐ Waiting room ☐ Open unit ☐ Group setting ☒ Internet Over the phone ☒ Other; specify: **The online consent will be completed directly by the studyparticipant.**
2. Specify how the research team will assure that subjects have sufficient time to consider whetherto participate in the research.

1. Describe assurance process: **On the first page of the survey with the study explanation, subjects will be assured their participation is anonymous and voluntary. They may refuse to participate or discontinue involvement at any time during the surveys and video and for any reason.**

2. Timeframe to consider consent: ☒ As much time as needed **OR** specify timeframe: **Type Here**

3. Address whether deception or incomplete disclosure is involved.

IMPORTANT! Per Federal regulations, the use of deception or incomplete disclosure may only be exempt (and considered for a Self Determination of Exemption at UCI) if the (prospective) subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subjectis informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Ifadvanced disclosure is not possible, submit an Application to the IRB for Expedited review.

☒ Not applicable: No deception or incomplete disclosure is involved.

1. **Maintain on file:** Appendix G
2. **Develop and use:** Debriefing Script, as applicable
3. **Check here** to confirm that the consent document, discloses the use of deception or incompletedisclosure

C. Special Subject Populations

4. If subjects may be vulnerable to coercion or undue influence (examples below), describe theprocedures to ensure the voluntary participation of these individuals.

- **Individuals who are economically or educationally disadvantaged**
- **Students (undergraduate, graduate, and medical students)**
- **Employees of UCI (administrative, clerical, nursing, lab technicians, post-doctoral fellows and house staff, etc.)**

☒ Not applicable: Subjects in this study are not vulnerable to coercion or undue influence.

Type Here

5. Will this study include Non-English Speaking Participants?

Only individuals who can read and speak English are eligible for this study. **Skip to Section 8.**

☒ The English version of the consent materials will be translated for non-English speaking participants. An interpreter will be involved in the consenting process.

6. Indicate how non-English speaking subjects will be consented in their language and who will be responsible for interpreting and facilitating the informed consent discussion for the non-English speaking subjects.

IMPORTANT! If study team members are responsible for obtaining informed consent from non-English speaking subjects, provide their qualifications to serve in this capacity (i.e. language fluency) in Section 2, as applicable.

☐ At least one member of the study team is fluent in the language that will be used for communication,and that study team member(s) will be available during emergencies.

The study team has 24-hour access to a translation service with sufficient medical expertise to discussthe research in this study.

☒ Other; specify: **Participants will be consented in their primary language (English or Spanish). Survey and consent language will be written in English and translated to Spanish by a native,fluent speaker.**

SECTION 8: RESEARCH PROCEDURES

A. Study Location

1. Specify where the research procedures will take place. Include additional rows for locations, as needed.

2. If research activities will be conducted at private non-UCI locations (e.g., educational institutions, community clinics, private social media), Letters of Permission or other documentation may be required.

Location	Required	Procedures
Physical Location e.g.,: • Irvine High School • UCI Douglas Hospital, CardiacCare Unit • UCI Main Campus,Hewitt Hall	1. Specify: **Type Here** 2. **Maintain on file:** Letter(s) of permission for private non-UCIlocations.	All procedures **OR** specify procedures: **Type Here**
Virtual Location e.g.,: • Amazonturk • Zoom • Telehealth/VirtualCare	1. Specify: **Type Here** 2. **Check here** to confirm that virtual location's privacy and usepolicies will be followed.	All procedures **OR** specify procedures: **Type Here**

☒ Other	1. Specify: **All research study will take place online. Physical location of study participant may vary.** 2. **Maintain on file:** Letter(s) of permission for private non-UCIlocations	☒ All procedures **OR** specify procedures: **Type Here**

B. Research Procedures

1. Provide a detailed chronological description of all research procedures.
Recruitment for participants will begin after IRB approval (including Cancer Committee review) during Fall quarter 2021 (September/October 2021). Participants will be able to view and consent toparticipate in the study during the timeframe in which the surveys are open. The surveys will openSeptember/October 2021 and close mid-January 2022. After the surveys are closed, gift cards will be sent to 100 randomly selected survey participants. Data will be collected and compiled for statistical analysis in January 2022 and analyzed in January/February 2022 (details for analysis plan below). Results from the study will be presented orally in May 2022 and submitted as part of a master's thesis which will be submitted in early June 2022. **Statistical analysis plan (Jan/Feb 2022): Primary end point will be a composite score comparison between Likert scale pre- survey questions and post-survey questions. Each question will be rescaled to point values out of 100; 4-point Likert scale questions will be valued at 0, 33.3, 66.7, and 100 (lowest level of knowledge/awareness to greatest level of knowledge/awareness) and 5-point Likert scale questions will be valued at 0,25,50, 75, and 100 (lowest level of knowledge/awareness togreatest level of knowledge/awareness). The change in these composite scores (pre- and post-survey) will be assessed for knowledge change after the video intervention. If data follows a normalcurve, a paired t-test will be used; if not, the nonparametric equivalent, Wilcoxon signed rank test, will be used.** **Secondary end point will look at the statistical significance of 4 individual domains (as a whole these 4 domains sum to the composite score assessed as the primary end point): knowledge, awareness, self-efficacy in locating, and confidence in knowing how to preserve the medical documents. The pre- and post-survey questions will be looked at in more detail through these individual domains to see if any domain(s) show larger change(s) compared to others (i.e. knowledge of medical documents improved while confidence in knowing how to preserve the documents did not change).** **Third end point will include another layer of analysis; use of Wilcoxon signed rank test for all subgroup analyses of pre- and post-score changes for each categorical independent variable (i.e. age, ethnicity, number of children, number of unique cancer diagnoses, location of primary cancer, presence of hereditary cancer syndrome detected through genetic testing, etc).** **These end points will measure the hypotheses of the study: the change in knowledge, awareness, self-efficacy for who to ask/where to find, and confidence in storing the medical documents, after watching the educational video. In addition to these end points, complete descriptives, histograms, means, medians, interquartile ranges, standard deviations, and frequencies will be completed.**
2. List all procedures involving the use and/or collection of photographs, or audio/video recording.

None	☐

3. Specify the total duration of a subject's participation in the study.

4. Multiple Time Points: Clearly outline the duration of participation for each study visit and sub-study, as applicable.

a. Specify the length of time and frequency between each visit, procedure, and study related follow-up.

b. It is strongly recommended that a table of visits, tests and procedures be included. Tables are easier to understand and may help to shorten long repeated paragraphs throughout the narrative.

Total duration: 20-35 minutes. Pre- and post-surveys and educational video (the total of these three study components should not exceed 35 minutes). The study should be completed in one visit, not to exceed 35 minutes.

5. List data collection tool (e.g., measures, questionnaires, observational tool). Include additionalrows for study instruments, as needed.

