LIGHTHOUSE AWARDS
American Excess Insurance

AMERICAN EXCESS INSURANCE EXCHANGE

Grant Application

1	**Project Title**	**eConsenting Implementation for Oncology Clinical Trials at Valley Children's Hospital**
2	Clinical or Operational Area	Operational
3	Healthcare System	Hospital
4	Hospital or Entity Name	Valley Children's Hospital
5	Applicant Name	Linda Grigsby
6	Applicant Title	Oncology Lead Clinical Research Coordinator
7	E-mail Address	lgrigsby@valleychildrens.org
8	Telephone	559-353-5487
9	Mailing Address, City, State, Zip Code	9300 Valley Children's Place, Madera, CA 93636
10	**Please list the names and titles/roles of the additional members of the project team:**	
	Name:	**Title/Role:**
	Padma Desai	Research Manager
	Trish Regonini	IRB Coordinator
	Raed Khoury	Clinical Sponsor
11	Name of Senior Risk Management or Corporate Insurance Representative	Nathan Powell, Chief Risk Officer
12	Mailing Address, City, State, Zip Code	9300 Valley Children's Place, Madera, CA 93636

13. The issue being addressed involves the following clinical areas: ***(Check all that apply)***

- ☐ Ambulatory Care
- ☐ Emergency Services
- ☐ Hospital/System-wide Focus
- ☐ Obstetrics/Perinatal
- ☐ Radiology/Imaging Services
- ☐ Surgical/Peri-Operative
- ×☐ Other (Please specify)

Oncology Department

14. Briefly describe the project and its importance to the organization: ***(two paragraphs maximum, please attach any supporting documentation)***

Obtaining informed consent is a crucial part of any clinical research trial. Inadequacies in collecting and recording this informed consent is among the top reported FDA audit findings. The FDA provided guidance and compliance requirements for the implementation of electronic informed consent in 2015. Valley Children's Hospital Research Department launched our eConsent platform for all departments outside of Oncology amid the pandemic in November 2020. Since then, several research projects have benefitted from having this functionality available at our institution. Our Oncology research department supports over 50% of the entire research portfolio with over 90 active clinical trials available for our patients in the central valley allowing them an opportunity to participate in these novel treatment and non- treatment studies. Electronic Consenting platform was not approved by Children's Oncology Group (COG) and Central Institutional Review Board (CIRB) for patients enrolled on cancer clinical trials until recently. Currently, oncology patients at VCH who agree to participate in clinical trials must complete the paper versions of the consent form indicating their participation interest, increasing the chances of errors including incorrect signatures and inadequate documentation. COG and CIRB have recently approved the use of electronic consenting for oncology research protocols. Non-treatment oncology studies including registries like "Project Every Child" and Late effect studies, offer patients opportunities to participate in research which evaluate continued wellbeing during and post rigorous therapies including chemotherapy, radiation or surgical management for managing their cancer. Early recognition of late-term treatment side effects is essential for patients' long-term health. Historically, research participation in these studies is minimal due to the inability to reach these patients beyond their active treatment period. The integration of eConsent in our active oncology studies allows for optimized patient reach and enhanced adherence to FDA informed consenting standards as we shift from traditional paper consents.
Our current limitation is the limited availability of mobile devices (ex: iPads) within the research department that can be used by our oncology research coordinators and clinic team members to facilitate the eConsenting platforms. If this project were to be approved, we aim to purchase up to 7 iPads dedicated to oncology research with secure eConsent platform access.

15. Describe how this project will improve patient safety or reduce the potential for liability. *(one paragraph maximum)*

The request is to pay for the iPads which will have the secure electronic consent platform access. The eConsent platform allows for mobile audio and video interactions along with English and Spanish interface. The secure link to connect to the platform will be shared in person or sent via email or phone text message to participants who consent face to face or remotely.
The platform allows us to continue enrollment in research studies without disruption to patient's treatment and infusion schedule in a busy oncology clinic or inpatient setting and in aiming to limit or reduce prolonged interactions as part of infection control thus improving patient safety of this vulnerable population. The eConsenting platform is also FDA and HIPAA compliant, thus significantly reducing the potential for consenting errors and documentation inadequacies. A significant portion of oncology patients live greater than 1 hour away from the hospital. With eConsenting available for registries and late effect studies, we may be able to offer these opportunities to patients who travel long distances and may only seldom come into the hospital or visit outside clinics for routine follow ups, thus improving patient experience, engagement and satisfaction. Electronic consenting modalities also offer improved patient privacy and reduce storage needs compared to paper consents and are available in languages other than English.

16. What metric(s) will be used to measure progress and determine the success of this project?? *(one paragraph maximum)*

With implementation of eConsenting, we propose routine monitoring of informed consenting related concerns caused due to incorrect signatures and inadequate documentation and decreasing these errors; We also hope to be able to offer enrollment opportunities to more eligible patients by 20% and increase our enrollment in registry, late effect and other applicable oncology studies.

17. Please describe the tangible results of the project that can be quantified and shared as best practices with other AEIX members? ***(one paragraph maximum)***

The tangible result will be to have zero informed consenting related errors with eConsenting implementation and in staying compliant with federal and institutional guidelines . In addition, this project will increase clinical trial outreach to patients living in rural areas.

