Biomedical Device Trial of Validation of Point of Care Liver Function Tests

NCT NUMBER: PENDING
NOVEMBER 28, 2018

Modification

Basic Info

Confirmation Number:	**chigbiga**
Protocol Number:	**829476**
Created By:	**EICHELDINGER, EMILY**
Principal Investigator:	**KHUNGAR, VANDANA**
Protocol Title:	**Validation of Point of Care of Liver Function Testing**
Short Title:	**Validation POC-LFT**
Protocol Description:	**This study is to test the accuracy of a point of care device that tests liver function. The target population is adults who have an indication to collect a liver function panel that will be drawn on the same day as their clinic visit or during their inpatient hospital admission. Participants will receive a finger prick and blood will be place on point of care device. Results will be compared to results from traditional blood draw.**
Submission Type:	**Biomedical Research**
Application Type:	**FULL**

PennERA Protocol Status

Approved

Resubmission*
No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Currently in Progress

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

0

Actual enrollment at participating centers

0

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

0

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date
Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
This modification is to expand recruitment to include patients admitted to inpatient services at The Hospital of the University of Pennsylvania.

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
No

If YES, please choose from the options below regarding re-consenting

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**KHUNGAR, VANDANA**
Dept / School / Div:	**4237 - DM-Gastroenterology**
Campus Address Mail Code	**6160**
Address:	**BIOMEDICAL RESEARCH BLDG 2** **421 CURIE BLVD**
City State Zip:	**PHILADELPHIA PA 19104-6160**
Phone:	-
Fax:	-
Pager:	
Email:	**Vandana.Khungar@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**06/04/2020**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**EICHELDINGER, EMILY**
Dept / School / Div:	**4237 - DM-Gastroenterology**
Campus Address Mail Code	**6160**
Address:	**Floor 7 3400 Civic Center Blv** **PCAM- South**
City State Zip:	**PHILADELPHIA PA 19104-6160**
Phone:	**215-360-0947**
Fax:	
Pager:	
Email:	**emily.eicheldinger@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**06/18/2020**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**FORDE, KIMBERLY**
Dept / School / Div:	**4237 - DM-Gastroenterology**
Campus Address Mail Code	
Address:	**600 CLINICAL RESEARCH BLDG** **415 CURIE BLVD**
City State Zip:	**PHILADELPHIA PA 19104-6140**
Phone:	**215-573-4264**
Fax:	-
Pager:	
Email:	**kimberly.forde@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**03/29/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

4237 - DM-Gastroenterology

Key Study Personnel

None

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST?**
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Clinical Trial*
Is this a clinical trial?
Yes

If Yes, please be aware that for each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available

Federal Web site that will be established as a repository for such informed consent forms.

Investigator Initiated Trial*
Is this an investigator initiated trial?
Yes

If Yes, please be aware that the investigator may be required to create and manage a record of this trial in https://clinicaltrials.gov.

Drugs or Devices*
Does this research study involve Drugs or Devices?
Yes: Investigational devices that may qualify as Non-Significant Risk.

IND Exemption

For studies that fall under an IND exemption, please provide the number below

For studies including IND or IDE's, please provide the number(s) below

IDE Review*
NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory. Consult the Penn Manual for Clinical Research: https://somapps.med.upenn.edu/pennmanual/secure/pm/investigational-product-management Please check the box Yes if you have reviewed the guidance.
Yes

Research Device Management*
Please indicate how research device(s) will be managed.
The device receipt, storage and dispensing is being conducted by the research team (please provide information in the protocol summary as to how this will be conducted)

Drug, Herbal Product or Other Chemical Element Management *
Please indicate how drugs, herbal products or other chemical entities will be managed.
Not Applicable (no drugs, herbal products or other chemical entities)

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Gene Transfer*
Does this research involve gene transfer (including all vectors) to human subjects?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
Yes

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Investigational Agent or Device within the Operating Room*
Does the research project involve the use of an investigational agent or device within the Operating Room?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Processing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

In-House Manufacturing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Tissue/biospecimen

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
x	**Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)**
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**FAKHERI, TANNAZ**
Dept / School / Div:	**4237 - DM-Gastroenterology**
Phone:	**215-573-8557**
Fax:	**6160**
Pager:	
Email:	**tannazf@pennmedicine.upenn.edu**

Department budget code

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Funding Sponsors

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?

Regulatory Sponsor

IND Sponsor

none

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Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Pending

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract
We are testing the accuracy of a point of care device that tests liver function within 20 minutes at a doctors office for FDA approval documentation. The target population is any patient who have an indication to perform liver function tests. Any adult patient who has been seen by a liver specialist and/ or been prescribed liver function testing to be drawn on the same day of their clinic visit or inpatient admission is eligible to participate in the trial. Their finger will be pricked and blood placed on the device. Results will be compared to results from traditional blood draw.

Objectives

Overall objectives
1. To obtain regression curves and a correlation coeficient to compare standard blood draws to the investigational diagnostic device.