Name of Tool	Standardized/validated
Pre-survey (Qualtrics) to measure participant's baseline level of knowledge and awareness.	☒ No: **Maintain on file:** InstrumentYes; citation: **Type Here**
Educational video (produced with Vyond software) to teach importance of which medical records should be preserved.	☐ No: **Maintain on file:** InstrumentYes; citation: **Type Here**
Post-survey (Qualtrics) to measure particpant's level of knowledge and awareness after the educational intervention.	☐ No: **Maintain on file:** InstrumentYes; citation: **Type Here**

C. Secondary Research Using Identifiable Private Information

☒ Not Applicable: The research does not involve the secondary use of identifiable private information. **Skipto Section 8.D.**

1. Indicate the types/sources of identifiable private information.

IMPORTANT!

- **When accessing/transferring data from a non-profit, please contact Grace J. Park atparkgj@uci.edu.**
- **When accessing/transferring data from a for-profit, please contact the Industry ContractOfficer at UCI Beall Applied Innovation assigned to your department.**
- **When transferring tangible research material between organizations, please contact UCI BeallApplied Innovation at MaterialTransfer@uci.edu.**

Information Source	Required
Identifiable photographs, images, or digital/audio/video recording	Specify: **Type Here**
UCI Student Education Records	1. Types: **Type Here** 2. **Maintain on file:** The FERPA[6] compliance letter from theUCI Registrar.
Non-UCI Student Education Records	1. Types: **Type Here** 2. **Maintain on file:** The FERPA compliance letter from thelocal school/district site.
UCI Student Health Medical Records	1. Types: **Type Here** 2. **Maintain on file:** The FERPA compliance letter from theUCI Registrar.
Other records	Specify: **Type Here**

2. Indicate whether the information was originally collected for research purposes.

[6] *34 CRF 99: Family Educational Rights and Privacy Act (FERPA) applies to this research.*

Original Collection	Require

	d
Not originally collected for research.	Explain how the information was originally collected: **Type Here**
Collected for research under aUCI IRB approved protocol.	☐ HS#: **Type Here**
Collected for research under a non-UCI IRB approved protocol.	1. **Check here** to confirm the IRB approved consentform does not preclude the research. 2. **Maintain on file:** Copy of the IRB approval and consentform for the original research collection.
Collected for research by acommercial vendor.	1. **Check here** to confirm the vendor's policy does notpreclude the research. 2. **Maintain on file:** Copy of the Vendor Policy/Letterattesting that the sharing of biospecimen is ethical.

☐

3. Provide a complete list of the data points, variables, and/or information that will be collected (i.e.data abstraction form).
Check here if the list is maintained as a separate document [i.e. case report form (CRF;eCRF)]. Variables or information: **Type Here**
4. Specify the time-frame of the data to be accessed (e.g. January 2002 to 2024).
Type Here

☐

D. Secondary Research Using Identifiable Biospecimens

☒ Not applicable: The research does not involve the secondary use of identifiable biospecimens.
Skip toSection 9.

SECTION 9: RISK ASSESSMENT AND POSSIBLE BENEFITS

A. Risks and Discomforts

1. Describe and assess any reasonably foreseeable risks and discomforts associated with each procedure for each subject population — physical, psychological, social, legal or other. **2. If this study will involve the collection of identifiable private information, even temporarily, for which the disclosure of the data outside of the research could reasonably place the subjects atrisk, include the risk of a potential breach of confidentiality.** **A bullet point list is recommended.**
See "Risks" section of the UCI consent document. **The study should provide minimal risks to participants. Due to the nature of the study population, it is foreseeable that the survey could result in psychological discomfort to participants due to currently facing/having faced a cancer diagnosis, possible surgeries and treatments, and follow up appointments. The survey questions could remind patients and their family members (all invited to participate in the study) of past or current experiences that may result in psychological discomfort.** **No identifiable private information will be involved for which the disclosure of data outside of thestudy could reasonably place subjects at risk.**
3. Discuss what steps have been taken and/or will be taken to prevent and minimize therisks/potential discomforts indicated above associated with each procedure. **Examples include:** • **designing the study to make use of procedures involving less risk when appropriate;** • **implement security provisions to protect confidential information.**
Contacts for local and national cancer support groups will be provided at the end of the study. **No PHI or private identifying information will be collected.** **Participation will be voluntary; subjects can choose to stop participating at any point and for any reason.**

B. Certificate of Confidentiality

☒ Not applicable: The research is not partially or wholly funded by NIH, including NIH Institutes and Centers.
Skip to Section 9.C.

1. Indicate whether research is protected by a NIH Certificate of Confidentiality (CoC).
This research is partially or wholly funded by NIH, including NIH Institutes and Centers. A CoC is automatically issued.
2. Indicate in what situations identifiable private information protected by a CoC will be disclosed. Check all that apply.

As required by Federal, State, or local laws, excluding instances of disclosure in any Federal, State, orlocal civil, criminal, administrative, legislative, or other proceeding. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm
yourself or others.

When necessary for the medical treatment of the individual to whom the information, document, orbiospecimen pertains and disclosed with the consent of such individual;

Disclosed with the consent of the individual to whom the information, document, or biospecimenpertains;

Disclosed for the purposes of other scientific research that is in compliance with applicable Federalregulations governing the protection of human subjects in research.

C. Potential Benefits

Describe the potential benefits to society, and, if applicable, to the participant.

IMPORTANT! Compensation (i.e., gift cards, cash, course credit, etc.) is not a benefit.

1. Societal Benefit: **The information learned in this study can increase knowledge and awarenessto others as this information is shared and used. Collecting certain medical records and an having an accurate knowledge of family medical history after a cancer diagnosis can help individuals follow individualized, recommended screening guidelines for early cancer detection. This study is beneficial to society because it will help simplify the process of collecting useful medical records. Hopefully this will help to avoid the situation of an individual presenting years later for an evaluation of a possible hereditary cancer predisposition without any documentation of the family history.**

2. Participant benefit: **Immediately beneficial, this education information can be put into practice for participants and their family members. Participants can use this information to put
together medical records to preserve for subsequent generations if they have not already doneso.**

ADDITIONAL SECTION FOR CFCCC's Data and Safety Monitoring Board (DSMB):

Data and Safety Monitoring Plan

This is a **risk level 3 study**, as defined in the Chao Family Comprehensive Cancer Center (CFCCC) Data and Safety Monitoring Plan (DSMP) because it is a survey-based study and does not involve the secondary use ofidentifiable private information. No identifiable private information will be involved for which the disclosure of data outside of the study could reasonably place subjects at risk. The study involves participants fill out a pre-survey, watch a brief educational video, and complete a post-survey. It should provide minimal risk due to thesurvey nature of this study. Foreseable minimal risks that could occur would be survey questions that may remind participants of previous cancer diagnoses, treatments, etc. and these memories may result in psychological discomfort. Participants may stop participation in the study for any reason and at any time.

The Principal Investigator (PI), co-investigator, clinical research coordinator, and statistician are responsible for monitoring of data and safety for this study. For studies that have stopping rules for safety and efficacy, the PI will be responsible for the implementation and make changes as applicable. The CFCCC Data and Safety Monitoring Board (DSMB) is an independent body responsible for the safety of study subjects as well as the dataintegrity of the protocol. Data and safety will be reported to the DSMB with submission of progress reports that include aggregated reports of adverse events, serious adverse events, deviations, and violations. In addition, certain adverse events, serious adverse events, deviations, violations, and unanticipated problems will be reported promptly to the DSMB for review according to the tables below.

