Background, Purpose, Study Procedures 1

Subject Population(a-g) 6

Subject Population(h-k) 7

Risks 8

Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy 10

Potential Conflict of Interest 17

Informed Consent 19

Assent 21

HIPAA 22

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* * * Background, Purpose, Study Procedures * * *

Title

EpxCogScreen

Complete Sections 1 - 12. In sections that allow reference to a grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate.

1. Background/Rationale

Page numbers from a grant may be referenced in 1a.

a) Provide an introduction and background information, including a review of the literature. Describe any past findings leading to the formulation of the study. *?HELP?*

Telemedicine is a modern field of clinical medicine that incorporates telecommunication and information technology to diagnose and managing health care remotely. Interventions range from telephone reminders to remote physician consultation by videoconference. Simple technology such as telephones and SMS texting are ubiquitous forms of communication that have the potential to increase the frequency of physician-patient contact. Such improvements in communication may improve patient adherence, promote education and engagement, allow real-time collection of critical biometric and clinical data over time, and bridge the gap between recognizing adverse events and actual disease management.

One disease that could benefit from earlier detection is dementia. Dementia is characterized by a loss of cognitive functions, such as memory, comprehension, visual-spatial orientation, and judgment. The most common form of dementia is Alzheimer's disease, but vascular dementia and Lewy-body dementia can also cause cognitive impairment. It is estimated that 47.5 million people are affected with dementia worldwide and it is the most common form of disability in the geriatric population over the age of 65, affecting 1 in 9 people in that population [1]. A formal diagnosis for Alzheimer's relies primarily on clinical evaluation by a neurologist and neuropsychometric screens or tests to determine whether cognitive impairment exists.

In 2011, the Affordable Care Act added routine cognitive screening as a component of the Medicare Annual Wellness Visit, but did not recommend a universal screening tool [2]. This initiative was supported by many public organizations, including the Alzheimer's Association. Typical neuropsychometric tests such as the Mini-Mental State Exam (MMSE) are administered in the physician's office and can take 7 to 15 minutes to complete [3]. This addition to the wellness visits demonstrates the increasing value of early diagnosis for Alzheimer's and other dementias. However, time constraints during patient visits may cause the physician to forgo a thorough cognitive screen. Unlike the MMSE, the Rapid Cognitive Screen (RCS) is a 3 item screening tool that takes less than 5 minutes to complete. This screen has exhibited

screening tool that takes less than 5 minutes to complete. This screen has exhibited remarkable sensitivity and specificity in detecting both mild cognitive impairment (sensitivity=0.87, specificity=0.70) and dementia (sensitivity=0.89, specificity=0.94) in patients over the age of 65 [4]. In addition, higher scores (less impaired) on the screen are indicative of lower rates of mortality. Due to the simplicity of this screening tool, it can be transformed into an at-home, telemedicine screen that would eliminate the time constraints that serve as a barrier to early detection.

While the U.S. Preventative Services Task Force (USPSTF) does not currently recommend frequent cognitive screening, there is very little evidence of potential risks from early screening and diagnoses [5]. Cognitive screens are meant to increase awareness of a patient's neurocognitive changes, not to diagnose. A formal diagnosis can only be completed after a physical exam of the patient, including neurological and psychiatric evaluations and lab tests by a geriatrician or neurologist, which decreases the likelihood of false positives.

While there are no current current disease-modifying therapies for dementia, the importance of early detection cannot be emphasized enough. An estimated 29-76% of Alzheimer's patients are undiagnosed because screening has not yet reached standard-of-practice in geriatric and primary care clinics [11-13]. The astounding number of undiagnosed patients would decrease with routine screening and would allow for patients and their caregivers to plan for their future. In addition, early intervention has been shown to delay placement into nursing homes, empower patients to be more involved with their care plan, and allow physicians to identify and manage comorbidities such as depression, malnutrition, and falls more effectively [6,7]. Delayed admission into nursing homes and fewer hospitalizations are associated with decreased healthcare costs for patients, their families, and the healthcare system [7, 14]. Furthermore, early detection will be critical for future pharmaceutical intervention, as nearly every major clinical trial for Alzheimer's is now targeting patients in the pre-clinical stage of disease [8-10].

