PCORI-1306-02918 Evaluation of Parent-Based Interventions to Support Children after Traumatic Injury

ClinicalTrials.gov ID: NCT02323204

5/07/2018

THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 201111728

To: Marizen Ramirez

From: IRB-01 Univ of Iowa, DHHS Registration # IRB00000099, DHHS Federalwide Assurance # FWA00003007

Re: Evaluation of Parent Based Interventions to Support Children After Traumatic Injury

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 05/07/18

Next IRB Approval Due Before: 05/07/19

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
☐ New Project	☐ Full Board:	☒ Children
☒ Continuing Review	Meeting Date:	☐ Prisoners
☒ Modification	☒ Expedited	☐ Pregnant Women, Fetuses, Neonates
	☐ Exempt	

Source of Support: Patient-Centered Outcomes Research Insitute

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

This approval has been electronically signed by IRB Chair:
Brian Bishop, CIP, MA
05/07/18 1605

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.) If hospital/clinic patients are being enrolled, a copy of the IRB approved Record of Consent form should be placed in the subject's electronic medical record.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.

Psychological First Aid for Injured Kids

PI: Marizen Ramirez
IRB ID #: 201111728

Project Details

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-01

I.2 ***Project Title:***
Evaluation of Parent Based Interventions to Support Children After Traumatic Injury

I.3 ***Short Title (optional):***
Psychological First Aid for Injured Kids

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

Phase 1
We propose to conduct eight focus groups: two composed of approximately 6-10 parents each at University of Iowa Children's Hospital and two composed of approximately 6-10 parents at Blank Children's Hospital. We will also conduct two of approximately 6-10 pediatric health care providers each from the University of Iowa Children's Hospital and two of approximately 6-10 pediatric health care providers each from Blank Children's Hospital. The purpose of the parent focus groups is to establish the parent's willingness to participate in a study to reduce the psychological effects of injury on their children, and a parent's acceptability of the LPC for Injured Kids materials. The purpose of the pediatric health care provider focus groups is to understand the types of trauma experienced by children, the psychosocial consequences encountered by traumatized children and the types of services perceived as available, accessible, and acceptable to families particularly from rural Iowa. In addition, providers will be asked to provide feedback on the LPC for Injured Kids materials. If a health care provider is unable to participate in the focus group but wishes to be interviewed individually, the purpose and the questions asked during the interview will be identical to those of the focus group. Each focus group/interview is expected to last between 60 and 90 minutes.

Phase 2
Children between 10-17 years of age presenting to the UIHC and Blank Children's Hospital with an unintentional injury requiring admission will be the sample population. Blank Children's Hospital has submitted a separate IRB for their participation in the study. A child will be included if they are 10-17 years old with an unintentional injury. Consenting children and their parents will be asked to complete a series of four questionnaires: before hospital discharge, at 6 weeks post discharge, 3-months and 6-months post discharge. The parent-child dyads will be randomized (1:1) to receive training in Link for Injured Kids or to receive Trauma Education (parent booklet, "So, you've been in an Accident"). The survey completed in the hospital will be a paper survey or online via iPads, and follow-up surveys can be completed on paper or online.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
Phase 1
Assess the feasibility of LPC for Injured Kids through qualitative research with parents of previously injured children and social workers and pediatric trauma providers from the UI Children's Hospital and Blank Children's Hospital. The focus group findings will also help inform and refine intervention materials and delivery.

Phase 2
Through a randomized trial, determine the range of potential psychosocial and behavioral health indicators possibly impacted by Link for Injured Kids. This will identify the types of outcomes which could include PTSD, depression, nonspecific distress, quality of life, absenteeism, school performance, coping skills, communication skills, and access to mental health.

I.6 ***Background and significance and/or Preliminary studies related to this project.***
(do not indicate "see protocol")
According to the Centers for Disease Control and Prevention, the number one cause of death and morbidity among children ages 1-19 is unintentional injury. Each year, approximately 12,000 children die from unintentional injury causes (1). Of all injury causes, motor vehicle crash leads to the most number of deaths to children in U.S. as passengers, teen drivers and pedestrians. Almost 400,000 injured teen drivers and occupants were seen in emergency departments in the US in 2005 (2). In the U.S., falls lead to the highest number of childhood injury emergency department visits followed by injuries due to being struck by or against an object (1). Fire or burns are also an important cause of injury as the second leading cause of injury death to children between 1 and 19 (1).

Unintentional injuries, particularly severe injuries that impact daily functioning, can have longlasting psychological effects. Prevalence of posttraumatic stress symptoms is estimated at 29% during the first month post-trauma and 13% between 3-6 months post-trauma. (3)

Within 12 months of being hospitalized because of injury, 19-32% of adolescents developed PTSD. (4) A variety of injury experiences can lead to PTSD symptoms including traffic crashes, burns, falls and animal attacks. (5) Adolescents involved in a mass burn incident had significantly more mental problems than community controls one year after the incident (6), and, 12% of schoolchildren exposed to an industrial fire met the criteria for PTSD. (7) Approximately 30% of pediatric pedestrian injury cases have acute stress disorder or PTSD. (8-10) Many cases of psychological trauma are missed in hospital settings and sent home. This proposed project will empower families with skills to identify trauma-induced mental health distress and resources for referral to advanced mental health care.

Our innovative project addresses the need for evidence-based practices to improve the acute care of children post-injury. Psychological First Aid (PFA), analogous to physical first aid (11), "uses interpersonal skills provided by individuals to respond to psychological consequences of [trauma] in their own lives, as well as in the lives of their family, friends, and neighbors (p. 4–5)" (11). Informed by previous research on posttraumatic risk and resilience, PFA provides information, education, comfort and support through human contact in order to accelerate recovery and promotion of mental health (12, 13).

In 2006, psychologists developed a child-focused version of PFA in school and community settings called "Listen, Protect, Connect (LPC)-Model and Teach." LPC outlines steps for administering PFA to children after any type of crises, either a large-scale disaster or local emergency. The effectiveness of PFA has not been scientifically evaluated. We propose to create an adapted version of LPC for families. LPC has the potential to be a national tool that possibly improves coping, access to mental health care, and acute PTSD symptoms for children impacted by both individual and community emergencies (see Approach for description of LPC).

Preliminary Studies
Dr. Ramirez (PI) has over ten years of experience conducting pediatric injury, violence and disaster preparedness research, including studies of school-related injuries to children with disabilities (14-16); high school sports injuries (17); and emergency preparedness among staff, students and parents (18-20). Recently, Dr. Ramirez began studies focused on the psychological trauma in school settings.
Studies of Psychological First Aids. In July 2008, Dr. Ramirez conducted studies of Listen Connect Protect (LPC) in the school setting, a precursor to the work proposed here. In the first study, 200 randomly selected flood-affected children were invited to participate, but only 8 enrolled into the study. In the second study, students seen at or referred to school nurses' offices potentially impacted by various types of trauma (e.g., unintentional injury, violence, the floods) were enrolled. In total, 20 students were treated with LPC and followed-up.
The LPC intervention had high fidelity and acceptance among clients and nurse providers. Specifically, 90% of sessions followed the Listen Steps, 85% the Protect Steps, and 75% the Connect Steps. Feedback from subjects and nurse providers was also extremely positive, with 80% of children reporting feeling comfortable speaking with the school nurse, and 60% of students indicating that the LPC sessions were helpful in dealing with recent life events. One student with elevated scores of distress on the K6 screening tool (PTSD screener included in the LPC repertoire) was immediately referred to advanced mental health care. Human subject protection approval for LPC has already been obtained, and protocols were developed and tested. The new project will adapt materials from this school-based study and apply the intervention to families of injured children seen at the UIHC.
Flood-induced stress among college students. In August 2008, Dr. Ramirez conducted a university-wide survey to measure disaster health impacts of the Great Flood of Iowa among University of Iowa students. Of the 10,500 summer enrolled students, 1,404 responded. Eight percent of students had symptoms consistent with PTSD. The most commonly reported symptom was feeling emotionally upset (12%). Another 7% reported frequent trouble sleeping and 6% reported frequent trouble concentrating. About 7% of students reported increased drug and/or alcohol use following the floods.