The CFCCC Stern Center for Cancer Clinical Trials and Research Quality Assurance Unit will conduct monitoring and auditing activities as per the UC Irvine CFCCC Quality Assurance Monitoring and Auditing Planand at the discretion of the CFCCC DSMB in order to ensure patient safety and data integrity oversight. By conducting internal monitoring and auditing, the CFCCC will ensure compliance with high quality standards andall applicable regulations, guidelines, and institutional policies. Trial monitoring and auditing may be completed remotely or on-site.

Risk Levels

Risk Level	Definition	Monitoring
Level 1	**High Risk** - UCI investigator-initiated interventional trials for which the PI holds Investigational NewDrug (IND) or Investigation Device Exemption (IDE). Example: Gene therapy, dendritic cell products from GMP suite, phase I/II development and phase I studies, first in human, etc.	Two months after subject enrollment
Level 2	**Medium Risk** - UCI investigator-initiated interventional trials for which IND/IDE is exempt by FDA. Example: Use of commercially available agents for an unapproved indication.	Six months aftersubject enrollment
Level 3	**Low Risk –** UCI investigator-initiated interventional trials that are minimal risk. Example: Phase III clinical studies, dietary intervention trials, and after-market studies.	Twelve months after subjec tenrollment
Exempt	Studies that are industry-sponsored, NCTN-sponsored, and/or trials that are monitored by an external DSMB.	N/A

Recording of Events

Adverse events, serious adverse events, deviations, violations, and unanticipated problems must be entered into the clinical trial management system (CTMS), OnCore. Adverse events and serious adverse events will becollected from the time the research participant begins the survey until 30 days after the study ends and the survey data is collected. All adverse events/serious adverse events should be followed until resolution or stabilization.

Event Definitions

Adverse event (AE) - An adverse event is any untoward medical experience or change of an existing condition that occurs during or after treatment, whether or not it is considered to be related to the protocolintervention.

Unexpected Adverse Event [Modified from the definition of unexpected adverse drug experience in FDA regulations at 21 CFR 312.32 (a)] – An adverse event is unexpected if it is not listed in the investigator's brochure and/or package insert; is not listed at the specificity or severity that has been observed; is not consistent with the risk information described in the protocol and/or consent; is not an expected natural progression of any underlying disease, disorder, condition, or predisposed risk factor of the research participant experiencing the adverse event.

Expected Adverse Event - Any event that does not meet the criteria for an unexpected event OR is an expected natural progression of any underlying disease, disorder, condition, or predisposed risk factor of theresearch participant experiencing the adverse event.

Serious Adverse Event (SAE) [21 CFR 312.32] - defined as *any expected or unexpected adverse event*

that result in any of the following outcomes:

- Death
- Is life-threatening experiences (places the subject at immediate risk of death from the event as itoccurred)
- Unplanned hospitalization equal or greater than 24 hours)) or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the outcomes listed above (examples of such events include allergic bronchospasm requiring intensive treatment inthe emergency room or at home, blood dyscrasias of convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated problem (UP) - Any incident, experience or outcome that **meets all three** of the following criteria:

1. Unexpected (in term nature, severity, or frequency) given the following: a) the research procedures described in the protocol-related documents such as the IRB approved research protocol, informed consent document or Investigator Brochure (IB); and b) the characteristics of the subject population beingstudied; **AND**
2. Related or possibly related to participation in the research (possibly related means there is a reasonablepossibility that the incident, experience, or outcomes may have been caused by the drugs, devices or procedures involved in the research); **AND**
3. Suggests that the research places subjects or others at greater risk of harm (including physical,psychological, economic, or social harm) than previously known or recognized.

Protocol Violation- A protocol violation is an accidental or unintentional change to or noncompliance with theIRB-approved protocol that increases risk or decreases benefit and/or affects the subject's rights, safety, welfare, and/or the integrity of the data. Examples of incidents that may be considered violations include: enrolling a participant who does not meet the inclusion criteria; obtaining verbal consent before the initiation ofstudy procedures when the IRB requires signed, written informed consent; and failure to collect screening labsbefore initiation of study procedures [Reference: Policy #57 UCI HRPP Policy and Procedure Glossary].

Protocol Deviation- a protocol deviation is an accidental or unintentional change to the research protocol thatdoes not increase risk or decrease benefit or have a significant effect on the participant's rights, safety or welfare, or on the integrity of the data. Deviations may result from the action of the participant, researcher, or staff. Examples: a rescheduled study visit, an omitted routine safety lab for a participant with previously normalvalues; or failure to collect an ancillary self-report questionnaire data (e.g., quality of life) [Reference: Policy #57 UCI HRPP Policy and Procedure Glossary].

Reporting Requirements to the

CFCCC DSMBUnanticipated

Problems

Event Type	Reporting Timeframe
Unanticipated Problems	5 business days from the date thePI is aware of the event

Adverse Event/Serious Adverse Events

Event Type	Reporting Timeframe
Serious Adverse Events (all attributions) that meet all of thefollowing criteria: ▪ Unexpected ▪ Grades 3-5 ▪ Occurring during treatment or within 30 days of theend of treatment*	5 business days from date the PIis aware of the event
Adverse Events that meet all of the following criteria: ▪ Unexpected ▪ Study related (possibly, probably, or definitely) ▪ Grades 3-4 ▪ Occurring during treatment or within 30 days of theend of treatment*	5 business days from date the PIis aware of the event
All other Adverse Events and Serious Adverse Events should be reported as noted in the 'Recording of Events' section	Prior to each scheduled progressreview
** Investigators are not obligated to actively seek information regarding the occurrence of new AEs or SAEs beginning after the 30-day post-treatment period. However, if the investigator learns of such an event and that event is deemed relevant to the study, he/she should promptly document and report the event.*	

Deviations/Violations

Event Type	Reporting Timeframe
Violations as defined above (e.g. wrong dosage of drug administered, safety procedures not being conducted atspecific time points)	5 business days from the date thePI is aware of the event
Deviations as defined above, including: ▪ Planned deviations (e.g. rescheduling a visit that willbe out of window due to a holiday) ▪ Unplanned deviations (e.g. rescheduled visit, a missed routine safety laboratory test for a participantwith previously normal values)	Prior to each scheduled progress review

Reporting Requirements to UCI IRB

Report adverse events, serious adverse events, violations, and deviations within 5 business days if the event/incident met the criteria for an unanticipated problem (UP). The current policy can found at the followinglink: UCI Office of Research

Reporting Requirements to Sponsor Not applicable

Reporting Requirements for an IND Not applicable

SAEs meeting the following criteria listed below require expedited reporting to the FDA, as an IND safety reportusing the MedWatch Form FDA 3500A for Mandatory Reporting which can found at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

- Any unexpected fatal or life threatening adverse experience associated with use of the drug must bereported to the FDA no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)]
- Any adverse experience associated with use of the drug that is both serious and unexpected must besubmitted no later than 15 calendar days after initial receipt of the information [21 CFR 312.32(c)(1)]
- Any follow-up information to a study report shall be reported as soon as the relevant informationbecomes available. [21 CFR 312.32(d)(3)]

Reporting Requirements for an IDE Not applicable

Medical Device Reportable (MDR) Events are the adverse events (AEs) or problems that the medical device regulation requires to be reported. These events include patient deaths and serious injuries that the medicaldevices have or may have caused or contributed to, i.e., the devices may have directly caused the events orplayed a role in the events.

