Impact of Nudges on Downloads of COVID-19 Exposure Notification Smartphone Apps: A Randomized Trial
NCT05080179
Approved 11/23/2020

Protocol Details

Basic Info

Confirmation Number:	**dchebgci**
Protocol Number:	**844564**
Created By:	**DIXON, ERICA L**
Principal Investigator:	**VOLPP, KEVIN G**
Protocol Title:	**Message Testing for COVID Alert PA Exposure Notification App**
Short Title:	**Message Testing for COVID Alert PA**
Protocol Description:	**The Commonwealth of Pennsylvania Department of Health has released an exposure notification app - COVID Alert PA - statewide to aid in the COVID-19 fight. In order to increase uptake of the app, we will be conducting message testing in a variety of populations in order to measure what message has the most success in leading to uptake. Populations include patients within health systems, college students, and employees across the state.**
Submission Type:	**Social and Biological Sciences**
Application Type:	**EXPEDITED Category 7**

Resubmission*
No

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**VOLPP, KEVIN G**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Campus Address Mail Code	**6021**
Address:	**BLOCKLEY HALL** **423 GUARDIAN DR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	**215-573-0270**
Fax:	**-**
Pager:	
Email:	**volpp70@wharton.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CME Credit for POR Expedited Review - SOM**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Study Contacts

Name:	**DIXON, ERICA L**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Campus Address Mail Code	**6021**
Address:	**BLOCKLEY HALL** **423 GUARDIAN DR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	
Fax:	**6021**
Pager:	
Email:	**erica.dixon@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Other Investigator

Name:	**SHARIF, MARISSA A**
Dept / School / Div:	**707 - Marketing**
Campus Address Mail Code	
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HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Responsible Org (Department/School/Division):

10599 - ME-Division of Health Policy

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

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
Study instruments will be e-mails sent to patients, employees, and/or students through the institution that is contacting individuals about the app. E-mails will always contain basic information about COVID Alert PA and a link to download - they will also include message variations based on what the institution wants to test, including messages emphasizing data privacy and security, social norming, individual vs. community protection, and more. See attached file for a sample draft message and variation.

Group Modifications
Describe necessary changes that will or have been made to the study instruments for different groups.
Groups will all receive the basic e-mail with background information on COVID Alert PA and a download link. Messages will vary between groups with message variations including emphasizing data privacy and security, social norming, individual vs. community protection, and more.

Method for Assigning Subjects to Groups
Describe how subjects will be randomized to groups.
Institutions will be responsible for selecting the group of subjects within their institution to send e-mails to, and will randomize from that group to 1 of 2 conditions. We will assist with randomization recommendations as needed.

Administration of Surveys and/or Process
Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable

private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.
E-mails will be sent through the institutions directly.

Data Management
Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.
Data reported back to the research team will include open rate of e-mails, click through rate of e-mails, and any deidentified demographic information associated with these rates that is available from the institution. No confidential or identifiable information will be shared with our research team. All information and data received back from institutions will be stored on Penn Box.

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

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

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

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

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

CTRC Resources*
Does the research involve CTRC resources?
No

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

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*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	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
x	**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:	**KENNEDY-SMITH, NANCY**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Phone:	**215-573-2769**
Fax:	**215-573-8778**
Pager:	
Email:	**KENNEDYN@pennmedicine.upenn.edu**

Department budget code

400 - 400 - 4 - 580184 - 5xxx - 2446 - 2398

Funding Sponsors

Name:	**PENNSYLVANIA DEPARTMENT OF HEALTH**
Type:	**UPENN Commonwealth of Pennsylvania**

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?
No

Regulatory Sponsor

IND Sponsor

none

400 - 400 - 4 - 580184 - 5xxx - 2446 - 2398

Industry Sponsor

None

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

Selected Proposals

Proposal No	Title
10079300	**Rapid Validation and Behavioral Economics to Increase Enrollment and Engagement with Digital Con**

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-Center Research

Penn as lead
1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?
No

Management of Information for Multi-Center Research

Penn irb of record
2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?
No

Other Sites

No other sites

Protocol

Abstract
PA DOH rolled out a digital contact tracing/exposure notification app statewide in September called COVID Alert PA. Digital contact tracing apps such as COVID Alert PA can help to quickly notify people who may have been in contact with a person testing positive for COVID-19. We will deploy message testing via e-mail to better understand what motivates people to download the app, at institutions ranging from health systems, to colleges and universities, to employers in the state of PA. The results of the research will be used to aid in the uptake of COVID Alert PA across the

Commonwealth of Pennsylvania.

Objectives

Overall objectives
To understand what message strategies work best to increase downloads of COVID Alert PA by a variety of groups, including patients, students, and employees of PA state employers.

Primary outcome variable(s)
The primary outcome variable is click through rate to the download link embedded in e-mails.

Secondary outcome variable(s)
Open rate of e-mails.

Background
The Commonwealth of Pennsylvania released a digital contact tracing/exposure notification app (COVID Alert PA) statewide in early September to aid in the COVID-19 fight. Contact tracing is used by public health authorities to contact and give guidance to anyone who has been near someone with COVID-19, but is hindered both by compliance issues and situations where a person does not know the names of people they may have been in contact with. Digital contact tracing apps such as COVID Alert PA can help to quickly notify people who may have been in contact with a person testing positive for COVID-19. The app uses Bluetooth to sense when phones with the app installed are in close proximity with each, and exchange digital handshakes containing random IDs between the phones. The app does not collect name, location, or movements and the data is collected and stored only on the phone itself until the person choose to release it. Through IRB# 843861 - Understanding Enrollment and Engagement with a Digital Contact Tracing App in the State of Pennsylvania we have been deploying surveys to measure why people may or may not download the app. The results of the survey are being used to aid in the development of strategies to increase the uptake of the application in the state of Pennsylvania. In order to test which messages may increase rates of download, we will help institutions such as health systems, colleges and universities, and businesses and employers with message testing to see what strategies work best to increase uptake.