"So you've been in an accident," the second early intervention strategy to be tested in the proposed study, takes into account the challenges of hectic hospital settings and busy families. Given time and other constraints, educational materials may be a simple, cost-effective early intervention option when nothing else is available. Dr. Kenardy (Co-I of this research project) tested his materials at two children's hospitals in Queensland. In the intervention hospital, pediatric trauma patients (11-17 years old) and their parents received booklets within 72 hours of admission, while control patients and parents at the other hospital received no materials. Over the follow-up period, children in the intervention hospital had significantly lower levels of stress. Their parents also showed promising outcomes such as fewer intrusive post-traumatic stress symptoms than control group parents. In their implementation evaluation of the materials, 97% of parents and 83% of children in the intervention arm reported reading them, and of those, 72% of parents perceived the booklets as having a positive effect on them and 57% thought the materials benefitted their children (18,19).

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***

1. Borse N, Gilchrist J, Dellinger A, Rudd R, Ballesteros M, Sleet D. CDC Childhood Injury Report: Patterns of Unintentional Injuries among 0 -19 Year Olds in the United States, 2000-2006. Atlanta: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2008.
2. CoI, Violence and Poison Prevention: American Academy of Pediatrics. Policy statement-Pedestrian safety. Pediatrics 2009;124(2):802-12.
3. Olofsson E, Bunketorp O, Andersson AL. Children and adolescents injured in traffic--associated psychological consequences: a literature review. Acta Paediatr 2009;98(1):17-22.
4. Zatzick DF, Jurkovich GJ, Fan MY, Grossman D, Russo J, Katon W, et al. Association between posttraumatic stress and depressive symptoms and functional outcomes in adolescents followed up longitudinally after injury hospitalization. Arch Pediatr Adolesc Med 2008;162(7):642-8.
5. Daviss W, Racusin R, Fleischer A, Mooney D, Ford J, McHugo G. Acute stress disorder symptomatology during hospitalization for pediatric injury. J Am Acad Child Adolesc Psychiatry 2000;39(5):569-75.
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7. March JS, Amaya-Jackson L, Terry R, Costanzo P. Posttraumatic symptomatology in children and adolescents after an industrial fire. J Am Acad Child Adolesc Psychiatry 1997;36(8):1080-8.
8. de Vries AP, Kassam-Adams N, Cnaan A, Sherman-Slate E, Gallagher PR, Winston FK. Looking beyond the physical injury: posttraumatic stress disorder in children and parents after pediatric traffic injury. Pediatrics 1999;104(6):1293-9.
9. Stallard P, Salter E, Velleman R. Posttraumatic stress disorder following road traffic accidents - a second prospective study. Eur Child

Adolesc Psychiatry 2004;13(3):172-8.
10. Winston FK, Kassam-Adams N, Vivarelli-O'Neill C, Ford J, Newman E, Baxt C, et al. Acute stress disorder symptoms in children and their parents after pediatric traffic injury. Pediatrics 2002;109(6):e90.
11. Institute of Medicine. Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy. Washington, DC: National Academies Press; 2003.
12. Everly GS, Jr., Flynn BW. Principles and practical procedures for acute psychological first aid training for personnel without mental health experience. Int J Emerg Ment Health 2006;8(2):93-100.
13. Berger R, Pat-Horenczyk R, Gelkopf M. School-based intervention for prevention and treatment of elementary-students' terror-related distress in Israel: a quasi-randomized controlled trial. J Trauma Stress 2007;20(4):541-51.
14. Ramirez M, Yang J, Bourque L, Javien J, Kashani S, Limbos MA, et al. Sports injuries to high school athletes with disabilities. Pediatrics 2009;123(2):690-6.
15. Ramirez M, Peek-Asa C, Kraus JF. Disability and risk of school related injury. Inj Prev 2004;10(1):21-6.
16. Limbos MA, Ramirez M, Park LS, Peek-Asa C, Kraus JF. Injuries to the head among children enrolled in special education. Arch Pediatr Adolesc Med 2004;158(11):1057-61.
17. Ramirez M, Schaffer KB, Shen H, Kashani S, Kraus JF. Injuries to high school football athletes in California. Am J Sports Med 2006;34(7):1147-58.
18. Kenardy J, Cobham V, Nixon RD, McDermott B, March S. Protocol for a randomised controlled trial of risk screening and early intervention comparing child- and family-focused cognitive-behavioural therapy for PTSD in children following accidental injury. BMC Psychiatry 2010;10:92.
19. Kenardy J, Thompson K, Le Brocque R, Olsson K. Information-provision intervention for children and their parents following pediatric accidental injury. Eur Child Adolesc Psychiatry 2008;17(5):316-25.

II. Research Team

II.1 ***Principal Investigator***

Name	E-mail	College
Marizen Ramirez	marizen-ramirez@uiowa.edu	College of Public Health

II.2 ***Team Members***

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Marizen Ramirez, PHD	marizen-ramirez@uiowa.edu	College of Public Health	Yes	Yes	No		Yes	No
Mallory Bolenbaugh, BS	mallory-ermler@uiowa.edu	Graduate College	No	No	No		Yes	No
Cassidy Branch, BS, MA	cassidy-branch@uiowa.edu	VP Research	Yes	No	No		Yes	No
Collin Calvert, MPH	collin-calvert@uiowa.edu	College of Public Health	No	No	No		No	No
Gretchen Cress, BSN, RN	gretchen-cress@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Jonathan Davis, MS	jonathan-a-davis@uiowa.edu	College of Public Health	No	Yes	No		No	No
Patricia Espe Pfeifer, PHD	patricia-espepfeifer@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	No
Javier Flores, BS	javier-flores@uiowa.edu	Graduate College	No	No	No		No	No
Kelly Guinn, BA	kelly-guinn@uiowa.edu	Graduate College	No	No	No		Yes	No
Charles Jennissen, MD	charles-jennissen@uiowa.edu	Carver College of Medicine	No	Yes	No		No	No
Corinne Peek-Asa, PHD	corinne-peek-asa@uiowa.edu	College of Public Health	No	Yes	No		No	No
Graeme Pitcher, MD	graeme-pitcher@uiowa.edu	Carver College of Medicine	No	Yes	No		No	No
Lisa Roth, BS	lisa-m-roth@uiowa.edu	College of Public Health	Yes	Yes	No		Yes	No
Ruthann Schrock, BSN	ruthann-schrock@uiowa.edu	University Hospitals	No	No	No		Yes	No
Karen Smith, RD, MS	karen-l-smith@uiowa.edu	College of Public Health	No	No	No		No	No
Kristel Wetjen, RN	kristel-wetjen@uiowa.edu	University Hospitals	No	Yes	No		Yes	No

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Tammy Wilgenbusch, PHD	tammy-wilgenbusch@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	No

Non-UI Team Members

Name	Institution	Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
Bridget Cho	University of Kansas-Lawrence	Lawrence, KS	00003310	Bridget is a clinical psychology practicum student working with study Co-I Dr. Briana Woods-Jaeger. In her role Bridget is involved with both clinical work and research with Dr. Woods-Jaeger and will be working under her supervision on this study.	Yes	No	No	No	Yes	bridget.cho@ku.edu
Sun Young Hwang	Children's Mercy Hospital	Kansas City, MO	00002496	Sun Young Hwang will be an intern that will be responsible for consenting participants and delivering the intervention and collecting data per protocol.	Yes	No	No	No	Yes	shwang@cmh.edu
Teresa Maag	Children's Mercy Hospital	Kansas City, MO	00002496	Teresa will serve as a clinical research coordinator and serve as the site coordinator for CMH.	Yes	No	No	No	Yes	tamaag@cmh.edu
Kimberly Randell	Children's Mercy Hospital	Kansas City, MO	00002496	Dr. Randell is an emergency room physician who will provide clinical oversight	Yes	No	No	No	Yes	krandell@cmh.edu