The timely reporting of MDR reportable events is required by the FDA using Form 3500A. The form can be downloaded at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

The following language is **required** for multi-center trials per the CFCCC DSMB.

Reporting of Events from Investigators at Participating Sites to the Sponsor Investigator

- Investigators at participating institutions must report AE, SAE, deviations, violations, and unanticipatedproblems according to their institutional policies.
- Investigators at participating institutions must also report AE, SAE, deviations, violations, and

unanticipated problems to the PI of the coordinating center (or other entity such as a contract research organization) in thefollowing timeframes:

Unanticipated Problems

Event Type	Reporting Timeframe to Sponsor Investigator (And any other entity monitoring/coordinating the trial)
Unanticipated problems	24 hours from the date the site isaware of the event

Adverse Event/Serious Adverse Events

Event Type	Reporting Timeframe to Sponsor Investigator (And any other entity monitoring/coordinating the trial)
Serious Adverse Events (all attributions) thatmeet all of the following criteria: ▪ Unexpected ▪ Grades 3-5 ▪ Occurring during treatment or within 30days of the end of treatment*	24 hours from date the site is aware ofthe event
Adverse Events that meet all of the followingcriteria: ▪ Unexpected ▪ Study related (possibly, probably, ordefinitely) ▪ Grades 3-4 ▪ Occurring during treatment or within 30days of the end of treatment*	24 hours from date the site is aware ofthe event
All other Adverse Events and Serious Adverse Events should be reported as noted in the 'Recording of Events' section	5 business days from the date the siteis aware of the event
** Investigators are not obligated to actively seek information regarding the occurrence of new AEs or SAEs beginning after the 30-day post-treatment period. However, if the investigator learns of such an event and that event is deemed relevant to the study, he/she should promptly document and report the event.*	

Deviations/Violations

Event Type	Reporting Timeframe to Sponsor Investigator (And any other entity monitoring/coordinating the trial)
Violations as defined above (e.g. wrong dosageof drug administered, safety procedures not being conducted at specific time points)	24 hours from the date the site isaware of the event

Deviations as defined above, including: ▪ Planned deviations (e.g. rescheduling avisit that will be out of window due to a holiday) ▪ Unplanned deviations (e.g. rescheduledvisit, a missed routine safety laboratory test for a participant with previously normal values)	5 business days from the date the siteis aware of the event

Additional Reporting for an IND

- For reportable events to the FDA, the participating site(s) should not report to the FDA and should reportto the coordinating center (sponsor), and the coordinating center (sponsor) will report to the FDA.

- The coordinating center PI (sponsor) will also inform the participating institutions by way of forwardingIND Safety Reports to participating sites so that the sites may submit the report(s) according to their institutional policies.

Recording of Events

- The participating institution must enter the above events into OnCore, according to the reportingrequirements of the CFCCC DSMB noted above.

Quality Assurance

- The coordinating center PI (sponsor) is primarily responsible for ensuring the study is conductedaccording to the investigational plan and protocol.
- Quality Assurance activities (QA monitoring and auditing) will be conducted as per UC Irvine Chao FamilyComprehensive Cancer Center Quality Assurance Monitoring and Auditing Plan in order to ensure patient safety and data integrity oversight.
- The participating institution should follow their own internal quality assurance policies in order to monitorpatient safety and data integrity oversight.
- The participating institution must permit study-related monitoring and auditing and provide access to study-related materials. Trial monitoring and auditing will be performed by the UC Irvine CFCCC SternCenter for Cancer Clinical Trials and Research Quality Assurance Unit.
- Trial monitoring and auditing may be completed remotely or on-site.

[If the study will be using an independent data monitoring committee (DMC) for the multi-center trial and theCFCCC DSMB is not the DSMB of record, describe the data and safety monitoring for the study. The plan should address the following]

- Reporting requirement to the DMC related to adverse events, SAEs, violations/deviations,unanticipated problems
- Frequency of progress review
- Quality assurance of the data collection
- Method for forwarding the DMC's recommendations to the Coordinating Center (Sponsor)
- [If there are other documents such as a DSMB Charter available, include the document as anappendix to the protocol]

SECTION 10: ALTERNATIVES TO PARTICIPATION

Describe the alternatives to participation in the study available to prospective subjects.
☒ No alternatives exist. The only alternative to study participation is not to participate in the study. Alternatives to earn extra course credit: ☐ Verified by SONA **OR** **Type Here** Other alternatives to study participation: **Type Here**

SECTION 11: PARTICIPANT COMPENSATION AND REIMBURSEMENT

Not applicable: No compensation or reimbursement. **Skip to Section 12.**

1. Specify whether compensation is applicable and, if so, the method, amount and schedule ofcompensation. Check all that apply.

IMPORTANT!

- **Compensation should be offered on a prorated basis when the research involves multiplesessions.**
- **Additional considerations are required when using lotteries, raffles, and drawings, see UCILottery Guidance.**
- **For compensation greater than or equal to $600, subject names and social security numbersmust be collected. This information must be reported to UCI Accounting for tax-reporting purposes.**
- **For additional information about researcher's/department's responsibilities and currentAccounting procedures, see UCI Policy Sec. 701-03.**

Compensation Method	Schedule	Subject Population
Cash; specify amount: **Type Here**	After each study visitAt the end of study Other; specify: **Type Here**	All subjects **OR** specify cohort: **TypeHere**
Check; specify amount: **Type Here**	After each study visitAt the end of study Other; specify: **Type Here**	All subjects **OR** specify cohort: **TypeHere**
☒ Gift Card; specify amount and retailer: **$5 Amazon.com**	After each study visitAt the end of study Other; specify: **Type Here**	All subjects **OR** specify cohort: **100 giftcard recipients will berandomly selected from all survey participants who choose to submit an email address**

Extra Credit; specify amount: **Type Here**	After each study visitAt the end of study Other; specify: **Type Here**	All subjects **OR** specify cohort: **TypeHere**
Other; specify: **Type Here**	After each study visitAt the end of study Other; specify: **Type Here**	All subjects **OR** specify cohort: **TypeHere**

2. Specify whether subjects will be reimbursed for out-of-pocket expenses. If so, describe any requirements for reimbursement (e.g., receipt).

☒ Not applicable: No reimbursement provided.