1). Van der Linde RM, Dening T, Blossom CM, et al. "Longitudinal course of behavioural and psychological symptoms of dementia: systematic review" The British Journal of Psychiatry. 2016 Aug; DOI: 10.1192/bjp.bp.114.148403
2). Cordell, CB. et al. "Alzheimer's Association recommendations for operationalizing the detection of cognitive impairment during the Medicare Annual Wellness Visit in a primary setting" Alzheimer's & Dementia: The Journal of the Alzheimer's Association. 2012; 9: 141-150.
3). Ebell MH. "Brief screening instruments for dementia in primary care" American Family Physician. 2009 Mar; 15:79(6):497-500.
4). Malmstrom T, et al. "Rapid Cognitive Screen: Sensitivity and specificity for cognitive dysfunction and predictive validity for poor health outcomes" Alzheimer's & Dementia: The Journal of the Alzheimer's Association , Volume 9 , Issue 4 , P773
5). Final Recommendation Statement: Cognitive Impairment in Older Adults: Screening. U.S. Preventive Services Task Force. May 2015. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/cognitive-impairment-in-older-adults-screening
6). Dubois B, Padovani A, Scheltens P, Rossi A, Dell'Agnello G. "Timely diagnosis for Alzheimer's disease: a literature review on benefits and challenges" Journal of Alzheimers Disease. 2015;49(3):617-31.
7). Weimer DL, Sager MA (2009) "Early identification and treatment of Alzheimer's disease: Social and fiscal outcomes" Alzheimers Dement 2009; 5: 215 226
8). Dubois B, Padovani A, Scheltens P et al. Timely diagnosis of Alzheimer's disease: A literature review on benefits and challenges. Journal of Alzheimer's Disease. (2016) 49:617-631.
9). Deardorff WJ, Feen E, Grossberg GT. The use of cholinesterase inhibitors across all stages of Alzheimer's disease. Drugs Aging. (2015) 32:537-54.
10). Reiman EM, Langbaum JB, Tariot PN et al. CAP – advancing the evaluation of preclinical Alzheimer disease treatments. Nature Reviews Neurology. (2016) 12:56-61.
11). Valcour VG, Masaki KH, Curb JD, Blanchette PL. "The detection of dementia in the primary

care setting" Arch Intern Med. 2000;160:2964-8.
12). Olafsdóttir M, Skoog I, Marcusson J. "Detection of dementia in primary care: the Linköping study" Dement Geriatr Cogn Disord. 2000; 11: 223-9.
13). Chodosh J, Petitti DB, Elliott M, Hays RD, Crooks VC, Reuben DB, et al. "Physician recognition of cognitive impairment: evaluating the need for improvement" J Am Geriatr Soc. 2004; 52:1051-9
14). Hurd MD, Martorell P, Delavande A, Mullen KJ, Langa KM. "Monetary Costs of Dementia in the United States" N Engl J Med. 2013; 368:1326-1334.

2. Purpose of the study

a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.

EpxCogscreen is a phone-based intervention that administers the Rapid Cognitive Screen, a well-validated screening tool for dementia, over SMS text messaging. All patients over the age of 65 should be screened regularly for cognitive decline because early detection is associated with better responses to treatment, planning options, and lower costs. The results of the screen are sent to the physician automatically, which allows for physicians to monitor their patients and gives them the ability to respond rapidly to any concerns of cognitive decline. In addition, the patient's at-home scores are compared to in clinic RCS scores to determine the correlation between the two and the validity of EpxCogScreen.

Page numbers from a grant may be referenced in 2b and 2c.

b) List your research objectives (specific aims & hypotheses of the study).