18. Please provide a financial estimate of the project Per VCH IT, iPAD Pro supports the application better than regular iPADs. Requesting $10,000: iPad Pro+Keyboard+Case+S&H is $1400 each; Requesting purchase of 7 sets for a total of $10,000

19. What is the expected timeframe for completion of this project? Purchase of iPads and eConsenting initiation for Project Every Child study expected within 3 months: Usage of eConsenting for outreach to patients in rural areas and preventing Informed consent related errors monitored routinely and will remain an ongoing quality metrics as part of standardized oncology study initiation workflow.

20. Is this project based on successful practices evaluated from literature or other healthcare providers? ☒ Yes ☐ No

This idea was novel to our organization during the pandemic in 2021 and we successfully implemented this practice for department outside of oncology. Oncology research in general has been conservative about implementing electronic consenting workflows. With recent changes made to allow eConsenting by Children's Oncology Group and Central IRB, this is a new practice for our Oncology department which supports over 40% of the total 200 plus research projects in our department

21. Is this project based on an original concept created by the project team? ☐ Yes ☒ No

22. Do you have plans to publish the project results in a professional publication or networking forum? ☒ Yes ☐ No

23. Is there anything else you'd like to share about this project?

The National Institutes of Health is mandated by the Public Health Service Act to ensure the inclusion of members of racial and ethnic minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study. The primary goal of this law is to ensure that research findings can be generalizable to the entire population. Additionally, the statute requires clinical trials to be designed to analyze whether study outcomes differ for women and members of racial and ethnic minority groups. By reaching out to VCH's rural community, we will be able to increase the diversity of our clinical trial enrollments, thus complying with the NIH's mandate.

Signatures required to submit this application

Primary Clinical Sponsor (The individual responsible for monitoring progress of the project, submitting receipts and other documentation supporting the use of grant funds, and will provide a summary report of the project outcome)

Signature	**VP Quality & Patient Safety & Clinical Value and Research**	8/15/24
	Title	Date

Alternate Clinical Sponsor (The individual responsible for supporting the responsibilities of the Primary Clinical Sponsor, and assuming those responsibilities if the Primary Clinical Sponsor is unable to fulfill the requirements of the project)

Signature	Research Manager	08/15/2024
	Title	Date

Senior Risk Management Leader

Signature	**Executive Director & Chief Risk Officer**	
	Title	Date

CEO or CFO of Applicant's Healthcare Facility

Signature	**President and Chief Executive Office**	
	Title	Date

Thank you for completing the application. Please follow these next steps.

- Save this document in Word format and gather your supporting documentation.

- Forward the application and documentation to your senior risk management leader or corporate insurance representative. *They will need to complete and sign the Evaluation of Awards Application Form on the final page of the application before submitting it to American Excess Insurance by* ***Friday August 16, 2024****.*

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Evaluation of Grant Application

The evaluation must be completed and signed by the senior risk manager or corporate insurance representative. Please evaluate the Award Application by indicating the best answer to the question.

1. **How will this project improve safety and/or reduce liability?**

☐ Little effect on safety and liability (1)
☒ Some improvement but metrics are not defined and/or it is not clear that measurable effect can be sustained (2)
☐ Strong effect with clearly defined metrics (3)

2. **What is the potential to share this project or practice with other AEIX members?**

☐ Little potential – i.e. *implementation requires major budgetary commitment, topic is highly specialized, and/or metrics are not clearly defined* (1)
☒ Some potential but process may be hard for another organization to implement, and/or its application may be limited
- i.e. major budgetary commitment, topic is highly specialized, and/or metrics are not clearly defined (2)
☐ Strong potential for producing best practices (3)

3. **What level of impact will this project or practice have on the severity of risk exposure?**

☐ Little chance of impacting severity of risk but could address other issues (1)
☒ Some potential to impact risk exposure (2)
☐ Strong ability to impact severe malpractice exposure caused by significant risk events (3)

4. **What level of innovation best describes this project?**

☐ Project/practice is new to this organization and is based primarily on firmly established best practices (1)
☒ Project/practice was created primarily by applicants with some assistance from an outside vendor and contains well-established best practices with additional innovative features (2)
☐ Project/practice was created solely by applicants and could be included in established literature or industry best practices (3)

5. **Share your comments or recommendations.**

Click or tap here to enter text.

Nikki W. Lee	**Executive Director & Chief Risk Officer**	**8/15/2024**
E-Signature	**Title**	**Date**
Click or tap here to enter text. 559-790-2420	Npowell1@valleychildrens.org	
Phone	**Email**	

Send the completed application in Word format, supporting documentation, and signed evaluation to lana_taylor@premierinc.com *by* ***Friday August 16, 2024.***

Thank you for your submission. In continued pursuit of our mission and vision to partner with forward-thinking healthcare leaders, inspire innovation, and provide the leading pathway for managing risk, we may share your project with other members of American Excess. However, this project will not be shared outside of the American Excess Insurance membership without your prior consent.