Primary outcome variable(s)
Regression curve and correlation coefficient

Secondary outcome variable(s)
The consistent accuracy of the diagnostic device

Background
Outpatient diagnostics are slow and expensive. This comes from long turnaround times, difficult workflows, and high costs. Turnaround time for diagnostics tests can be up to 10 days or more, as patients have to travel to a separate facility to have labs drawn, and those lab draws follow a complex workflow. Since testing is offsite, a significant number of patients never make it to their appointments and are therefore not retained in the system. Time delay or non-compliance can make acute problems even more serious. Additionally, lab samples have to be sent to a third location to have actual clinical testing performed on them. This causes patients to be lost to follow up when doctors attempt to provide patients with results, but are unable to get in touch. Beyond time and workflow difficulties, tests can cost anywhere from $15-100 per test depending on a myriad of factors such as insurance, plan

coverage, and provider. Given that over two-thirds of all clinical decisions are based on laboratory testing (COLA, 2015) and in a 2002 survey of the US, 77% of providers were unable to contact their patients with abnormal diagnostic results (White, 2002), diagnostics are not working efficiently for outpatient providers. These studies show that lack of access to fast point of care results leads to significant problems in continuum of care and effective care. Very few point of care (POC) diagnostics are used by doctors, as modular machines are often cost or workflow prohibitive. Many POC diagnostics require a trained technician and have high cost hardware and certifications. The POC diagnostics that are often used are tests such as pregnancy tests or rapid strep tests that are multiple different platforms and are rate-limited in how many tests a practice can adopt. Group K is revolutionizing healthcare through innovative POC diagnostics. We solve the inefficiencies of current lab solutions by bringing the "lab" to the provider and allowing practitioners to run diagnostic tests onsite in doctors offices and clinics. With a low cost, reliable system providers have actionable information before the patient leaves the office. Doctor offices will be able to pay a low cost for the product and bill insurers for running diagnostics. Group Ks quick, inexpensive, and accurate diagnostic platform will be able to improve care for patients all around the world. Group K is developing a paper microfluidic platform with an accompanying mobile application(app). The paper microfluidic device is a simple, inexpensive wax backed device with three testing areas. These areas have a mix of dried proprietary reagents that when combined with a patients drop of blood, or in the future, saliva or urine, will produce results in a color change. An app is then used to interpret the color change and output results to a doctor.

Study Design

Phase*
Not applicable

Design
The design of the study is to investigate 200-400 patient finger prick samples to prove the ability of Group Ks Diagnostic app to identify liver function values on the multidiagnostic. The values will be stored on a Penn Server correlating the patient data obtained from the multiagnostic with a random code, and then the random code correlated to the patient identifier (name and date of birth) and then the patients record of the results of their standard liver function test.

Study duration
The estimated length of the study will be approximately one year. Recruitment will be approximately 4 months. Subjects will participate in one study visit during a previously scheduled clinic visit or during an inpatient hospital admission.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
All investigators and study staff on this protocol are well trained on the study and all have current CITI certifications. Subjects will only be seen by the PI and members of the research study in a private clinic room. Patients will be given ample time to have all of their questions answered.

Characteristics of the Study Population

Target population
The target population is adults (18 years and old) with varying liver health who have had a hepatic function panel or equivalent tests completed at the same day as their finger prick sample obtained; ALT, AST, ALP, albumin, bilirubin and total protein.

Subjects enrolled by Penn Researchers
400

Subjects enrolled by Collaborating Researchers
0

Accrual
The study population will be drawn from adults who have an indication to perform liver function tests during their GI clinic visit or during an inpatient hospital admission. The investigators on this protocol are the Hepatology physicians and therefore will be treating these patients as standard of care. Dr. Khungar and the research staff will identify subjects.

Key inclusion criteria
1. Have a liver function testing for the required 6 tests completed (ALT, AST, ALP, albumin, bilirubin, and total protein) 2. 18 years or older

Key exclusion criteria
1.Inadequate blood sample obtained from finger stick 2. Inconclusive liver function testing 3. Not all 6 liver tests completed on the same sample 4. Liver tests not drawn for normal method at same time as finger stick.

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
Although not directly targeted, mentally disabled persons, economically or educationally disadvantaged persons, and/or employees or students of the University of Pennsylvania will not be denied enrollment and any special protections and/or additional safeguards will be undertaken in order to protect the rights and welfare of these subjects from coercion or undue influence as appropriate.

Subject recruitment
The study recruitment will be accomplished by personal interviews conducted by the PI or study staff during their clinic visit or inpatient hospital admission. Potential subjects will be informed of the criteria for study inclusion, data to be collected during study inclusion, as well as the risks and benefits of study enrollment. The information will be provided in the body of the consent form and presented verbally during the consent process. Consent will be documented by signature of the subject. A copy of the signed consent will then be provided to the subject for their records.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Not applicable

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
All patients, 18 years or older, with varying degrees of liver health seen in the Penn Gastroenterology clinic and/or who have been prescribed liver function testing to be drawn the same day as their clinic visit or inpatient hospital admission will be approached for consent. A finger prick will be collected after receiving consent. Blood sample will be tested with Group K's device. These results will be compared to results from a standard hepatic function panel or equivalent test (ALT, AST, ALP, albumin and total protein).

