Creative Arts Therapy (CAT) in the Center for Cancer and Blood Disorders

Dr. Jennifer Raybin
Associate Professor, Pediatrics
University of Colorado
Children's Hospital Colorado

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COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
CAMPUS BOX F-490 TELEPHONE: 303-724-1055
Fax: 303-724-0990

Project Title:	**Creative Arts Therapy (CAT) in the Center for Cancer and Blood Disorders**
Principal Investigator:	**Jennifer Raybin, RN, MSN, CPNP**
Co-Investigators:	**Molly Hemenway, RN, CPNP**
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I. Hypotheses and Specific Aims

The purpose of the study is to evaluate the effectiveness of Creative Arts Therapy (CAT) on pediatric patients undergoing chemotherapy in the Infusion Center at Children's Hospital Colorado Center for Cancer and Blood Disorders. Findings from a previous pilot study support the hypothesis that CAT may improve quality of life (QOL), resiliency, physical posture, and emotional response to pain of pediatric oncology patients undergoing chemotherapy.

Specific aims include:

a. Does CAT improve the child's reported QOL?
b. Is the child's resiliency enhanced by CAT?
c. Does CAT influence the physical posture of the child?
d. Does CAT impact the child's emotional response to pain?
e. Are patients, families, and staff satisfied with the CAT program?

II. Background and Significance

Although survival rates of children with cancer are improving, their QOL is known to be poorer than their healthy peers. As survival rates of pediatric cancer now approach 85%, the need for quality psychosocial care including creative arts has increased (Askins & Moore, 2008). Oncology patients are known to have significant morbidity during treatment as a result of the surgery, radiation and chemotherapy, but little is published on the day to day effects of treatment on the quality of life of pediatric oncology patients (Banks, 2008). Tremolada et al looked at parental perception of QOL in newly diagnosed children with leukemia and found that increasing the knowledge of QOL may improve communication and psychosocial care during initial treatment for leukemia (2010). In addition, quality of life among adolescents with cancer may be worse during treatment than for those not currently on therapy (Ward-Smith et al., 2007). Another study has shown that interventions to promote happiness may be a good predictor of QOL in adolescent cancer survivors (Bitsko et al., 2008).

It has been acknowledged that even the act of coming to the clinic weekly for chemotherapy infusions impacts on the patient's life. In addition, vincristine, a commonly used chemotherapy, is also well-known to cause significant morbidity (leg pain, numbness, tingling, and constipation) requiring dose-limiting regimes. Steroids are another common medication with toxicities affecting QOL. Toxicities of steroids include weakness, sleep and mood disturbance, and pain with dose reduction (Sanford et al., 2008; Hinds et al., 2007).

Resilience is a subset of QOL that has been studied in pediatric chronic illness including cancer (Haase et al., 2004). Resilience has been defined as a characteristic that moderates stress and the ability to cope with change or misfortune (Wagnild & Young, 1993). Resilient individuals have positive outcomes in spite of adversity (Rew & Horner, 2003). Therefore nurses who understand resilience can promote those characteristics during times of illness or stress (Ahern et al., 2006). There is a paucity of literature directly studying resilience in pediatric oncology patients and further work is warranted.

Emotional response to pain is another subset of QOL that has been measured in this population. It is well known that pediatric oncology patients experience pain (Lervat, 2009). Experts recommend rigorous research using established measures to evaluate childrens' response to pain (McGrath et al., 2008). The Faces scale has been studied with children as young as 5 years to evaluate their emotional response to pain compared with their parents' perceptions (Breau et al., 2001). Pilot data on emotional response on the Faces scale has been shown to improve after group CAT (Madden et al., 2010).

Physical functioning and muscle strength are aspects of QOL that have been shown to be worse than healthy peers in children with cancer (Hartman et al., 2008). This aspect may also be affected by the central venous access lines placed in almost all pediatric cancer patients. Long-term central venous access is critical in pediatric cancer patients and the evolution of these devices has improved QOL in terms of pain and distress of venipuncture (Spagrud, 2008). The literature is rich with discussion of complications and risk of infection, but little is published about the effects on body image and QOL (Albanese, 1993; Nam, 2010). Anecdotally, patients have improved body awareness and posture (less kyphosis) after CAT. In addition, it has been postulated that increased kyphosis may correspond with psychosocial factors including anxiety, depression, and insecurity. Body awareness is a type of physical functioning that may be measured by kyphosis. Measuring posture with an inclinometer has been shown to be reliable, but further work is needed to establish validity (Lewis & Valentine, 2010). Piloting this tool may establish a way to physically measure an individual's sense of self by the way that he or she stands.