Overall Hypothesis: The Epharmix caregiver administered Rapid Cognitive Screen will have statistically significant correlation to the screen administered by a healthcare professional in the clinic.

Aim: Patient- Provider Communication -- To determine if the Epharmix EpxCogScreen can be used to obtain more timely clinical data about cognitive impairment for ongoing physician review, than by traditional methods.

Please save frequently

c) Describe the study design (e.g., outline the experimental procedures, describe the ethnographic observation and/or interviewing procedures, or outline survey research methods). Also, indicate if the subjects will be randomized in this study.

Patients and their caregivers at Saint Louis University Geriatric Clinic will be included in this study and both must consent to participate in the study. The designated caregiver will enroll in the Epharmix program and will receive SMS text messages after one month. The messages will remind the caregiver of when to administer the Rapid Cognitive Screen and give them the option to receive all instructions via text or to use directions from a handout that the caregiver received while in clinic. All patient responses will be recorded through text and all patients will have been previously screened in the geriatric clinic by a health care professional. If the patient has an at-home RCS score decrease of three or more points, the patient's physician will be notified immediately through the Epharmix system and can then contact the patient for follow-up. Subjects will have the ability to opt out of the study electronically via text and phone at any point during the study. The scores of the screen from clinic and home administration will then

be analyzed to determine if a caregiver administered Rapid Cognitive Screen has high correlation to the screen administered in the clinic. A decrease in the baseline clinic score of three or more points will send an alert to the physician so that they can further evaluate the patient.

The clinic scores will be compared to the at-home RCS scores to determine the correlation coefficient between the two. In addition, at home scores will be compared to clinical diagnoses of dementia obtained from chart review. This will determine the validity of EpxCogScreen use in the geriatric population.

3. Study Procedures

a) **Does this study involve conduct of research at multiple sites and the SLU PI is the direct recipient of a federal grant for this research? If yes, please complete and attach the Supplemental Application for Coordinating Center Activities.** N

Page numbers from a grant may be referenced in 3b and 3c.

b) **Describe all study procedures; from recruitment through end-of-study, that the human subject must undergo in the research project. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#12).**

Patients will be screened with the Rapid Cognitive Screen (RCS) in clinic as a part of the normal standard of care. Patients and caregivers will receive information about the study and a handout with instructions in the physicians office and can consent if they are interested in participating. If they enroll in the study, the caregiver will receive text message instructions for the RCS one month later. The caregiver can choose to administer the screen with instructions only via text or by using the handout received in the office. He/she will read the instructions to the patient and record responses via text message. The screen will take no more than 15 minutes to complete.

After the data is compiled from the at-home screen, a medical record review will occur. This will look at previously diagnosed medical conditions, which have been indicated in the "Epharmix Data Collection Sheet" in Section 12, and will compare this data to scores received on the RCS screens.

c) **Describe how data analysis will be performed (statistical tests, methods for evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.**

Data analysis will occur between the patient's at-home and in-clinic RCS scores. The scores will be plotted against one another to determine the correlation between them. The total score correlation, along with the correlation for each individual component of the screen (free recall, clock-drawing, and insight). In addition, the sensitivity and specificity of the at-home screen will be determined based upon clinical diagnoses of patients based on chart review.

d) **State if audio/video recording or photographing of subjects will occur. Describe how the recordings will be maintained during and upon completion of the project. Describe what will**

become of the recordings after use (e.g., shown at scientific meetings, erased, etc.). Please note audio or video recordings of voice and pictures or video recordings of a face or a unique body marking would be considered identifiers. Please address this in your response.

Please save frequently

e) State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#9) and the debriefing script/statement must be uploaded in the Attachments section (#12). See IRB Deception Guidelines.

f) Saint Louis University Hospital. All research involving Saint Louis University Hospital, including the Emergency Department, inpatient or outpatient services (including outpatient surgery at ABI and the infusion center at DOB) and medical record access, requires approval from the Saint Louis University Hospital Research Review Committee prior to study initiation. This effort is coordinated through the SLU Clinical Trials Office via eRS. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. Documents should be submitted as soon as possible, or at the latest, concurrently with IRB submission. Please contact the Research Compliance Office at 577-8113 or sluh-research@ssmhealth.com or the SLU Clinical Trials Office at 977-6335 or clinical-trials-office@health.slu.edu for more information.