Specify reimbursement requirements: **Type Here**

SECTION 12: CONFIDENTIALITY OF RESEARCH DATA

1. Information and/or Biospecimens StorageIndicate how information and/or biospecimens (including signed consent forms) will be stored.Check all that apply.

2. Specify the storage location.

3. For enterprise cloud storage, select the location that adheres to the UCI Protection Levelrequired for the research information.

a. If storing data in location that that isn't tied to a UCInetID, the research data is not coveredby UCI enterprise contracts.

IMPORTANT! For more information about best practices for electronic research data security, review the UCI Information Security website: Information and Resource Classifications.

Storage Method	Location
Information will be maintained on a UCI enterprise cloud platform.	P1: Public data, low risk P2: Internal data, mediumrisk Google Drive Microsoft OneDrive Microsoft Teams Microsoft SharePoint

	P3: Proprietary data, high riskP4: Statutory data, high risk ☐ ☐ Microsoft OneDrive ☐
☒ Information will be maintained electronically. Information will bepassword protected and maintained in an encrypted format.	**Qualtrics survey (personalaccount through UCI protected with password and Duo-protected through verification of an approved2nd device)** ☐
Information will be maintained in hard copy. Information will be stored in a locked area that is not accessible to non-study team members.	**Type Here**
Biospecimens will be stored in a locked lab/refrigerator/freezerthat is not accessible to non-study team members.	**Type Here**
Other method; specify: **Type Here**	**Type Here**

A. Subject Identifiers

Not applicable: No subject identifiers will be collected or retained. **Skip to Section 12.D.**

1. Will any subject identifiers be collected or retained for data analysis, recruitment, consentingand/or compensation?	
Names All elements of dates (except year) for dates that are directly related to an individual: birth date, admission date, discharge date, death date, and all ages over 89. All geographic subdivisions smaller than a state: street address, city, county, precinct, ZIP code, and geocodes Telephone numbers Vehicle identifier and serial numbers: license plateDevice identifiers and serial numbers Email addresses	Web Universal Resource Locators (URLs)Social security numbers Internet Protocol (IP) addresses Medical record numbers Biometric Identifiers: finger and voice prints Health plan beneficiary numbers Full-face photographs and any comparable images Account Numbers Any other unique identifying number, characteristic, or code; specify: **Type Here**

2. Will a code be used to link subject identifiers with the information and/or biospecimens?

IMPORTANT! Retaining identifiers and information/biospecimens together increases the risk to participants and requires additional justification.

☒ A code will not be used. Subject identifiers will be kept separately from the information/biospecimens.

A code will be used. Subject identifiers will be kept separately from the information and/or biospecimens. The code key will be destroyed at the earliest opportunity, consistent with the conductof this research. **IMPORTANT!** Research that is Exempt Category 4ii may not use a code.

A code will not be used. Subject identifiers will be kept directly with the information/biospecimens;address the following:

1. *Rationale*: **Type Here**

2. *Specify how identifiers are attached:* **Type Here**

3. If subject identifiable data/biospecimens will be transported or maintained on portable devices (e.g., laptop, smartphone, external hard drive, etc.) specify the device or method of transportation and explain why doing so is necessary.

IMPORTANT! Only the "minimum data necessary" should be stored on portable devices or transported as doing so makes it susceptible to loss or theft. If there is a necessity to use a portable device, the research files must be encrypted, and subject identifiers transferred to a secure system as soon as possible. If transporting data/biospecimens the method of transport must be secure.

☒ Not applicable: Research data/biospecimens will not be transported or maintained on portable devices.

1. Specify device(s)/method(s) of transportation: **Type Here**

2. Provide rationale: **Type Here**

4. Specify who will have access to subject identifiable information/biospecimens as part of this study. Check all that apply.

☒ Not applicable: No subject identifiers will be collected.

Authorized UCI personnel such as the research team and appropriate institutional officials such as theOffice of Human Research Protections (OHRP) Regulatory entities such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH)

Study sponsor or the

sponsor's agents

Other: **Type Here**

5. Specify whether subject identifiers be disclosed in presentations and/or publications.

☐

☐

☐

☐

☐

☒ Subject identifiers will not be disclosed.

Subject identifiers will be disclosed. Text regarding the disclosure will be included in the consent document and specific permission to disclose will be discussed with subjects.

6. Specify how long all subject identifiers will be retained. This includes identifiers stored inpaper format, stored electronically as well as video recordings, audio recordings, photographs, etc.

IMPORTANT! Investigators must destroy PHI at the earliest opportunity, consistent with the conductof this study, unless there is an appropriate justification for retaining the identifiers or as required bylaw.

Destroyed after data collection. ☐

Destroyed after compensation. ☐

☒

☐

☐

B. Collection of Photographs, or Audio/Video Retention & Recording

☒ Not applicable: No collection or use of photos or audio/video recordings. **Skip to Section 12.D.**

C. Research Information and/or Biospecimens Retention

Indicate how long research information/biospecimens will be retained.

☒ In accordance with UCOP policy, information/biospecimens will be retained for 10 years after the end ofthe calendar year in which the research is completed, unless otherwise specified in the award agreement.

In addition, if the research involves the investigation of FDA regulated products, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation isdiscontinued and the FDA is notified per FDA sponsor requirements.

This research includes the potential for future secondary research using information/biospecimens whichwill be stored and maintained indefinitely.

Other; specify time frame and provide the rationale: **Type Here**

D. Information/Biospecimens Sharing

☒ Not applicable: No information and/or biospecimens shared. **End of form.**

SECTION 13: LEAD RESEARCHER ASSURANCE

The Lead Researcher (and Faculty Sponsor – if applicable) assure the following.

As Primary Lead Researcher and Faculty Sponsor, we have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and applicable UCI policies, as well as state statutes for research involving human subjects.

We hereby assure or acknowledge the following:

1. The information provided in this application is accurate to the best of my knowledge.

2. All named individuals on this project have read the procedures outlined in the protocol, are aware ofand have reviewed relevant HRPP Policies and Procedures and understand their role on the study.

3. All named individuals on this project have completed the required electronic educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46) and acknowledge the importance of the Belmont Principles - Respect for Persons, Beneficence and Justice in conducting research involving human participants. Also UCI has signed the Federalwide Assurance (FWA) that is available for review on the Human Research Protections (HRP) website.

4. Minor changes to the research that do not increase risk to participants, or significantly alter the studyaims or procedures, such as the addition or removal of students researchers, do not require additional self-confirmation of exemption or approval from the IRB. Major changes that increase risk or constitute substantive revisions to the research including procedural changes will require a new self-confirmation of exemption or approval from the IRB.

5. When conducting research at a non-UCI location outside of California (but within the United States),Lead Researchers must comply with the requirements and policies of the location and State laws regarding human research procedures.

6. When collaborating with another entity (e.g., another UC, CHOC, CSUF, or a local school district), the collaborators who are engaged in human research activities are responsible for securing their own (non-UCI) IRB exemption/approval.