The use of complementary and alternative medicine (CAM) is one intervention that has been shown to improve QOL in this population. Current trends show increasing popularity of the use of CAM in even among children with cancer. Martel et al (2005) looked at prevalence of use of CAM in children. In their survey, almost 50% of the children used at least one type of CAM. Specifically to cancer, in 2009, Post-White et al used a survey of 281 patients to show that CAM was used in 59% of pediatric cancer patients versus 36% of general pediatric patients. The authors confirmed that children with cancer and other chronic illnesses use more CAM therapies than children seen in primary care clinics. Roth et al (2009) examined pediatric oncologists' perceptions of CAM and found that although they place importance in CAM, they lack time and knowledge to ask about patients' use of CAM. These authors recommend CAM research in pediatric oncology on modalities that could improve QOL.

CAT is a subset of CAM that may improve QOL. CAT is a broad term encompassing the modalities of dance/movement, music, art. Bringing creativity into health care is a current trend in oncology nursing and throughout the medical professions (Garland et al., 2007; Lane, 2006; Petterson, 2001; Strickland, 2008). There is a growing body of literature establishing the use of CAT, but the studies use non-standardized tools, small sample sizes, adult populations, and non-rigorous designs. Much of the work on CAT in cancer patients studies adult populations using qualitative measures (Forzoni et al, 2010; Jones et al., 2009; Visser, et al, 2008; Bar-Sela, et al., 2007; Nainis et al., 2006). Other work looked at the family caregivers of patients with cancer and showed significantly reduced stress, anxiety, and increased positive emotions after a creative arts intervention (Walsh et al., 2004). Randomized controlled studies are in the literature and have shown improvement in QOL, but only for the population of women with breast cancer (Oster et al, 2006; Monti et al, 2006; Svensk et al, 2009; Thyme et al, 2009). Music was shown to decrease heart rate in children with leukemia, but the therapeutic aspects were not studied (Kemper et al., 2008). The literature is rich with other examples of types of music, art, movement therapies that may improve QOL in adult and pediatric oncology patients, but there are few rigorous studies to document the importance of CAT during the cancer treatment (Sencer et al, 2007; Dibell-Hope, 2000; O'Callaghan et al, 2007; Robb et al, 2003; Barrera, 2002; Hilliard, 2006).

Therefore, a pilot study of CAT on the QOL of pediatric brain tumor patients used a mixed-model approach with a randomized, controlled phase comparing CAT to a control. Pre- and post- measurements using the PedsQL showed statistically significant improvement on Parent report of child's hurt (problems with having a lot of pain), $p=0.03$ and Parent report of child's nausea (becoming nauseated while thinking about medical treatment), $p=0.0061$. The second non-randomized phase pre- and post- tested any child in group session of CAT. The subjects showed improved mood with statistical significance on the Faces Scale ($p < 0.01$), and patients were more excited ($p < 0.05$), happier ($p < 0.02$), and less nervous ($p < 0.02$) on the Emotional Responses Checklist (Madden et al, 2010).

Rationale

The pilot study was limited by the small sample size; therefore we propose a study with a larger sample size and broader inclusion criteria. We would also like to explore outcomes of resilience and body awareness measured by physical posture based on our observations during the pilot study.

Significance

Nurses have been shown to provide valuable information on QOL for this population (Klaassen et al, 2010). In addition, the pediatric oncology nurse is in a key position to incorporate the art and science of nursing to improve psychosocial treatment outcomes (Cantrell, 2007). Therefore this nursing research study will provide valuable insight to contribute to the body of knowledge of CAM for pediatric oncology patients. The use of CAM for pediatric oncology patients may improve QOL, resiliency, emotional response, and body awareness.

III. Preliminary Studies/Progress Report

See above regarding the previous pilot study. Small sample size limited the statistical significance.

IV. Research Methods

A. Outcome Measure(s)

1. Peds QL—Cancer module

The PedsQL 4.0 Cancer Module is evolved from the PedsQL 4.0 Generic Core Scale (Varni, 1998). The system employs a Parent-Proxy Report for ages 2-18 years and a companion Child Self-Report for children aged five years and older. Validity and reliability testing for both the Core Scale and Cancer Module has been extensive.