Name	Institution	Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
				for the project team at Children's Mercy Hospital						
Chris Sexton	Children's Mercy Hospital	Kansas City, MO	00002496	Dr. Chris Sexton is a research associate and will assist in executing the study protocols.	Yes No	No	No		Yes	csexton@cmh.edu
Emily Siedlik	Children's Mercy Hospital	Kansas City, MO	00002496	Emily will be a research assistant and adhere to study protocols. She will be delivering intervention and conducting data collection	Yes No	No	No		Yes	easiedlik@cmh.edu
Lauren Slagel	Children's Mercy Hospital	Kansas City, MO	0002496	Lauren is a research assistant who will assist in engagement activities and collecting stakeholder feedback.	Yes No	No	No		Yes	leslagel@cmh.edu
Shallyn Ward	Children's Mercy Hospital	Kansas City, MO	00002496	Shallyn is a research assistant at Children's Mercy Hospital. She will be assisting with participant follow-up, booster calls, and survey data entry. She will also assist with PCORI stakeholder engagement activities and may provide back-up for screening, recruitment, and	Yes No	No	No		Yes	slward@cmh.edu

Name	Institution	Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
				intervention for eligible participants at CMH.						
Chalott Williams	Children's Mercy Hospital	Kansas City, MO	00002496	Charlott will be a research assistant and adhere to all protocols. She will be delivering the intervention and conducting data collection.	Yes No	No	No		Yes	cwilliams@cmh.edu
Briana Woods-Jaeger	Children's Mercy Hospital	Kansas City, MO	00002496	Briana Woods-Jaeger will work remotely as a research team member to assist in fidelity testing of audio recordings.	Yes No	No	No		Yes	bwoodsjaeger@cmh.edu

II.3 ***The Principal Investigator of this study is:***
Faculty

II.6 ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as "key personnel." For information about other team members who should be designated as "key personnel" please click on the help information.***

Name	Is Key Personnel
Marizen Ramirez, PHD	Yes
Mallory Bolenbaugh, BS	No
Cassidy Branch, BS, MA	No
Collin Calvert, MPH	No
Gretchen Cress, BSN, RN	No
Jonathan Davis, MS	Yes
Patricia Espe Pfeifer, PHD	Yes
Javier Flores, BS	No
Kelly Guinn, BA	No
Charles Jennissen, MD	Yes
Corinne Peek-Asa, PHD	Yes
Graeme Pitcher, MD	Yes
Lisa Roth, BS	Yes
Ruthann Schrock, BSN	No
Karen Smith, RD, MS	No
Kristel Wetjen, RN	Yes
Tammy Wilgenbusch, PHD	Yes
Bridget Cho	No
Sun Young Hwang	No
Teresa Maag	No
Kimberly Randell	No
Chris Sexton	No
Emily Siedlik	No

Name	Is Key Personnel
Lauren Slagel	No
Shallyn Ward	No
Chalott Williams	No
Briana Woods-Jaeger	No

II.5 ***Select research team member who is the primary contact for study participants.***
Cassidy Branch

III. Funding/Other Support

III.1 ***Funding Sources***

Type	Source	Grant Title	Name of PI on Grant	Status	Status Description
* Private Foundation/Association	Patient-Centered Outcomes Research Insitute	Evaluation of Parent_Based Intervention to Support Children after Traumatic Injury	Marizen Ramirez	Awarded	

* new source name

III.2 ***Which office will process the agreement for this project***
Sponsored Programs - Federal/State/Local Agency Funded

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the Conflict of Interest in Research policy? If yes, please indicate which members below.***

Name	Has Conflict of Interest
Marizen Ramirez, PHD	No
Mallory Bolenbaugh, BS	No
Cassidy Branch, BS, MA	No
Collin Calvert, MPH	No
Gretchen Cress, BSN, RN	No
Jonathan Davis, MS	No
Patricia Espe Pfeifer, PHD	No
Javier Flores, BS	No
Kelly Guinn, BA	No
Charles Jennissen, MD	No
Corinne Peek-Asa, PHD	No
Graeme Pitcher, MD	No
Lisa Roth, BS	No
Ruthann Schrock, BSN	No
Karen Smith, RD, MS	No
Kristel Wetjen, RN	No
Tammy Wilgenbusch, PHD	No
Bridget Cho	No
Sun Young Hwang	No
Teresa Maag	No
Kimberly Randell	No
Chris Sexton	No
Emily Siedlik	No
Lauren Slagel	No
Shallyn Ward	No
Chalott Williams	No
Briana Woods-Jaeger	No

III.5 ***What is the current status of this funding source?***

Source	Status	Other Status Description
Patient-Centered Outcomes Research Insitute	Awarded	

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project.***
10/17/2011

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
No

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

V.21 ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?***
Yes

V.22 ***Will this project use any resource/patients of the HCCC?***
No

V.25.a ***Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?***

- ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
- ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***

No

V.26 ***The study involves nursing, nursing resources or evaluates nursing practices.***
Yes

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
300

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
75.0

VI.4 ***What is the percentage of adult male subjects?***
50

VI.5 ***What is the percentage of adult female subjects?***
50

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
300

VI.7 ***What is the age of the youngest minor subject?***
10.0

VI.8 ***What is the age of the oldest minor subject?***
17.2

VI.9 ***What is the percentage of minor male subjects?***
50

VI.10 ***What is the percentage of minor female subjects?***
50

VI.11 ***Will any of the minors enrolled be in foster care or Wards of the court?***
No

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***
- ***Studies under IRB-03 enrolling non veterans as part of the subject population must present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members), and the research is relevant to the care of Veterans or active duty military personnel.***

Phase 1
University of Iowa Children's Hospital- UI Children's (Complete)
Parent population: Parent's of children ages 10-17 years of age who are treated for a unintentional traumatic injury in the last 12 months at UI Children's Hospital. Parents of children with intentional injuries will be excluded from the focus groups. Only one parent of a potential parent dyad (mother or father) will be included in the focus group.

Provider population: Emergency Medicine and Trauma physicians, nurses, pediatric psychiatrists and psychologists, social workers, and parent advocates serving the pediatric unintentional traumatic injury population.

Blank Children's Hospital- Complete
Qualitative formative research will be conducted at Blank Children's Hospital to solidify themes and confirm that the research protocol can be effectively itengrated into both settings. Two provider focus groups will be held at Blank Children's Hospital

Parent population: Parents of children 10-17 years of age who are treated for a unintentional traumatic injury in the last 12 months at Blank Children's Hospital. Parents of children with intentional injuries will be excluded from the focus groups. Only one parent of a potential parent dyad (mother or father) will be included in the focus group. Two parent focus groups will be held in the Des Moines area.

Provider population: Emergency Medicine and Trauma physicians, nurses, pediatric psychiatrists and psychologists, social workers,child life specialist and parent advocates serving the pediatric unintentional traumatic injury population.

Phase 2
Children with new unintentional injuries (not a complication from previous injury) will be recruited to participate in the randomized trial. All children will be between the ages of 10-17.2 (17 years, 3 months) years of age. All children admitted for injury will be identified, and direct questioning later will screen out those who had intentional injuries. Children with unintentional injuries will be administered the COAT which is a measure of orientation to self, place and memory, and those that pass the COAT will be recruited into the study. One parent of the child will be recruited for participation. Inclusion and exclusion criteria are the same for both randomization groups. Exclusions include non-English speaking, diagnosis of intellectual deficit or psychosis, suicide attempt in the last year, and residential treatment placement in the last year.

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
Phase 1
University of Iowa Children's Hospital-UI Children's(complete)

Parent population- UI Children's: Approximately 140 pediatric patients between the age of 10 and 18 are treated by UI Children's Hospital each year, therefore, approximately 140 parents will be eligible for participation in the focus group.

Provider population- UI Children's: Approximately 10-15 UI Children's Hospital providers serve the injured pediatric population. All providers will be eligible for the focus group or a personal interview.