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

Analysis Plan
Lowest level frequency of detection must be detected 90% of the time. This will become the functional lower limit. The same with the highest level of frequency. We will exclude any data from tests that did not follow standard operating procedures or were not performed in a controlled, laboratory setting as well as any blood that has expired before liver function tests were completed. Each data point will represent one observation or one test run. We will use regression methods to determine the linear relationship between standard lab results and Group K diagnostic's device. We will also determine the correlation coefficient and measure of scatter around the regression line. This will be shown in equation form and in the form of graphs. The dependent variable will be our test results, the independent variable the standard of care.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Data confidentiality

x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**

x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

x **Wherever feasible, identifiers will be removed from study-related information.**

A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality

Blood and corresponding results, will be linked to original results via unique random identifiers. The linking set will be maintained but kept on an encrypted, password protected computer with no PHI. The investigator assures that subjects anonymity will be maintained and that their identities are protected from unauthorized parties. The subjects will be informed that representatives of the IRB or EC, or regulatory authorities may inspect their medical records to verify the information collected, and that all personal information made available for inspection will be handled in strictest confidence and in accordance with local data protection laws. Only necessary study staff will have access to data. Though we do not expect any breaches of confidentiality, if they do occur they will be reported directly to the IRB within 24 hours of after discovery.

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?

No

Subject Privacy

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).

In all disclosures outside of University of Pennsylvania Health system and school of Medicine, Name, social security number, address, telephone number, or any other direct personal identifier will not identify subjects unless law requires disclosure of the direct identifier. In records and information disclosed outside of the University of Pennsylvania Health system and School of Medicine, subject will be assigned a unique code number. No subjects will be identified in any report or publication about this study. Patients seen in the clinic with a referring clinician will be given the opportunity to obtain further information if they choose. All safeguards will be used to ensure privacy. Subjects will only be seen by the PI and members of the research team in the private clinic room and will not be identified to anyone in clinic practice as anything other than a regular patient.

Data Disclosure

Will the data be disclosed to anyone who is not listed under Personnel?

De-identified data will be disclosed to Group K Diagnostics. Blood and corresponding results, will be

linked to original results via unique random identifiers. The linking set will be maintained and kept on an encrypted, password protected computer o HUPs servers. All information will be de-identified prior to Group K receiving it for FDA submission. Group K will receive confirmation that patient was above the age of 18 years old along with the results from Penn Pathology and the result from our device.

Data Protection*

x	**Name**
	Street address, city, county, precinct, zip code, and equivalent geocodes
x	**All elements of dates (except year) for dates directly related to an individual and all ages over 89**
	Telephone and fax number
	Electronic mail addresses
	Social security numbers
x	**Medical record numbers**
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable.

Consent

1. Consent Process

Overview
Study recruitment will be accomplished primarily by personal interviews conducted by the PI or study staff during gastroenterology clinic visit or inpatient hospital admissions. Potential subjects will be informed of the criteria for study inclusion, data to be collected and the risks and benefits of study enrollment. This information will be provided in the body of the consent form. Subjects will be given ample time to have all questions answered. Consent will be documented by signature of the participant. A copy of the signed consent form will be provided to the participant for their records.

Children and Adolescents
Not applicable.

Adult Subjects Not Competent to Give Consent
Not applicable.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
No Waiver Requested

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
Study inclusion poses no more than minimal risk to the participant enrolled. There should be no adverse events associated with the collection of vital signs or the finger prick sample. Participants may

experience mild pain from the finger prick but no more than a standard of care blood draw. Patients and caregivers will have clear instructions as to how to reach the team in the event that it is after hours. There is a potential risk of loss of privacy and breach of confidentiality. We will minimize this risk by linking individual identifying information with participant ID numbers only in one single secure file that will only be accessed by the study team in the case of an adverse medical event, participant dropout, or if otherwise deemed necessary by the Principal Investigator.

Potential Study Benefits
There will be no direct benefit to the subjects from analysis; the data and conclusions derived from this study, however, are likely to push forward towards approval the development of a technology that will greatly benefit patients and the developing world in particular.

Alternatives to Participation (optional)
Participation is voluntary and optional. The alternative to participation is not participating in the study.

Data and Safety Monitoring
Data will be monitored by the PI and Co-investigator. Any adverse events will be reported to the IRB.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
This study offers no direct benefit and only minimal risk to the subjects. There is significant societal benefit, however, as a better understanding of releasing a novel device will allow us to help multiple patients obtain cost effective. As such, the minimal risk to the subjects is outweighed by the potential societal benefit.

General Attachments

The following documents are currently attached to this item:

Cover Letter (coverletter_29nov2018.docx)