Reliability, assessed by internal consistency, yielded coefficient alphas ranging from .80-.90 across total and individual scales and are, thus, appropriate for the group comparisons planned in this study. The Cancer Module is a 27-item instrument that assesses eight subscales (Pain and hurt, nausea, procedural anxiety, treatment anxiety, worry, cognitive problems, perceived physical appearance, and communication). It is easily completed by parents in less than 10 minutes and reverse-scored and linearly-transformed in five minutes or less. Validity for both the Core Scale and the Cancer Module was established by expert panel review; similarly, construct validity for both measures was performed by comparing the responses of children with cancer across both measures to a group of healthy matched controls. In all cases, the Peds QL 4.0 Cancer Module was able to distinguish the responses of children with cancer from those of healthy children at a statistically significant level.

The instruments have been successfully employed in several small studies of children with cancer (Bhat, 2005; Meeske et al, 2004). The PedsQL has been shown to be the most responsive to change when compared with other measures of QOL used with children undergoing chemotherapy (Banks et al, 2008; Klaassen et al, 2010).

2. ***The Resilience Scale (RS)***
   The RS-14 is a 14-item scale using a 7-point rating (1-7). The construct of resilience is measured by two factors: personal competence and acceptance of self and life. Wagnild and Young have completed psychometric testing that established internal consistency reliability and concurrent validity (Wagnild & Young, 1993). Many studies have validated that the scale may be used with samples of any age or ethnic background (Ahern et al, 2006), but it is written at a 6th grade level. The authors who developed the tool are currently using it in adolescents (personal communication, 5/25/10). Given that it is expected that half the population of this study will be teenagers, this tool will be used with subjects ages 12 and over to obtain initial data on CAT's effect on resilience.

3. ***Faces Scale***
   The Faces Scale has been used for evaluating emotional responses to pain on children 3-17 years old. It is a one page form with nine faces in order of happy to upset. Numerical values are given to each face as determined by childrens' perspectives for an affective value by asking 200 children to directly scale the feelings depicted by the faces. Consistent rating was measured by children over 5 years regardless of age, gender, or health status (McGrath, 1990). The scale is a facial affective scale and has been integrated as a routine measure for management of acute, recurrent, and chronic pain (McGrath, 1990; McGrath et al., 1996). For children less than 3 years old, parents will be asked to complete the Faces Scale. Although this scale has been used for emotional response to pain, it is felt to be an appropriate measure for the emotional response to the discomfort and anxiety in the infusion room.

4. ***Postural Measurement***
   Thoracic kyphosis will be measured using two gravity dependent inclinometers (Isomed Inc.). Spinal processes will be determined by palpation by a registered nurse or pediatric nurse practitioner. The feet of the inclinometers will be placed over the spinal processes thought to be at T1, T2 and T12, L1. The measurements will be taken in relaxed standing and measured 3 times in succession. Clinical assessment of the thoracic kyphosis angle is considered essential in postural examination, but can be time

consuming when measured radiographically (Lewis, 2010). Lewis and Valentine studied intra-rater reliability in subjects with and without symptoms and found measurements of less than 1.7 degrees should be considered measurement error. The test-re-test reliability established excellent intra-rater reliability. Although validity of this measure is less studied, the measurement is thought to provide guidance of how much change of the kyphoscoliosis angle is a real consequence of intervention over time (Lewis, 2010).

5. ***Patient/Family Surveys***

A brief ten minute written survey will be administered to subjects to ascertain level of satisfaction with the program.

B. Description of Population to be Enrolled: Study Design and Research Methods

1. *Population*

The Center for Cancer and Blood Disorders (CCBD) at Children's Hospital Colorado sees approximately 240 new Oncology patients each year. Approximately 45% of these patients receive vincristine, a chemotherapy agent that is known to affect physical functioning. In addition, about 25% of these patients receive steroids, another medication known to affect physical functioning and quality of life. About half of the new patients each year are anticipated to fit the inclusion criteria. Therefore, we expect approximately 100 eligible subjects per year, with a 50% attrition rate, for a total sample size of 100 subjects over a two year period.

Enrollment for this study was reached in 2019. At this time, an additional 10 patients will be allowed to enroll on study to help supplement the data.

2. *Eligibility Criteria*

Inclusion

- Center for Cancer and Blood Disorders (CCBD) patient with Oncology or Neuro-oncology diagnosis
- No more than 2 previous sessions of CAT as an outpatient in the CCBD
- English speaking
- Receiving outpatient chemotherapy, biotherapy, or transfusions in the infusion center approximately weekly for at least 3 months.
- Ages 3 to 18 years

Exclusion

- Hematology or other patients in the infusion center
- Patients who have previously received more than 2 sessions of CAT in the infusion center
- Non-English speaking patients

3. *Study Design*

A repeated measures design will be used with each patient serving as his/her own control.