Blank Children's Hospital- Complete
Parent Population-Approximately 100 pediatric patients between the age of 10 and 18 are treated by Blank Children's Hospital each year, therefore, approximately 100 parents will be eligible for participation in the focus group.

Provider population- Approximately 10-15 Blank Children's Hospital providers serve the injured pediatric population. All providers will be eligible for the focus group or a personal interview.

Phase 2
Approximately 480 pediatric patients between the age of 10 and 17 are admitted by UI Children's and Blank Children's Hospital each year, therefore, for a 2.5 year study period, approximately 1200 parent-child dyads will be eligible to participate in the study.
Children's Mercy Hospital in Kansas City admits 540 children who were age 10-17 on an annual basis. As they join year 3 of the study this will be the number of parent-child dyads eligible to participate in the study from that site.

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
Phase 1
University of Iowa Children's Hospital(completed)
Parent population: Using the Iowa Trauma Database, Ms. Wetjen, UIHC Pediatric Nurse Trauma Coordinator, will identify parents whose children previously received an unintentional injury and were treated at the UIHC in the past 12 months.

Provider population: Given Ms Wetjen's leadership role in the UIHC Trauma team, she will facilitate the invitation and recruitment of pediatric unintentional injury health care providers.

Blank Children's Hospital- Completed
Parent population: Using the Iowa Trauma Database, Ms. Wetjen, UIHC Pediatric Nurse Trauma Coordinator will work with Blank Children's Hospital Pediatric Trauma Coordinator to identify parents whose children previously received an unintentional injury and were treated at the Blank Children's Hospital in the past 12 months.

Provider population: Given Ms Wetjen's leadership role in the UIHC Trauma team, she will work with Blank Children's Hospital Pediatric Trauma Nurse to identify pediatric unintentional injury health care providers.

Phase 2
The UIHC and Children's Mercy Hospital team will review patient admission records morning and afternoon/evening to identify eligible patients (injury admissions between 10-17 years of age). The UIHC team will determine if the child meets inclusion criteria by reviewing information collected from EPIC. The Children's Mercy Hospitial team will determine if the child meets inclusion criteria by reviewing information collected from Cerner medical record system.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

Yes

VI.19 ***Provide justification for why these subjects must be included in the study.***
Phase 1
There is very limited pediatric psychiatric and psychological staff within the UIHC staff, therefore a staff member of Dr. Wilgenbusch's clinic will be asked to participate in the health care provider focus group.

Phase 2
These groups will not be enrolled.

VI.20 ***Will subjects provide any information about their relatives?***
Yes

VI.21 ***Describe in detail how this information will be obtained. NOTE: The collection of identified data about family members makes the family member a subject in the study. This would require a consent process with the family member or a request for waiver of consent to collect these data. See the Research Guide for more information.***
Phase 1
Parents will be asked to describe the circumstances and resulting injuries their children received.

Phase 2
Parents will be asked to complete a questionnaire that gathers information about their child/adolescent's (the subjects in this study with the injury) symptoms of traumatic stress and quality of life. Parents will also complete a participant information form asking for

information about the child/adolescent's age, injury, and general family information.

VI.22 ***List the data to be collected about subject relatives including the names of any surveys, questionnaires etc. to be used. Attach data collection tools under the Relative/Proxy Data Collection Instruments category.***
Phase 1
None of the child's identifying information will be recorded or the circumstances around their injury.

Phase 2
Foa PTSD - Parent Version
Strengths and Difficulties - Parent Version
Quality of life - Parent Version

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
Yes

VI.24 ***Describe in detail how this information will be obtained.***
Phase 1 : No

Phase 2
Parents will be asked to complete a questionnaire that gathers information about their child/adolescent's (the subjects in this study with the injury) symptoms of traumatic stress and quality of life. Parents will also complete a participant information form asking for information about the child/adolescent's age, injury, and general family information.

VI.25 ***List the data to be collected from proxy individuals including the names of any surveys, questionnaires etc. to be used. Attach data collection tools under the Relative/Proxy Data Collection Instruments category.***
Phase 2
Foa PTSD - Parent Version
Strengths and Difficulties - Parent Version
Quality of life - Parent Version
Participant Information Form

VI.26 ***Is this project about pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VII.A. Project Description (A)

VII.A.1 ***Where will project procedures take place (check all that apply)?***
- UIHC - UI Children's Hospital
- Other UI campus site - Westlawn
- U.S. off-campus - Blank Children's Hospital, Children's Mercy Hospital and Clinics

VII.A.2 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***
Yes

VII.A.3 ***What is the UI site's role(s) for this project (check all that apply)?***
- Clinical/participating site
- Coordinating Center
- Statistical/Data Management Center

VII.A.4 ***Provide specific and detailed information describing how the UI investigator will coordinate all aspects of the study, such as:***

- ***Name, location, and IRB of record for each site,***
- ***Verification of IRB approval and continuing review for all sites***

- ***Managing variation in requirements from the IRBs or institutional policies of the different sites.***
- ***Outline all activities that will occur at each participating site***

The University of Iowa researchers will participate in all aspects of data collection, management, and analysis. Because of it's larger size and higher number of pediatric trauma admissions, the University of Iowa is anticipated to collect roughly two thirds of the data proposed. The UI researchers will act as the coordinating center for the multi-site collaboration, and will provide information and interim reports to Blank Children's Hospital and Children's Mercy Hospital as outlined below. The UI researchers will also ensure adherence to IRB protocol, and communicate progress with the funding agency.

VII.A.5 ***Describe in detail the procedures that will be used to identify and report unanticipated problems from participating sites to the lead institution.***

The University of Iowa researchers convene with Blank Children's Hospital researchers in monthly meetings where progress and problems can be discussed. The team members at Children's Mercy Hospital will be given meeting updates via phone or email. If an unanticipated problem requires urgent attention, Blank Children's Hospital and Children's Mercy Hospital will contact the University of Iowa PI, project manager, and(or) site coordinator via phone or email to report the problem.

VII.A.6 ***Describe in detail the procedures that will be used to identify and report unanticipated problems from the lead institution to participating sites.***

The University of Iowa researchers convene with Blank Children's Hospital and Children's Mercy Hospital researchers in monthly meetings where progress and problems can be discussed. If the unanticipated problem requires urgent attention, the University of Iowa team will contact the Blank Children's Hospital study coordinator, and the Children's Mercy Hospital study coordinator, via phone or email to report the problem.

VII.A.7 ***Describe in detail the procedures that will be used to communicate protocol modifications from the lead institution to the participating sites.***

The University of Iowa researchers convene with Blank Children's Hospital and Children's Mercy Hospital researchers in monthly meetings, where any protocol modifications can be discussed. If immediate change is required, the University of Iowa team will contact the study coordinator at Blank Children's Hospital and the study coordinator at Children's Mercy Hospital to communicate the modifications. These modifications will then need to be reflected in an IRB modification at each institution.

VII.A.8 ***Describe in detail the procedures that will be used to communicate interim results from the lead institution to the participating sites.***

Interim results will be reported at monthly meetings, and any updates sent to the funding agency will be forwarded to Blank Children's Hospital and Children's Mercy Hospital.

VII.A.9 ***Describe in detail the procedures that will be used to communicate other new information which may impact a subject's willingness to participate, or continue participating from the lead institution to the participating sites.***

The University of Iowa researchers convene with Blank Children's Hospital and Children's Mercy Hospital researchers in monthly meetings, where such information could be discussed. If immediate attention is required, the University of Iowa team will contact the study coordinator at Blank Children's Hospital and the study coordinator at Children's Mercy Hospital to communicate the new information.

VII.A.10 ***What are collaborating site roles for this project?***

- Clinical/participating site - Blank Children's Hospital, Children's Hospital and Clinics of Minnesota, and Children's Mercy Hospital-Kansas City, 3 sites

VII.B. Project Description (B)

VII.B.1 ***Does this project involve any of the following (Check all that apply):***

- ☐ **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.(UI Guide)
- ☐ **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)
- ☐ **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- ☐ **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and ClinicalTrials.gov & FDA)
- ☐ **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as “translational” or “basic science” aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting,

special diets, etc.