7. The Exempt Self-Determination, consent documents including recruitment materials and data collection materials will be maintained by the Lead Researcher or Faculty Sponsor for 10 years beyond the completion of the research. If you will cease your affiliation with UCI during this 10 yearperiod and intend to transfer your identifiable data to a new institution, please notify your Faculty Sponsor and Department to determine whether this is permissible.

8. This research study is subject to routine monitoring by the Human Research Protections (HRP) unit of the Office of Research. Through the Education Quality and Improvement Program (EQUIP) program, HRP staff conduct periodic quality improvement monitoring and educational outreach.

Please sign below, indicating that you agree with the above.

Lead Researcher's Signature	**August 3, 2021** **Date**
Faculty Sponsor's Signature (if applicable)	**August 10, 2021** **Date**

Appendix E: English survey instructions and questions about cancer

Preserving Medical Records After a Cancer Diagnosis forSubsequent Generations to Use

Lead Researcher: Elise Glines, Division of Genetic and Genomic Medicine,Department of Medicine, UC Irvine School of Medicine

Faculty Sponsor: Dr. Jason Zell, Division of Hematology/ Oncology,Department of Medicine, UC Irvine School of Medicine

Individual medical records contain critical information that may also benefit other family members. These are particularly important for anyone with a family history of cancer. Certain medical records can be essential to having an accurate family history of cancer and they are often poorly preserved, lost,or discarded entirely. By saving specific documents, other family members, including siblings, children, and grandchildren, will have an accurate family medical history and be able to have this critical information available if it is needed in the future.

The purpose of this study is to provide people with cancer and their families a simple process that teaches which medical documents should be collected after a cancer diagnosis and how to preserve them for future use byother family members. We would like you to complete an anonymous surveyto learn about your knowledge and awareness of medical records to preserve after a cancer diagnosis for subsequent generations to use.

Findings from the study could help participants and their families betterunderstand which medical records are beneficial to preserve and the importance of doing so.

Study participants must be **18 years of age** or older **and one or more of the following** are true:

- have or had cancer;
- has a spouse or partner who has or had cancer;
- Or, has a 1st or 2nd degree family member* who has or had cancer

**1st or 2nd degree family member: child, sibling, parent, aunt/uncle, niece/nephew, grandchild, grandparent*

Participation in this **anonymous survey** is voluntary. You may refuse toparticipate or discontinue your involvement at any time or for any reason. Participants may click here to provide their email address now or at the end of the survey to enter a lottery for one of 100 $ 5 Amazon.com gift cards. Your email address will NOT be tied to your survey responses or used for anything other than to email you a gift card, if you are randomly selected.

Estimated time to complete the study: 20-35 minutes

All research data collected will be stored securely and confidentially. If you have any questions regarding this study, please contact the lead researcher, Elise Glines, at berrye@hs.uci.edu or the faculty sponsor, Dr. Jason Zell, at jzell@hs.uci.edu. If you have any questions or concerns about your rights as aresearch participant, you may contact the UCI Institutional Review Board by phone: (949) 824-6662, or by email: IRB@research.uci.edu.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in the research. The IRB also assures thatthe study complies with applicable regulations, laws, and institutional policies.If you would like to participate in this study, select "I agree" below. Then click the arrow button to start the survey.

0 I agree

Instructions before beginning the survey: Survey questions about cancer diagnoses may be answered for the followingscenarios: yourself, a spouse/ partner, and/ or a 1st or 2nd degree family member (child, sibling, parent, aunt/uncle, niece/nephew, grandchild, or grandparent).

You may answer corresponding survey questions for **all scenarios** that apply to you. If you have more than one 1st or2nd degree family member with cancer, please

select one family member and answer all questions with **this familymember** in mind.

Have you ever been diagnosed with cancer?

Has your spouse/ partner ever been diagnosed with cancer?

Has a 1st or 2nd degree relative (child, sibling, parent, aunt/uncle, niece/ nephew, grandchild, grandparent) everbeen diagnosed with cancer?

Primary, metastatic, and secondary cancers are often confused.

Primary cancer: the original site (organ or tissue) wherecancer began

Metastatic cancer: spread of the original primary cancer toanother region of the body

Secondary cancer: a different type of cancer than one hadin the past

For example, someone whose primary breast cancer spread to the lungs would have one unique cancer diagnosis of breast cancer. Someone diagnosed with primary breast cancer and diagnosed with uterine cancer at a different time would have two unique cancer diagnoses.

How many unique cancers has you or this family member with cancer been diagnosed with?

What was the original site(s) (organ or tissue) where cancer began?

What type of treatment(s) were completed or planned to becompleted as part of any cancer diagnosis?

At what age was the cancer diagnosed? (If multiple diagnoses, answer with the age at the first cancer diagnosis.)

Age in years (approximate age if exact unknown) ☐

Has anyone in your family (including yourself) had genetic testing to look for a hereditary cancer syndrome?

Did genetic testing show a mutation in a gene associated with a hereditary cancer syndrome that may increase the chance for cancer?

How well do you understand these terms?

	I don't know what this means.	I have seen this before but don't know what this means.	I probably know what this means.	I know this well and understand what this means.
Genetic test results				
Relatives with cancer				
Oncology note				
Urine/blood/biopsy				
results from tumor				
testing				
Pathology report				
Surgical history				

I know who to ask or where to find:

	I don't know what this is.	I have no idea who to ask or where to find this information.	I might know who to ask or where to find this information.	I definitely know who to ask or where to find this information.
Genetic test results				
Relatives with cancer				
Oncology note				
Urine/blood/biopsy				
results from tumor testing				
Pathology report				
Surgical history				

Knowing one's family cancer history is helpful.

Strongly agree
Somewhat agree
Neither agree nor disagree
Somewhat disagree
Strongly disagree

Saving copies of medical records after a cancer diagnosiscan help family members receive appropriate care.

Strongly agree
Somewhat agree
Neither agree nor disagree
Somewhat disagree
Strongly disagree

I know which medical records to keep for family members touse in the future.

Definitely yes
Probably yes
Might or might not
Probably not
Definitely not

I know how to save medical records for future use.

Definitely yes
Probably yes
Might or might not
Probably not
Definitely not

You will now be shown a short video, less than 5 minutes in length. The screen will not advance until the video is complete. Please watch until the end and answer a few questions after the video to complete your participation in the survey.

Post survey

Thank you for watching the video. Please answer the following questions to complete the survey:

Knowing one's family cancer history is helpful.

Strongly agree
Somewhat agree
Neither agree nor disagree
Somewhat disagree
Strongly disagree

Saving copies of medical records after a cancer diagnosiscan help family members receive appropriate care.

Strongly agree
Somewhat agree
Neither agree nor disagree
Somewhat disagree
Strongly disagree

How well do you understand these terms?

	I don't know what this means.	I have seen this before but don't know what this means.	I probably know what this means.	I know this well and understand what it means.
Genetic test results				
Relatives with cancer				
Oncology note				
Urine/blood/biopsy				
results from tumor				
testing				
Pathology report				
Surgical history				

I know who to ask or where to find:

	I don't even know what this is.	I have no idea who to ask or where to find this information.	I might know who to ask or where to find this information.	I definitely know who to ask or where to find this information.
Genetic test results				
Relatives with cancer				
Oncology note				
Urine/blood/biopsy results from tumor testing				
Pathology report				
Surgical history				

I know which medical records to keep for family members to use in the future.