Any Oncology patient in the CCBD who has not previously received more than two sessions of CAT in the outpatient unit and who will be receiving approximately weekly infusions of at least one hour in the infusion center will be identified by a research assistant. The study will be explained to the patient/family and informed consent will be obtained by the principal investigator or the research assistant. A demographic form will be completed including the information of diagnosis, age, treatment, educational level of parents, zip code, prior experience with art, music, movement.

The intervention will consist of approximately weekly CAT in the infusion center during cancer therapy. The interventionist is a Master's prepared, licensed dance/movement therapist who is experienced in music and art therapies as well. The CAT includes dance/movement such as playing with a parachute, simple yoga breathing and postures, and work with physioballs. The music includes singing, listening to music, and playing instruments. The art consists of drawing, finger painting, working with clay. The CAT may occur in individual sessions in private infusion rooms, or in groups in the middle of the infusion center. The CAT is not only a distraction, but also a therapeutic process addressing the stressors of cancer and its treatment. The "dose" of CAT will be recorded (number and type of sessions) and will be factored into the analysis.

The subjects and/or parents will be tested with all instruments before the intervention, and approximately every 30 days for no less than 3 months and a maximum participation of 6 months. Treatment time points will be at least 30 days apart. Because some subjects are not scheduled to come into the clinic every 30 days for SOC appointments, they are unable to complete 3 sessions of CAT in a 3 month time period. For those subjects who are scheduled to come into clinic every 1-2 months for SOC appointments, study participation may take up to 6 months. This 6 month time period would allow for the completion of 4 different time points of CAT.

The testing will take place in an exam room after vital signs have been completed upon intake to the clinic. The trained research assistant, trained RN, or PI will administer the questionnaires. The PedsQL includes a subject report (ages 5 and over) and a parent report. The Resilience Scale is a self-report and will be used for ages 12 and over. The Faces Scale will use parent report for ages less than 5 and self-report for ages 5 and over. In order to confirm consistency, the posture measure will be completed by the PI (nurse practitioner) or registered nurse on the study after training with the manual included with the inclinometer tool.

Off Study Criteria

1. Subject discontinues CAT
2. Unable to complete 4 time points in 6 months

C. Description, Risks and Justification of Procedures and Data Collection Tools

The anticipated risks include psychological distress incurred by completing the outcome measure questionnaires as well as the therapeutic process. This risk will be minimized by the presence of the Master's prepared, experienced dance/movement therapist. The patients' social workers through the clinic will be available during the intervention as well.

D. Potential Scientific Problems

Based on the pilot data, the anticipated scientific problem is slow accrual due to unforeseen events during the traumatic time of a new diagnosis in pediatric oncology. We are unable to randomize because CAT is standard of care for any patient in the infusion center and therefore we feel it is unethical to deny CAT to a control arm. Therefore, we will compare the subjects to themselves over time to look at longitudinal changes of CAT.

E. Data Analysis Plan

The primary outcome is Peds QL at approximately 3 months; secondary outcomes will be the Resilience Scale, Faces Scale, and postural measurement at approximately 3 months. A repeated measures analysis of variance will be used to analyze the primary and secondary outcomes. We will also use the repeated measures analysis of covariance with the addition of covariates, depending on their statistical significance, such as gender, age, cancer diagnosis, and previous exposure to arts/music/dance. All of the analysis will be adjusted for baseline measures.

We expect to recruit 100 patients, we also expect patients will be equally distributed in the following 3 categories: receiving low (0-3), intermediate (4-6) and high (7+) CAT sessions due to the nature of each patient's random visits. Power analysis was done based on pair-wised T-Test with these assumptions for simplicity. With 33 patients in each group, assuming 80% power and 0.017 significance level of alpha after Bonferroni ad justification of multiple comparisons, we will observe a minimum effect size of 0.813. This is to say that 80% of the Peds QL scores in the lower session CAT group will be below the average of scores in the higher session CAT group. Thus, what we would expect to see in the positive dose-response relationship.

We will also conduct subgroup analysis by age group if the sample size is large enough since Peds QL is designed by age group.

F. Summarize Knowledge to be Gained

Integrative and holistic therapies are being used throughout healthcare. We know that families are using alternative therapies without rigorous evidence documenting their worth. We therefore strive to build a body of literature showing evidence that CAT helps children with cancer feel better.

G. Appendices

1. PedsQL
2. Resilience Scale
3. Faces Scale
4. Inclinometer information
5. Patient/Family Survey

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Principal Investigator: **Jennifer Raybin, RN, MSN, CPNP**

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In this form, we use the words “you” and “your.” If you are reading this form and deciding for someone else, the words ‘you’ and ‘your’ refer to that other person, not to you.