- [x] **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
- [ ] **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition (ClinicalTrials.gov & FDA)
- [ ] **Non-clinical** – any college/department that would regularly submit to IRB-02
- [ ] **Other**

VII.B.1.b ***Provide the NCT (National ClinicalTrials.gov Identifier) number***

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***
No

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***
No

VII.B.18 ***Does this project involve testing the safety and/or efficacy of a medical device?***
No

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- E-mail -
- Letter -
- Use of any information available to the researchers or their colleagues because this person is a patient OR use of any information considered to be Protected Health Information (PHI) OR review of patient/clinic records - Phase 1 Name, address and telephone contact information for parent's of children identified in the UIHCTrauma system as having an unintentional injury. Phase 2 Name, address and telephone contact information for parents of children identified in the UIHCTrauma system as having an unintentional injury.
- Other - Phase 1 - Blank Children's Hospital will use Name, address and telephone contact information for parents of children identified in the Blank Children's Trauma system as having an unintentional injury. Blank Children's Hospital staff will do mailing of introductory letter so no PHI will be shared with UI research staff.

VII.D.2 ***List the individual data elements you will need to access/use from the patient or clinic records to identify potential subjects for recruitment***
Phase 1
-Injured child's age to ensure the child is between 10 and 17 years of age
-Type of injury to determine intention
-Parent names
-Parent address to send informational sheet and consent letter
-Parent phone numbers to follow-up after study information sheet

Phase 2
-Injured child's age to ensure the child is between 10 and 17.2 years of age
-Admission to UIHC and Children's Mercy Hospital Pediatric Unit for injury. Later, direct questioning will be used to determine whether the injury was intentional, and thus if the child is eligible.
-Parent and child names

VII.D.3 ***Describe why you could not practicably recruit subjects without access to and use of the information described above***
Phase 1
Unintentional injuries among children ages 10-17 are not rare but severe injury requiring a visit to an Emergency Department and Trauma activation are difficult to identify. Use of the Iowa Trauma database allows the researchers to identify this high risk population.

Phase 2
Unintentional injuries among children ages 10-17 are not rare but severe requiring a visit to an Emergency Department, Trauma activation and hospital admission. These are difficult to identify. Use of medical record data allows the researchers to identify this high risk population.

VII.D.4 ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.***
It would not be practicable to contact subjects to ask if you can review the medical record to see if they are eligible because you won't know who to contact until you do review the medical record.

VII.D.5 ***Describe plans to protect the identifiers from improper use or disclosure***
All identifying information will be kept in password-protected computer files that are only available to the research team.

VII.D.6 ***Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research***
Phase 1
Following the completion of the focus groups or interview identifying information will be destroyed.

Phase 2
Following completion of the randomized trial and data analysis the identifying information will be destroyed.

VII.D.7 ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule***
Yes

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?***
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
Phase 1
Among the parent focus group, verbal consent will take place on the phone. The parental focus group will take place at the Coral Ridge Community Center. Parental focus groups for the Blank Children's Hospital site will take place at the Blank Park Zoo.

If a parent is unable to attend a focus group a telephone interview option will be provided. The parent will again give consent over the phone.

The consent process with providers will take place via a letter with elements of consent included. The research team will discuss the elements of the study with each provider upon arrival to the focus group. The provider focus group will take place at Blank Children's Hospital.

Phase 2
This discussion will likely take place in the child's hospital room. If it is a shared room, we will work with Kristel Wetjen- Trauma Coordinator at UI Children's to use another private room on the same floor. Children's Mercy Hospital staff will identify private space for the discussion.

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
Yes

VII.D.11 ***Describe:***
Phase 1
UI Children's Hospital-A research team member will contact potential parent focus group participant by phone to explain the purpose of the focus group/telephone interview after the parent has received the introductory letter and the letter with consent elements. Each potential provider participant will receive an email with elements of consent.

Blank Children's Hospital- After the parent has received the introductory letter and has emailed or called the UI research staff to express interest in participating in the study, a research team member will then send out the letter with consent elements. Research staff will then contact potential parent focus group participant by phone to explain the purpose of the focus group/telephone interview and answer any questions. Each potential provider participant will receive a letter with elements of consent.

Phase 2
No, the discussion will be done in person.

VII.D.12 ***Who will be involved in the consent process (including review of consent document, answering subjects' questions)?***

Name	Consent Process Involvement
Marizen Ramirez, PHD	Yes
Mallory Bolenbaugh, BS	Yes
Cassidy Branch, BS, MA	Yes
Collin Calvert, MPH	No
Gretchen Cress, BSN, RN	Yes
Jonathan Davis, MS	No
Patricia Espe Pfeifer, PHD	Yes
Javier Flores, BS	No

Name	Consent Process Involvement
Kelly Guinn, BA	Yes
Charles Jennissen, MD	No
Corinne Peek-Asa, PHD	No
Graeme Pitcher, MD	No
Lisa Roth, BS	Yes
Ruthann Schrock, BSN	Yes
Karen Smith, RD, MS	No
Kristel Wetjen, RN	Yes
Tammy Wilgenbusch, PHD	Yes
Bridget Cho	Yes
Sun Young Hwang	Yes
Teresa Maag	Yes
Kimberly Randell	Yes
Chris Sexton	Yes
Emily Siedlik	Yes
Lauren Slagel	Yes
Shallyn Ward	Yes
Chalott Williams	Yes
Briana Woods-Jaeger	Yes

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***

- Letter or Information sheet containing elements of consent
- Consent Document
- Assent Document

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
Yes

VII.D.17 ***Choose one of the following to indicate why you are requesting that the IRB waive the requirement to obtain a subject signature as documentation of consent:***
A. The research presents no more than minimal risk (minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

AND

The study involves no procedures for which consent is normally required ouside of a research context. *(This type of waiver is often permitted for a minimal risk mail-out survey that includes a cover letter with all elements of consent, and returning the survey indicates consent. You cannot request this waiver if the study also involves the use of any protected health information (PHI).)*

VII.D.18 ***Explain why this meets the chosen criteria in A. or B. above:***
Phase 1
As defined in the risk section, this study will involve minimal risk to the parents including psychological/emotional response to discussing the injury to their child. The child will not be involved in the study in any way. The study involves minimal risks for the providers as they will be discussing content of the program and how the program will fit into the clinic setting. Providers will not be asked to report any personal information.

Phase 2
The waiver will not be applied to Phase 2

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?***
Yes

VII.D.20 ***List any screening questions you will directly ask the potential subject to determine eligibility.***
To verify that a child's injury is unintentional, we will speak with the child's nurse or Kristel Wetjen, the nurse on our research team, as she is usually in contact with all pediatric patients. Children's Mercy Hospital research staff will work with nursing staff for verification of unintentional injury. The modified version of the COAT, a measure of orientation and awareness, will be given to all eligible children to ensure the child has the capacity to assent.

1. What is your name?
2. How old are you? What is your birthday?
3. Where do you live?
4. What is your father's name?

What is your mother's name
5. What school do you go to?
What grade are you in?
6. Where are you now?
7. Is it daytime or night-time?
7. What is the month?
8. What is the year?

A child will be required to score 55 (of a potential score of 65) to be eligible for the study.

We would speak with the nurse or review medical records to determine if the parent of the patient is not English speaking; if patient is diagnosed with intellectual deficit or psychosis; if patient has previously attempted suicide; or if patient had been in residential treatment.

VII.D.21 ***Will you keep a screening log or other record that would include information on people who do not enroll in the study?***
Yes

VII.D.22 ***Describe the information being collected and the purpose for keeping this information.***
For children who screen ineligible, we will record their score, age and mechanism of injury so that we can describe the differences in children who did and did not participate in the study.

VII.D.23 ***Will this information be shared with anyone outside the UI research team members?***
No

VII.D.25 ***<u>After</u> the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***
No

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
Phase 1
Potential focus group members will have approximately a week between receipt of the letter/email with elements of consent to consider participation. In addition, they will be allowed time during the phone conversation with research staff to consider participation.

