- 1. Complete application cover sheet
- 2. Following the outline on page 3, describe the proposed research project. Sections A-D must not exceed 5 pages.
- 3. Attach NIH biosketches for the principal investigator and other key personnel. The NIH Biosketch template can be found at: (<u>http://grants.nih.gov/grants/funding/phs398/phs398.html</u>)
- 4. Provide a budget with a justification (see example on page 4)
- 5. Submit forms to Linda Crossette <u>crosset2@upenn.edu</u> on or before April 15, 2013. You will receive email confirmation of receipt the following business day.

# **Center for Health Care Improvement and Patient Safety** Application for pilot study funding

Applicant Information		
Principal Investigator		
Co-Investigator(s)		
(if applicable)		
Mentor (if applicable)		
Project Title		
Telephone		
Email address		
Abstract (250 words maximum)		
Human Subject Research	Human Subject     Does the research involve human subjects?     Yes     No	
nesedicii	If yes, has the protocol been submitted for IRB review? Yes No (IRB submission not required prior to application.)	
	Has the protocol been approved?  Yes No DateProtocol #	
Proposed Timeline		
	(must not exceed 12 months) From To	
Funds requested	\$	
Have you applied for or received support for this research from another source? If yes, please attach details of that proposal or funding.		
Attachments	Biosketch(s) Research proposal Budget and justification	

# Research Protocol

**Project Title:** 

Principal Investigator: Co-Investigator(s): (if applicable)

# A. Aims/Project Summary

A brief description of the proposed work including background and significance including specific aims long-term objectives and relevance to RFA.

#### **B. Study Design and Methods**

Concisely describe the background, rationale, research strategy, study design and methods for achieving the stated aims.

Human Subjects Research:

- 1. If <u>no human subjects</u> are involved, write, "No activities involving human subjects are planned at any time during the proposed project period." and skip this section.
- 2. If human subjects are involved indicate whether the research is **<u>exempt.</u>** If the study meets the HHS criteria for Exempt write, "Exempt" and indicate the rationale referring to the criteria found at: <u>http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101</u>
- If the research involves human subjects and is <u>not exempt</u>, certification of IRB review and approval is not required at the time of the application but must be provided to CHIPS before funds are awarded. If the study will undergo IRB review, provide the following information:
- a) <u>Inclusion/exclusion criteria</u>: Describe the subject population, including number, age range, and health status if relevant. If applicable, explain the rationale for the involvement of vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.
- b) <u>Recruitment and consent:</u> Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- c) <u>Potential risks and benefits</u>: Describe all potential risks to subjects and planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.

# C. Data Collection Methods

Describe the research material obtained including specimens, records, or data. If applicable, indicate who will have access to individually identifiable private information about human subjects. Provide information about how the specimens, records, and/or data are collected, managed, and protected.

# D. Data Analysis Plan

Describe how the data will be collected, analyzed, and interpreted.

# E. References

#### F. Letter of support

(Pre/post docs only) Provide a letter of support from a mentor.

# Project Title: PI Name: Budget and Justification:

Category	Items	Cost
Personnel	Research Assistant	\$9600
Personnel	Clinical Data Reporting Specialist	\$1000
Supplies	IPad	\$477
Supplies	Office supplies, printing & copying	\$50
Other	Participant remuneration	\$500
Total		\$11,627

Justification:

# Research assistant (RA) salary

A graduate student level RA will be hired in month 2. The RA will obtain participant consent, conduct a brief 10-item survey, distribute participant remuneration (gift cards) and meet weekly with the PI to review progress. The RA will provide 50% effort in months 2-7. The hourly rate for graduate student RAs at UPenn ranges from \$15-\$20 per hour commensurate with experience. We will require 20 hours/week of RA time for 24 weeks a total of \$9600 for RA support.

# Clinical Data Reporting Specialist (RS) salary

The RS will meet with the research team in month 1 to learn about the project. By month 2, s/he will create a report that generates a daily list of potentially eligible subjects that will include subject location in the hospital and name of attending MD. In month 8, the RS will create a query to identify patients who meet control group criteria and will create a de-identified data set containing clinical and administrative data elements specified in the protocol and approved by the IRB. **We have budgeted \$1000 for 30 hours of RS support.** 

# Apple iPad (2) 16GB, wifi and case

An iPad will be used to record subject responses to 10-item survey. The RA will access a RedCAP survey developed by the PI via the internet enabling secure and simultaneous data collection and entry. Cost for one (1) Ipad 2 is \$400. A Smart Case for Apple iPad 2<sup>nd</sup> Generation is \$50 shipping costs are \$27.00 **Total cost for IPad and case \$477.** 

# Office supplies, printing & copying

Each study participant will receive a copy of the signed consent form and the one will kept on file. We will require paper, printing and photocoping (\$0.10 per page), pens for signing the consent forms clipboards, and filing folders and other miscellaneous office supplies. **Office supply costs are \$50.** 

# Participant Remuneration:

Subjects (N= 100) who complete the brief 10- item survey will receive a \$5 WAWA gift card. Total cost for participant remuneration is \$500.