Study Design

Phase*
Not applicable

Design
Participants will be randomized as to what message they receive in their e-mail; as all communication will be done via e-mail, this is considered internet research.

Study duration
This study will be ongoing for the duration of the COVID Alert PA app deployment, currently estimated to run through 06/30/2021. A subject's participation depends on the amount of time it take for them to read the e-mail and click through to download, if they choose; estimated at 3-5 minutes. We propose to start this on November 30th, 2020.

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.
PI: Kevin Volpp Co-I's: Marissa Sharif, Laura Gibson Design Strategist: Carolina Garzon-Mrad Project Manager: Erica Dixon Data Analyst: Elizabeth Bair All research staff are currently working on IRB# 843861 - Understanding Enrollment and Engagement with a Digital Contact Tracing App in the State of Pennsylvania, which is an exempt survey project researching motivations for downloading, or not downloading, COVID Alert PA, and thus are adequately aware of the application, the protocol, and their research related duties. As this is internet based research, there are no facilities required for this research beyond current work environments.

Characteristics of the Study Population

Target population
Adult residents of the Commonwealth of Pennsylvania

Subjects enrolled by Penn Researchers
10000

Subjects enrolled by Collaborating Researchers
50000

Accrual
Populations will be identified by institutions who are interested in message testing and outreach for COVID Alert PA. Based on an institution's predicted open rate of e-mails, we will create estimates for # of subjects needed for sample size to make comparisons between groups (ideally n=250 as the minimum per condition, though in a smaller institution, this may not be possible).

Key inclusion criteria
18 and over Resident of PA

Key exclusion criteria
Under age 18 Not a resident of PA

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
N/A

Subject recruitment
Identification and recruitment is done by the institution interested in doing message testing - we will provide the messages, and they will send out to their target audiences. We will provide guidance as necessary in terms of numbers for testing messages.

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?
Yes

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting

research recruitment text.*
Message testing is likely to include subjects in a variety of roles at Penn such as Penn Medicine patients, undergraduate students, employees of Penn Vet, and any other department or org that is interested in message testing. Therefore, Penn communications or marketing may be involved in sending the e-mails out to subjects, however, there is no recruitment to the study in a traditional sense, as we are simply measuring link clicks in e-mails.

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

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
1. Institution will identify population of interest for receiving e-mails about COVID Alert PA 2. Research team will provide messages to test, and recommendations for # of subjects per message 3. Institution will randomize to group and send e-mails to population of interest, tracking open rate and click through rate 4. Institution will return data to research team regarding # of e-mails sent, open rate and click through rate by message, and any de-identified demographic information of interest to institution and research team 5. The only potential follow-up for participants would be receiving additional e-mails from the institution about COVID Alert PA

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
Descriptive statistics, two-sample t-tests for percent download between message groups

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

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.

x **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
Researchers will only receive de-identified data from institutions, there is no risk to subject confidentiality

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).
Subjects will not interact with researchers, only with their own institutions

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Only de-identified and aggregate data will be disclosed in reporting to the Commonwealth of Pennsylvania.

Data Protection*

	Name
	Street address, city, county, precinct, zip code, and equivalent geocodes
	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
	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
x	**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
Requesting waiver of informed consent

Children and Adolescents
N/A

Adult Subjects Not Competent to Give Consent
N/A

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver or alteration of required elements of consent

Minimal Risk*
The research involves no more than minimal risk - participants will be sent e-mails from their institution recommending COVID Alert PA, including a link to download.

Impact on Subject Rights and Welfare*
Subjects are not required to open the e-mail, read the e-mail, or click on the link in the e-mail, similar to any other e-mail campaign they may receive from their institution. Link clicks are commonly tracked by organizations, and do not require written consent outside of the research context.

Waiver Essential to Research*
In our prior study - IRB# 843861 - Understanding Enrollment and Engagement with a Digital Contact Tracing App in the State of Pennsylvania - we have asked people what they may do, or are likely to do, if presented with the opportunity to download COVID Alert PA. In this context, we want to measure what people would actually do when provided the opportunity to download as suggested by their institution via e-mail. Without a waiver of consent, subjects may be influenced in their response via the process of being informed about the research and going through the consent process.

Additional Information to Subjects
Institutions may chose to send additional information about COVID Alert PA to recipients of e-mails.

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
N/A - no potential risks are associated with the research, other than any that would be associated with typical behaviors of opening e-mail or clicking a link

Potential Study Benefits
Individuals may benefit if they chose to download the COVID Alert PA app, but other than that there is no direct benefit to subjects. Benefits may accrue to society in general if messaging strategies to increase app downloads aid in uptake of the app which has benefit in slowing the spread of COVID-19.

Alternatives to Participation (optional)
Subjects may simply not open the e-mail or not click on the link in the e-mail. Subjects may also download COVID Alert PA at any time - this study does not provide preferential access.

Data and Safety Monitoring
Principal Investigator (Kevin Volpp) and Project Manager (Erica Dixon) will monitor data and safety, ensuring that no personally identifiable information is sent along with deidentified data.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
Minimal risk, no more than those ordinarily encountered in daily life. Potential benefits will be to society at large if the findings help frame appropriate public education efforts around COVID-19 digital contact tracing apps.

General Attachments

The following documents are currently attached to this item:

Cover Letter (irbcoverletterforpadohcovidalertpa11.192020.docx)

Additional forms (examplee-mail-privacyvariation.docx)