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about how creative arts therapy will affect your quality of life during your treatment for cancer.

You are being asked to be in this research study because you will be receiving outpatient therapy in the Center for Cancer and Blood Disorders for the next few months.

Other people in this study

Up to 110 people from Children’s Hospital Colorado will participate in the study.

What happens if I join this study?

If you decide to join this study:

- Before the study starts, you will be asked to complete a demographic form with a member of the study team. This will help us find out more about you, your therapy, and what kind of experience you have had with art, music, and movement.
- You will be asked to complete the following measurements before the study starts and then 3 more times over a three to six month period (depending on how often you come to the clinic for your regularly scheduled visits). You will complete these with a member of the study team to assess the effect of creative arts therapy on your quality of life during your treatment for cancer:
  - **PedsQL** – This is a survey that asks questions about your level of pain and hurt, anxiety, worry, problems with thinking, your physical appearance, and communication. This survey has 27 questions and should take less than 10

    minutes each time to complete. Your parent may be asked to complete a portion of this survey.
    - **Resilience Scale** – This is a scale that measures how well you are able to cope with the changes in your life that have come with your cancer diagnosis and treatment. This scale has 25 items and should take less than 10 minutes to complete.
    - **Faces Scale** – This is a scale that measures your emotional response to your treatment for cancer. This scale has 9 items and should take less than 5 minutes to complete.
    - **Posture Measurement** – A member of the study staff will measure the angle of your back three times during each of these visits. This should take less than 10 minutes to complete.
    - **Patient/Family Survey** – This is a survey that asks questions about your parent's satisfaction with the creative arts therapy program. This survey has 13 questions and should take less than 10 minutes to complete.
- Once you have completed these four visits over three to six months, you will be finished with this study.

You will be allowed to do creative arts therapy during your clinic visits as many times as it is offered and as much as you would like to participate. This study will not limit the number of times you can do creative arts therapy, and it will not require you to do more creative arts therapy visits than you want to do. We will track how many times you receive creative arts therapy over a three-month period in the clinic.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include some stress you may feel while completing the measurements. If you feel this stress, please let the study staff know.

Other possible risks include the risk of the loss of confidentiality of your protected health information; however, the chance of such a loss is small. Children's Hospital Colorado has procedures in place to keep your information private. No identifiable information about you will be published or presented at scientific meetings.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how creative arts therapy affects children who are receiving treatment for cancer.

This study is not designed to treat any illness or improve your health.

Who is paying for this study?

This study is being paid for by a grant from The Daisy Foundation.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the primary investigator thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Jennifer Raybin, RN, CPNP immediately. Her phone number is 720-777-3407.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Jennifer Raybin, RN, CPNP. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Jennifer Raybin at 720-777-3407. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Jennifer Raybin with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055.

Who will see my research information?

Children's Hospital Colorado has rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institution involved in this study is Children's Hospital Colorado.

CHCO shares a medical record system with the Barbara Davis Center and PedsConnect; therefore it is also possible that your information could be viewed by healthcare professionals at these organizations.

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Children's Hospital Colorado and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Primary Investigator Name:	Jennifer Raybin RN, CPNP
Primary Investigator Address:	Children's Hospital Colorado 13123 E. 16th Ave. B115 Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- Jennifer Raybin, RN, CPNP and her team of researchers.
- The Daisy Foundation, who is the organization paying for this research study.
- Officials at Children's Hospital Colorado who are in charge of making sure that we follow all of the rules for research
- The Clinical Investigations Shared Resources at the University of Colorado Cancer Center who also make sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will also make *all or some* **of the following health information about me available to:**

- The Cancer Clinical Trials Office at the University of Colorado Cancer Center

Information about me that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Name and demographic portions of my previous and current medical records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, Laboratory or tissue studies, radiology studies, procedure results
- Research visit and research test records
- The results of your Peds QL, Resilience Scale, Faces Scale, postural measurements, and Patient/Family Survey.

What happens to Data that is collected in this study?

Scientists at Children's Hospital Colorado involved in this study work to find the causes and cures of disease. The data collected from you during this study is important to this study and to future research. If you join this study:

- The data is given by you to the investigators for this research and so no longer belongs to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data is in a form that identifies you, Children's Hospital Colorado may use it for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Consent and Authorization Form Approval

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature: ____ Date:________
Subject (if 18 years old); OR Parent/Guardian

Print Name: ____

Signature: ____ Date:________
Subject (Ages 13-17, in addition to Parent Signature)

Consent form explained by: ____________________________________ Date:________

Print Name: ____