Definitely yes
Probably yes
Might or might not
Probably not
Definitely not

I know how to save medical records for future use.

Definitely yes
Probably yes
Might or might not
Probably not
Definitely not

Have you already saved information from the GROUPSdocuments?

	Yes I have	No, not yet
Genetic test results		
Relatives with cancer		
Oncology note		
Urine/ blood/ biopsy		
results from tumor		
testing		
Pathology report		
Surgical history		

How helpful was the video?

Extremely helpful
Very helpful
Moderately helpful
Slightly helpful
Not helpful at all

The video motivated me to collect medical records after acancer diagnosis to keep for future use.

Definitely yes
Probably yes
Maybe
Probably not
Definitely not

I will use the GROUPS checklist to collect medical records.

Definitely yes
Probably yes
Might or might not
Probably not
Definitely not

Where did you learn about the survey?

UCI clinic visit
Via email from a friend or colleague
Social media (Facebook, Instagram, Twitter, etc)
FORCE
Other cancer support group
I am not sure/prefer not to share

Please share any thoughts you may have on the survey and/or video (example: why or why not the video or checklistmay be helpful):

Enter your email address if you would like to be entered in alottery to be randomly selected to receive one of 100 $5 Amazon.com gift cards.

APPENDIX F: Spanish survey

Conservar los historiales médicos después de un diagnóstico de cáncer para que los utilicen las siguientes generaciones

Investigador principal: Elise Glines, División de Medicina Genética y Genómica, Departamento de Medicina, Facultad de Medicina de la UC Irvine
Patrocinador: Profesor, Dr. Jason Zell, División de Hematología/Oncología, Departamento de Medicina, Facultad de Medicina de la UC Irvine

Los historiales médicos individuales contienen información fundamental que también puede beneficiar a otros miembros de la familia. Son especialmente importantes para cualquier persona con antecedentes familiares de cáncer. Ciertos historiales médicos pueden ser esenciales para tener una historia familiar precisa del tipo de cáncer y a menudo no se conservan bien, se pierden o se descartan por completo. Al guardar determinados documentos, otros miembros de la familia, incluidos los hermanos, los hijos y los nietos,

tendrán un historial médico familiar preciso y podrán disponer de esta información fundamental si la necesitan en el futuro.

El objetivo de este estudio es proporcionar a las personas con cáncer y a sus familias un proceso sencillo que les enseñe qué documentos médicos deben recopilarse después de un diagnóstico de cáncer y cómo conservarlos para que los utilicen en el futuro otros miembros de la familia. Nos gustaría que completara una encuesta anónima para conocer sus conocimientos sobre los documentos médicos que deben conservarse tras un diagnóstico de cáncer para que los utilicen las siguientes generaciones.

Los resultados del estudio podrían ayudar a los participantes y a sus familias a comprender mejor cuales historiales médicos son conveniente conservar y la importancia de hacerlo.

Los participantes en el estudio deben tener **18 años cumplidos o más y una o más de las siguientes** características deben ser ciertas:

1. tener o haber tenido cáncer;
2. tiene un cónyuge o pareja que tiene o tuvo cáncer;

3. tiene un familiar de primer o segundo grado* que tiene o ha tenido cáncer

*Familiar de primer o segundo grado: hijo, hermano, padre, tía/tío, sobrino, nieto, abuelo

La participación en esta encuesta anónima es voluntaria. Puede negarse a participar o interrumpir su participación en cualquier momento o por cualquier motivo. Los participantes pueden hacer clic aquí para proporcionar su dirección de correo electrónico ahora o al final de la encuesta para participar en un sorteo de una de las 100 tarjetas regalo de 5 dólares de Amazon.com. Su dirección de correo electrónico NO se vinculará a sus respuestas a la encuesta ni se utilizará para nada más que para enviarle por correo electrónico una tarjeta de regalo, si resulta seleccionado al azar.

Tiempo estimado para completar la encuesta: 20-35 minutos

Todos los datos de la investigación recopilados se almacenarán de forma segura y confidencial. Si tiene alguna pregunta sobre este estudio, póngase en contacto con la investigadora principal, Elise Glines, en berrye@hs.uci.edu o con el patrocinador de la facultad de Medicina, el Dr. Jason Zell, en jzell@hs.uci.edu. Si tiene alguna pregunta o duda sobre sus derechos como

participante en la investigación, puede ponerse en contacto con la Junta de Revisión Institucional de la UCI por teléfono: (949) 824-6662, o por correo electrónico: IRB@research.uci.edu.

¿Qué es uns Junta de Revisión Institucional? Una Junta de Revisión Institucional (IRB) es un comité formado por científicos y no científicos. La función de esta junta es proteger los derechos y el bienestar de los sujetos humanos que participan en una investigación. La junta también asegura que el estudio cumple con las regulaciones, leyes y políticas institucionales aplicables. Si desea participar en este estudio, seleccione "Estoy de acuerdo" a continuación. A continuación, haga clic en el botón de la flecha para iniciar la encuesta.

○ Estoy de acuerdo

Instrucciones antes de comenzar la encuesta: Las preguntas de la encuesta sobre el diagnóstico de cáncer pueden

responderse para los siguientes casos: usted mismo, un cónyuge/pareja, y/o un familiar de primer o segundo grado (hijo, hermano, padre, tía/tío, sobrina/sobrino, nieto o abuelo).

Puede responder a las preguntas de la encuesta correspondientes a todos los escenarios que se apliquen a usted. Si tiene más de un familiar de primer o segundo grado con cáncer, seleccione un miembro de la familia y responda a todas las preguntas teniendo en cuenta a este miembro.

¿Alguna vez le han diagnosticado cáncer?

¿A su cónyuge / pareja le han diagnosticado cáncer alguna vez?

¿Alguna vez un pariente de primer o segundo grado (hijo, hermano, padre, tía / tío, sobrina / sobrino, nieto, abuelo) ha sido diagnosticado con cáncer?

Los cánceres primario, metastásico y secundario a menudo se confunden.

Cáncer primario: el sitio original (órgano o tejido) donde comenzó el cáncer
Cáncer metastásico: diseminación del cáncer primario original a otra región del cuerpo
Cáncer secundario: un tipo de cáncer diferente al que tenía en el pasado

Por ejemplo, alguien cuyo cáncer de mama primaria se había extendido a los pulmones tendría un diagnóstico de cáncer único de cáncer de mama. Alguien diagnosticado con cáncer de mama primario y luego diagnosticado en otro momento con cáncer de útero tendría dos diagnósticos de cáncer únicos.

¿Cuántos cánceres únicos le han diagnosticado a su cónyuge / pareja?

¿Cuál fue el sitio (s) original (es) (órgano o tejido) donde comenzó el cáncer?