Phase 2
The parent-child dyad will be given approximately 15 minutes to consider participation and be allowed to discuss their participation with each other.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
Phase 1
Focus groups and telephone interviews will occur approximately 1-2 weeks after the letter with elements of consent for parents and 1-2 weeks after email with elements of consents for providers. Provider key informant interviews will also follow this same timeline.

Phase 2
The study procedures will begin as soon as consent is received.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

Phase 1

UI Children's Hopsital-Ms. Wetjen will identify potential parent focus group members through the Iowa State Trauma Registry (as previously described). Ms. Frederick will prepare and mail the introductory letter to potential focus group members. Within a week of mailing the introductory letter, Ms. Frederick will mail the letter with elements of consent to potential parent participants. One week after mailing the consent letter, Drs. Harland, Ramirez or Ms. Fredrick will attempt to contact the potential subjects to discuss the study over the phone. The researchers will strictly adhere to phone scripts when contacting potential subjects over the phone to reduce the possibility of coercion. If the initial phone contact is not successful, the research team will try to contact the potential subject two additional times within a week of the initial phone call. If phone contacts are unsuccessful than the team will contact potential subjects by e-mail with a maximum of two e-mails. All letters contain information allowing potential subjects to opt out of the study by calling or e-mailing Dr. Harland or Ms. Frederick. Dr. Harland, Dr. Ramirez, or Ms. Fredrick will complete the consent process over the phone with the parents. If a parent agrees to participate in a focus group a letter confirming the date, time and location of the focus group will be mailed to the parent. The letter will include materials to

be discussed during the focus group and a map. The materials may also be delivered by email. If a parent agrees to participate in an interview, the materials will be mailed or sent by e-mail per the participants request.

For the provider focus groups, Ms. Wetjen will e-mail the providers about their potential participation in the study focus group. The e-mail content will be the introductory letter with the elements of consent. Providers interested in participating will be asked to RSVP through a doodle calendar link or they may contact Dr. Harland either by phone or email to enroll in the focus group or discuss any questions they may have about the group. If a healthcare provider is unable to participate in a schedule focus group but wishes to provide a key informant interview the interview will be completed by Dr. Harland or Dr. Ramirez.

Blank Children's Hospital-
For parent focus groups- Pediatric Trauma Coordinator at Blank Children's Hospital will identify potential parent focus group members through the Iowa State Trauma Registry (as previously described). Pediatric Trauma Coordinator will provide a cover letter from Blank Children's Hospital expressing their willingness to forward information about the study and noting the attached recruitment materials from UI Researchers. Staff from Blank Children's Hospital will mail the introductory letters out so no PHI information will be provided to UI . Interested participants will be able to contact UI research staff via the study email provided or by calling Ms. Roth at the number listed in the letter. Once they have positively responded via email or phone about their interest in the study, UI research staff will mail the letter with elements of consent to potential parent participants. Potential participants will be contacted one week after mailing the consent letter, UI reserach staff will attempt to contact the potential subjects to discuss the study over the phone. The researchers will strictly adhere to phone scripts when contacting potential subjects over the phone to reduce the possibility of coercion. If the initial phone contact is not successful, the research team will try to contact the potential subject two additional times within a week of the initial phone call. All letters contain information allowing potential subjects to opt out of the study by calling Ms. Roth or emailing the study email address. UI research staff will complete the consent process over the phone with the parents. If a parent agrees to participate in a focus group a letter confirming the date, time and location of the focus group will be mailed to the parent. The letter will include materials to be discussed during the focus group and a map. The materials may also be delivered by email. If a parent agrees to participate in an interview, the materials will be mailed or sent by e-mail per the participants request.

For the provider focus groups, Pediatric Trauma Coordinator will provide a cover letter from Blank Children's Hospital expressing their willingness to forward information about the study and noting the attached recruitment materials from UI Researchers. Materials will be distributed to all providers at Blank Children's Hospital who interact with traumatically injured children. The materials will include the introductory letter with the elements of consent. Providers interested in participating will be asked to RSVP through email to the study email or to Lisa Roth, Project Manager to enroll in the focus group or discuss any questions they may have about the group. If providers do not respond after first correspondence they will not be recontacted. Providers may also indicate by email or phone if they do not wish to participate in this study. If a healthcare provider is unable to participate in a schedule focus group but wishes to provide a key informant interview the interview will be completed by Dr. Ramirez.

Phase 2
A study team member will be texted or notified if a child is admitted to the UIHC/Children's Mercy Hospital with trauma. The text/notification will not contain identifying information, just information like "A patient is added to the database." The research team will review the child's medical record to determine if he/she meets eligibility criteria, and consult the child's care team to determine if the injury was truly unintentional. On a daily basis, the research team will review each child's medical record to determine when the child is likely to be discharged. On the day of discharge or any convenient time recommended by the provider, a member of the research team will present to the child's room to determine if the child has an appropriate level of consciousness to complete the consent process (a COAT orientation score of at least 55), and if appropriate recruit the dyad. The team member will discuss the study and complete the consent process with the dyad in-person. If timing is inconvenient due to a conflicting event, such as a medical procedure, the team member will give the PCORI infographic to the parent. This half-sheet contains brief information about the study and contact information for the study team. The team member will only give this half-sheet to families they have approached in person, and they will return at a more convenient time to continue the recruitment process. To minimize the possibility of coercion during the consent process, the research team will follow the consent document closely and stress to the dyad that the child's health care will not be affected by participation in the study.

For research subjects that were assented as children but turned 18 prior to the end of their involvement in the study, the research team will mail a re-consent instruction letter along with a new consent document to the subject. The consent document will be different than the consent document signed by the parent at initial recruitment. The documents will be mailed to research subjects via U.S. mail and provided a postage paid envelope in which to return the signed consent document to the research team.

VII.D.30 ***Describe how you will obtain the consent of the parents or legal guardians for child/minor subjects in this study***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use FIRST person, and provide detail as to order of events***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

The ICTS flexible nursing staff will alert the research team if a child presents to the UIHC as an admission for trauma. Children's Mercy Hospital research staff will be alerted by Emergency Room staff if a child present for admission of a trauma. The research team will review the child's medical record to determine if he/she meet eligibility criteria, and consult the child's care team to verify that the injury was indeed unintentional. On a daily basis, the research team will review each child's medical record to determine when the child is likely to be discharged. On the day of discharge, a member of the research team will present to the child's room to determine if the child has an appropriate level of consciousness to complete the consent process, and if appropriate recruit the dyad. If timing is inconvenient due to a conflicting event, such as a medical procedure, the team member will give the PCORI infographic to the parent. This half-sheet contains brief information about the study and contact information for the study team. The team member will only give this half-sheet to families they have approached in

person, and they will return at a more convenient time to continue the recruitment process. The child-parent dyad will be recruited simultaneously therefore the parent or legal guardian will be available at the time of the child's assent. The team member will discuss the study and complete the consent process with the dyad in-person. To minimize the possibility of coercion during the consent process, the research team will follow the consent document closely and stress to the dyad that the child's health care will not be affected by participation in the study.

For research subjects that were assented as children but turned 18 prior to the end of their involvement in the study, the research team will mail a re-consent instruction letter along with a new consent document to the subject. The consent document will be different than the consent document signed by the parent at initial recruitment. The documents will be mailed to research subjects via U.S. mail and provided a postage paid envelope in which to return the signed consent document to the research team.

VII.D.31 ***What are the plans for the assent process for children/minors in this study? (You may choose more than one procedure if you have different child populations in your study)***

- Children/minors will sign an assent or consent document -

VII.D.36 ***Provide a detailed description and rationale for each of the procedures chosen above and describe the child/minor populations to which they apply in your study.***

Phase 2
All children 10-17.2 years of age will be asked to sign an assent document. We chose to use the assent document for all participants aged 10-17.2 years because the language is simple and easy to understand, especially since the children are undergoing medical procedures in the hospital.

It was discovered on 7/15/2016 that some children who signed the assent document turned 18 at some point during the 9-month follow-up period of the study. For research subjects that were assented as children but turned 18 prior to the end of their involvement in the study, the research team will mail a re-consent instruction letter along with a new consent document to the subject. The consent document will be different than the consent document signed by the parent at initial recruitment. The documents will be mailed to research subjects via U.S. mail and provided a postage paid envelope in which to return the signed consent document to the research team.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
Yes

VII.E.1.a ***Will any subjects be blinded to which study arm they have been assigned?***
No

VII.E.2 ***Describe randomization scheme/assignment including ratio such as 1:1, 2:1 etc.***
Phase 1: No randomization
Phase 2
The parent-child dyad will be randomized at a 1:1 ratio by a program developed in Microsoft Access or Excel.

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
Yes

VII.E.4 ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)***
Phase 1
Two focus group questionnaires have been developed: a questionnaire for parents of injured children and a questionnaire for staff who serve these injured children. The questions for the parent interview will be equivalent to the parent focus group questions. The questions for provider key informant interviews will equivalent to those of the provider focus group. At each focus group, one study staff member will ask the questions and a second person will take notes on the answers from the participants. In the telephone interview, notes will be taken by the research staff member completing the telephone interview

Phase 2

The parent and child will be asked to answer 4 questionnaires each over the course of the study: one during hospitalization, one at 6-weeks, one at 3-months and one at 6-months post hospitalization. The 6-week, 3-month and 6-month questionnaires will be the same questionnaire.

Both parent and child will complete the baseline questionnaire and follow-up questionnaire three times.

The parent and the child questionnaires will contain the following validated questionnaires: Strengths and Difficulties Questionnaire; the Pediatric Quality of Life Inventory; CESD; Foa PTSD; Multidimensional scale of perceived social support; open family communication; and how I cope under pressure.

The questionnaires listed are contained within the attached documents. Please see the following for where they can be found in both parent and child surveys. Parent Baseline Survey #11 is Foa PTSD (#8 in follow-up surveys) #13 is Multidimensional scale of perceived social support (#2 in follow-up) #14 is CES-D (#3 in follow-up) #16 is How I cope under pressure (#5 in follow-up) #17 is Open family communication (#7 in follow-up) #21 is Quality of Life (#9 in follow-up) #22 is Strengths and Difficulties (#10 in follow-up) Child Baseline Survey #6 is the Pediatric Quality of Life Inventory (#9 in follow-up surveys) #7 is Strengths and Difficulties (#10 in follow-up) #9 is Foa PTSD (#3 in follow-up) #10 is CES-D (#4 in follow-up) #11 is How I cope under pressure (#5 in follow-up) #12 is Multidimensional scale of perceived social support (#7 in follow-up) #13 is Open family communication (#8 in follow-up)

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
Yes

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

Phase 1
Participants will be asked to come to a 60-90 minute focus group session at the University of Iowa and Blank Children's Hospital. During each focus group, participants will be asked questions about their opinions, recommendations and additions to the LPC for Injured Kids materials, and the applicability of the program in a rural Iowa population. Each focus group will be audio recorded to ensure all recommendations, additions or corrections are documented. This audio recording will be done with a hand held audio recorder. Audio transcripts of each focus group will be downloaded into a password protected computer. The expected time to complete the telephone interview is 20-30 minutes and will answer the questions asked of the focus group.

If a health care provider is unable to attend the focus group but interested in participating in a key informant interview, Dr. Ramirez will complete the interview. The key informat interview questions will be equivalent to those of the provider focus group. These interviews will also be audio recorded, transcribed and downloaded into a password protected computer.

The time commitment will be 60-90 minutes. There will be no follow-up visits.

Participants are free to not respond to any questions they prefer not to answer.

Phase 2

All subjects: Following consent, the research team will collect contact information (address, phone number, e-mail addresses) from the parent-child dyad. The parent-child dyad will then complete their baseline questionnaires. Each questionnaire will take approximately 10 minutes to complete. The questionnaire will measure depressive symptoms, symptoms of post traumatic stress disorder, social support, strengths and weakness, quality of life and family communication. The contact information and baseline questionnaires will be collected with an iPad or by paper form, and entered into electronic databases upon return to the research team space in Westlawn at the UIHC site and the Clinical Trials Coordinators office in the Division of Developmental and Behavioral Sciences at Children's Mercy Hospital and filed in locked filling cabinets. Identifying data will be kept separate from questionnaire data.

Link is our new program of psychological first aid adapted from LPC. After our early formative phase 1 work, we had made some modifications to LPC that were not in agreement with the original developers. In order to translate LPC to a program that was acceptable and appropriate for our population, and also after consultation with UI Legal Counsel, we decided to create Link. Therefore, we would not run into copyright issues. Link has elements similar to that described in the LPC program that we created - including screening for stress and motivational interviewing skills. The large difference in Link is that the three original LPC steps - Listen Protect and Connect are not referenced. However, both programs are based on psychological first aid.

Link Intervention: Intervention parents will get a 20-45 minute training on the Link for Injured Kids Program during their child's hospitalization. The training will involve viewing a Link training program on an iPad and a brief training in motivational interviewing. All Link training sessions will be audio recorded to ensure fidelity among the research team. Two weeks after hospital discharge, a packet will be

mailed to the family's home address containing the Link pocket card, trifold, and instructional DVD. At 6-weeks post-discharge, the instructor will conduct a telephone booster session with the parent trained in Link.

Trauma Education Intervention: Parents will be given the booklet "So Your Child Has Been in an Accident... An Information Booklet for Parents." This booklet will be sent again to the family's address 2-weeks after their hospital release. At 6-weeks post-discharge, the interventionist will conduct a brief telephone survey to assess the parent's perceptions regarding the Trauma Education program.

All subjects: The dyads will be asked to complete follow-up questionnaires at 6 weeks, 3-months, 6-months post hospitalization. The questionnaire will measure depressive symptoms, symptoms of post traumatic stress disorder, social support, family communication, strengths and difficulties and quality of life and asks about any mental health or community resources they may have used since the last questionnaire. The research team will e-mail a link for the parent and the child to complete their surveys as well as mail a hard copy version of the questionnaire with a cover letter explaining that the survey can be completed on paper or online and a postage paid envelope. If completed online, the questionnaires will be done electronically using REDCap, a U of I supported online survey system. A telephone call will be placed to the dyad the day the hard copy questionnaire is mailed informing the dyad of the mailing; the dyad will also have the option of completing the survey over the phone at the time of the call.
For subjects that were consented as children, but turned 18 prior to the end of their involvement in the study: after obtaining re-consent when the subject turns 18, these subjects will complete follow up questionnaires at the same intervals described for all subjects.

If an online or mailed questionnaire is not returned within 7 days the research team will attempt to contact the dyad by phone 12 times (for each follow-up period) to remind them to complete the questionnaire or to make arrangements for the questionnaire to be completed at an already scheduled follow-up appointment at the hospital. For 6-week questionnaire, they will be contacted 12 times up to 6 weeks following their eligibility to complete that questionnaire. For 3-month questionnaire, they will be contacted 12 times up to 3 months following their eligibility to complete that questionnaire. For 6-month questionnaire they will be contacted 12 times up to 6 months following their eligibility to complete that questionnaire. After a month of no response for any survey timepoint, we will resend the package or online link. If a dyad does not complete the 6-week questionnaire, they will still be asked to complete the 3-month and 6-month questionnaires.

The research team will complete the medical record abstraction within 12 months of receiving the medical record consent. The data collected from the medical record includes measures of injury severity, the type of injury the child sustained, external cause of injury, length of stay, diagnostic procedures, Glasgow Coma Scale measures, comorbidities, and initial vital signs and all discharge codes.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - those lost to followup will not be recontacted

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
Yes

VII.E.10 ***Cash***
No

VII.E.11 ***Gift Card***
No

VII.E.12 ***Check***
Yes

VII.E.13 ***Who will be providing the research compensation check to the subject?***
Accounting Services directly via the e-Voucher system

VII.E.16 ***Other***
Yes

VII.E.17 ***Describe:***
Phase 1: A light meal will be provided to all focus groups. For the parent focus groups, on-site child care will also be provided.