¿A qué edad se diagnosticó el cáncer? (Si hay varios diagnósticos, anote la edad en el momento del primer diagnóstico de cáncer).

Edad en años (edad aproximada si se desconoce exactamente) ☐

¿Qué tipo de tratamiento se completó o se planeó completar como parte de cualquier diagnóstico de cáncer? (seleccione todo lo que corresponda)

¿Alguien de su familia (incluido usted mismo) se ha sometido a pruebas genéticas para detectar un síndrome de cáncer hereditario?

¿Las pruebas genéticas mostraron una mutación en un gen asociado con un síndrome de cáncer hereditario que puede aumentar la probabilidad de cáncer? (seleccione todo lo que corresponda)

¿Qué tan bien entiende estos términos?

	No sé lo que esto significa.	He visto esto antes, pero no sé qué significa.	Probablemente sepa lo que esto significa.	Sé esto bien y entiendo lo que esto significa.
Resultados de pruebas Genéticas	○	○	○	○
Familiares con cáncer(es)	○	○	○	○
Nota Oncológica	○	○	○	○
Resultados de orina / sangre / resultados de pruebas de una biopsia de tumores	○	○	○	○
Informe de Patología	○	○	○	○
Historia quirúrgica	○	○	○	○

Sé a quién preguntar o dónde encontrar:

	No se que es esto.	No tengo idea a quién preguntar ni dónde encontrar esta información.	Podría saber a quién preguntar o dónde encontrar esta información.	Definitivamente sé a quién preguntar o dónde encontrar esta información.
Resultados de pruebas Genéticas	○	○	○	○
Familiares con cáncer(es)	○	○	○	○
Nota Oncológica	○	○	○	○
Resultados de orina / sangre / resultados de pruebas de una biopsia de tumores	○	○	○	○
Informe de Patología	○	○	○	○
Historia quirúrgica	○	○	○	○

Es útil conocer los antecedentes familiares de cáncer.

- ○ Totalmente de acuerdo
- ○ Algo de acuerdo
- ○ Ni estoy de acuerdo ni estoy en desacuerdo

- ○ Algo en desacuerdo
- ○ Muy en desacuerdo

Guardar copias de los registros médicos después de un diagnóstico de cáncer puede ayudar a los miembros de la familia a recibir la atención adecuada.

- ○ Totalmente de acuerdo
- ○ Algo de acuerdo
- ○ Ni estoy de acuerdo ni estoy en desacuerdo
- ○ Algo en desacuerdo
- ○ Muy en desacuerdo

Sé qué registros médicos debo conservar para que los miembros de la familia los utilicen en el futuro.

- ○ Definitivamente si
- ○ Probablemente sí
- ○ Puede o no puede que sepa

○ Probablemente no
○ Definitivamente no

Sé cómo guardar registros médicos para uso futuro.

○ Definitivamente si
○ Probablemente sí
○ Puede o no puede que sepa
○ Probablemente no
○ Definitivamente no

Video

Ahora se le mostrará un video corto, de aproximadamente 6 minutos de duración. La pantalla no avanzará hasta que se complete el video. Mire hasta el final y responda algunas preguntas después del video para completar su participación en la encuesta.

Post survey

Gracias por ver el video. Responda las siguientes preguntas para completar la encuesta:

Es útil conocer los antecedentes familiares de cáncer.

○ Totalmente de acuerdo

- ○ Algo de acuerdo
- ○ Ni estoy de acuerdo ni estoy en desacuerdo
- ○ Algo en desacuerdo
- ○ Muy en desacuerdo

Guardar copias de los registros médicos después de un diagnóstico de cáncer puede ayudar a los miembros de la familia a recibir la atención adecuada.

- ○ Totalmente de acuerdo
- ○ Algo de acuerdo
- ○ Ni estoy de acuerdo ni estoy en desacuerdo
- ○ Algo en desacuerdo
- ○ Muy en desacuerdo

¿Qué tan bien entiende estos términos?

	No sé lo que esto significa.	He visto esto antes, pero no sé qué significa.	Probablemente sepa lo que esto significa.	Sé esto bien y entiendo lo que esto significa.
Resultados de pruebas Genéticas	○	○	○	○
Familiares con cáncer(es)	○	○	○	○
Nota Oncológica	○	○	○	○
Resultados de orina / sangre / resultados de pruebas de una biopsia de tumores	○	○	○	○
Informe de Patología	○	○	○	○
Historia quirúrgica	○	○	○	○

Sé a quién preguntar o dónde encontrar:

	No se que es esto.	No tengo idea a quién preguntar ni dónde encontrar esta información.	Podría saber a quién preguntar o dónde encontrar esta información.	Definitivamente sé a quién preguntar o dónde encontrar esta información.

Resultados de pruebas Genéticas	○	○	○	○
Familiares con cáncer(es)	○	○	○	○
Nota Oncológica	○	○	○	○
Resultados de orina / sangre / resultados de pruebas de una biopsia de tumores	○	○	○	○
Informe de Patología	○	○	○	○
Historia quirúrgica	○	○	○	○

Sé qué registros médicos debo conservar para que los miembros de la familia los utilicen en el futuro.

○ Definitivamente si

- ○ Probablemente sí
- ○ Puede o no puede que sepa
- ○ Probablemente no
- ○ Definitivamente no

Sé cómo guardar registros médicos para uso futuro.

- ○ Definitivamente si
- ○ Probablemente sí
- ○ Puede o no puede que sepa
- ○ Probablemente no
- ○ Definitivamente no

¿Ya ha guardado información de los documentos de GRUPOS?

	Si lo tengo	No, todavia no
Resultados de pruebas Genéticas	○	○

Familiares con cáncer(es)	○	○
Nota Oncológica	○	○
Resultados de orina / sangre / resultados de pruebas de una biopsia de tumores	○	○
Informe de Patología	○	○
Historia quirúrgica	○	○

¿Qué tan útil fue el video?

- ○ Extremadamente útil
- ○ Muy útil
- ○ Moderadamente útil
- ○ Ligeramente útil
- ○ No es útil en absoluto

El video me motivó a recopilar registros médicos después de un diagnóstico de cáncer para guardarlos para uso futuro.

- ○ Definitivamente si
- ○ Probablemente sí
- ○ Puede o no puede que sepa
- ○ Probablemente no
- ○ Definitivamente no

Usaré la lista de verificación de GRUPOS para recopilar registros médicos.

- ○ Definitivamente si
- ○ Probablemente sí
- ○ Puede o no puede que sepa
- ○ Probablemente no
- ○ Definitivamente no

Comparta cualquier pensamiento u opinion que pueda tener sobre la encuesta y / o el video (ejemplo: por qué o por qué no el video o la lista de verificación pueden ser útiles):

Ingrese su dirección de correo electrónico si desea participar en una lotería para ser seleccionado al azar para recibir una de las 100 tarjetas de regalo de Amazon.com de $ 5.

De lo contrario, deje el campo en blanco y haga clic en la flecha hacia la derecha para completar la encuesta.
¡Gracias!