Phase 2: None

VII.E.18 ***If you plan to compensate subjects using cash, checks or cash equivalent does your unit have a Cash Handling Procedure in place that has been approved by Accounting Services?***
Yes

VII.E.19 ***Describe the compensation plan including***

- ***Compensation amount and type per visit***
- ***Total compensation***
- ***Pro-rating for early withdrawal from study***

Phase 1
Since the focus groups will take place at common meal times (lunch for providers and dinner for parents), a light meal will be provided before the focus group. Parent focus group participants will receive a $20 gift card to compensate them for their time upon completion of

the focus group. In addition, for the parent focus groups, on-site child care will be provided. Parents will also be compensated for mileage to travel to and from the focus group in the form of a gift card. The rate of $0.55/mile will be paid and the gift card will be rounded up to the nearest $5 increment. Parent interviews will receive the $20 compensation for completion of the interview.

Providers participating in a key informant interview will not be compensated.

Phase 2
Trauma Education group: Both the parent and the child will receive $25 for completion of each questionnaire for a total of $100/subject or $200/family.

Link Intervention group: Both the parent and the child will receive $25 for completion of each questionnaire for a total of $100/subject or $200/family.

For both the Trauma Education and Link Intervention group, both the parent and child will receive a $25 check for each completed questionnaire delivered via the e-voucher system.

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial
- legal or social
- physical?

Phase 1
This study involves minimal risk. Responding to focus groups questions may incur some emotional or psychological risks to parents whose children suffered a traumatic injury. Providers may also have this response when talking about a particularly severe traumatic injury of a child they treated.

Phase 2
This study involves minimal risk. Responding to questionnaire items may incur some emotional or psychological risks to a parents or child. Data abstracted from the medical record will be data related to the unintentional injury admission.

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Phase 1
Staff who are experienced in conducting focus groups will be used in this project. If a focus group participant become visibly upset during the session, they will be referred to Dr. Tammy Wilgenbusch, Pediatric Psychology, UI Children's Hospital.

In the parent focus group, participation in the focus group may risk a loss of confidentiality although parents will only be asked to use their first name or a pseudo name during group introductions.

In the provider focus group, providers will be asked to remove their UIHC/ Blank Children's Hospital badges to reduce the risk of loss of confidentiality. Only the research team will receive the RSVP's through the doodle link or email to ensure confidentiality.

Phase 2
All parent-child dyads recruited at UIHC will be provided contact information for Dr. Patti Espe-Pfeiffer and the UIHC pediatric psychiatry clinic should either experience an emotional/psychological issue requiring further attention. All parent-child dyads recruited at Children's Mercy Hospital will be provided with contact information for a general social work hersupport should with either experience an emotional/psychological issues requiring further attention.
Medical record abstraction data will be recorded by study subject identification number to reduce the likelihood of breach of confidentiality.

As mandatory reporters, the discovery of child abuse by a research team member will result in an immediate report to the University of Iowa Police and local police, consistent with Iowa Code 262.9(37).

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
Participants may not benefit from being in this study.

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***

Phase 1

Parents of children with a traumatic unintentional injury, the children themselves, and health care providers of these injured children may potentially benefit from the development of this new program to reduce psychological trauma following an unintentional injury.

Phase 2

Parents of children with a traumatic unintentional injury and the children themselves may potentially benefit from these programs to reduce psychological trauma following an unintentional injury.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***

Phase 1

Information from the focus groups will be recorded in an anonymous fashion. Telephone interviews will not be recorded. The research team will only ask questions that will help them to answer the study questions. During the provider focus groups, providers will be asked to remove their UI/ Blank Children's Hospital identification badge before entering the session.

Phase 2

All dyads will be assigned a random identification number. The questionnaire, and medical record data and the personal identifiers will be kept in seperate databases and be made available only to research staff. Data abstracted from the medical record will only be related to the unintentional injury hospital admission and recorded on forms that document only the study identification number.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***

No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Phase 1 Hand written notes from the sessions will be placed in a locked filling cabinet. The notes will not contain identifying information. Focus group participants will be recorded as Participant A, B, etc. Transcriptions of key Informant interviews will be not contain identifying information. Phase 2 The baseline questionnaire and medical record abstraction form may be hard copies. The participants will be asked to place their completed questionnaire in a manilla envelope only identified by their study ID number. These envelopes will be collected by the research team and transported from the UIHC/Children's Mercy Hospital to the study offices in Westlawn or the Clinical Trail Coordinators office in the Division of Development and Behavioral Sciences at Children's Mercy Hospital The hard copies will be stored in a locked filling cabinet in Westlawn (UIHC) or Clinical Trials Coordinator Office in the Division of Development and Behavioral Sciences (CMH).If follow-up questionnaires are completed in hard copy, the hard copy will only contain the study identification number and be returned in first class postage paid envelopes.
- Electronic records (computer files, electronic databases, etc.) - Phase 1 All audio files, and electronic documents containing the transcription of the audio files, will be saved on the College of Public Health servers and will be password protected. Following the focus groups, the audio recorders will be placed in locked filing cabinets. Once transcription has been completed and verified, the audio files will be deleted from the audio recorders. Phase 2 The questionnaires will be completed using REDCap, an electronic online survey system supported by the U of I. A subject's study ID will be linked to the data and no identifying information will be in the follow-up surveys. Two electronic ACCESS databases will be created for tracking research subjects and for entering the baseline questionnaire. Audio recordings from external sites will be sent to the University of Iowa research team via uploading the audio files to a group SharePoint site. On the SharePoint site, each external site will have a site-specific audio file folder that is only accessible to their staff and the UI research team for the purpose of downloading files to the CPH secure servers. All audio recordings and electronic files will be stored on secure servers and only be accessible by password protected computers by the research team. Non-UI team members will be issued a HawkID in order to access the data files stored in REDCap.
    - Name - Tim Shie
    - Title - Director of Information Technology, College of Public Health
    - University Job Classification - IT Director

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***

No

X.6 ***Describe***

Because the funding agency requires engagement activities of projects, we will identify partners to be consultants to the research team. Consultants may include previous study participants. These consultants may provide services by providing: feedback/suggestions about their experience with study processes, ideas about dissemination, testimonials, or collaborating on presentations. They will not be engaged in any research activities, and will not have access to any coded or identifiable data.

X.7 ***Does your study meet the NIH criteria for a Certificate of Confidentiality or will you be applying for Certificate of Confidentiality?***

No

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***

Phase 1
The focus group data and key informant interviews will be analyzed using content analysis and identification of themes. Focus group and interview data will also be used to incorporate changes into the LPC for Injured Kids program.

Phase 2
If we achieve randomization, we will compare the differences in distributions between intervention and control groups using simple chi-square tests for categorical outcomes (low, medium, high levels of coing; being symptomatic for PTSD, Depression, etc.) and t-tests or Wilcoxon rank-sum tests for continuous variables depending on their normality (e.g. scores for PTSD, depression, social support).

If we do not achieve randomization (i.e. distribution of demographics are not balanced across intervention and control arms), we will also adjust for confounding using Generalized Linear Models and appropriate link functions (logit for binary outcomes, linear for continuous outcomes).

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
Phase 1
The research team needs each final focus group to contain at least 6 parents or providers to get an adequate response to the focus group questions. The focus group will have potentially unpredictable schedule, either due to children in the home (parents) or heavy work load (providers) therefore we are recruiting 10 members per focus group to ensure we have at least 6 attending each focus group.

Phase 2
We conducted sample size based on testing a moderate effect size of 0.5 standard deviation comparing Trauma Education vs Link. With an alpha of 0.05, a sample size of 134 parent-child dyads in each of the arms (n=268) has 100% power to examine comparisons. We will oversample by 12% for a total n = 300.

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
No

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
No