X Not Applicable
Yes, study requires Saint Louis University Hospital review

g) SSMSL. All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy.Young@ssmhealth.com for more information.

X Not Applicable
Yes, study requires RBR review

h) ClinicalTrials.Gov Registration and GCP Training. Is this project subject to   the NIH GCP Training and ClinicalTrials.gov Registration Requirements? Y

Protocol Title: EpxCogScreen

As of January 1, 2017, a new NIH policy mandated biomedical and behavioral "Clinical Trials" to be registered on ClinicalTrials.gov. In addition, NIH policy requires personnel on NIH "Clinical Trials" to take GCP training every three years. Please review relevant definitions here. Contact the CTO at clinical-trials-office@slu.edu with questions about registering on ClinicalTrials.gov and refer to the training page of the IRB website for information on NIH GCP Training requirements.

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* * * Subject Population(a-g) * * *

4. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested).

a) Number of evaluable subjects to be accrued.

200 (100 patients and 100 caregivers)

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3b.

b) What is the expected age range of subjects? (For example: ≥ 18 yrs to 90 yrs).

Patients must be over the age of 65 to participate. Caregivers can be greater than 18 years old to 90.

c) Requested Participant Description (e.g., gender, ethnicity, socio economic status, etc.). Include description of each group requested.

The population used will include all genders, socioeconomic, and ethnic backgrounds. Both patients with and without diagnoses of dementia will be included in the study.

d) If including vulnerable populations (<a href=https://www.slu.edu/Documents/research/IRB/Minors_in_Research.doc target=_blank>minors, <a href=https://www.slu.edu/Documents/research/IRB/Pregnant_Women_Fetuses.docx target=_blank>pregnant women and fetuses, <a href=https://www.slu.edu/Documents/research/IRB/Neonates.docx target=_blank>neonates, <a href=https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc target=_blank>non-English speaking, economically or educationally disadvantaged, <a href=https://www.slu.edu/Documents/research/IRB/Prisoner_Research.doc target=_blank>prisoners, <a href=https://www.slu.edu/Documents/research/IRB/Adults_Unable_to_Provide_Consent.docx target=_blank>adults temporarily or permanently unable to consent for themselves): 1) provide the rationale for the importance of including this population in the research, and 2) specify the measures being taken to minimize risks to potentially vulnerable subjects. Click on hyperlinks to access <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-

Protocol Title: EpxCogScreen

(irb)/general-guidelines target=_blank>SLU Guidelines containing additional considerations and strategies for mitigating risks.

Any patient that visits the geriatric clinic at SLU and is over the age of 65 is eligible to participate in the study. Cognitive impairment and dementia are prevalent in this population, and early diagnosis is important to allow for patients to plan for their futures and have early intervention in the disease. Screening tools are used for early diagnosis, and this study would determine if an at home dementia screen could be used in the general geriatric population for earlier detection of disease.

Patients will be informed of the risks before the study, and all patients have the right to accept or decline participation in the study. However, if the patient has an appointed proxy, the proxy will be informed of the risks and will then make a decision of participation for the patient.

e) If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. If federally funded reference appropriate section of the grant.

N/A

f) If any subjects are students or employees, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects. See <a href=https://www.slu.edu/Documents/research/IRB/Students_Employees.docx target=_blank>SLU Guidelines for additional considerations and strategies for mitigating risks.

g) How will potential participants be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? Upload recruitment materials in the Attachment Section (#12). Important to remember: potential subjects cannot be contacted before IRB approval.

Recruitment will occur at the Saint Louis University Geriatric Clinic waiting room as part of the check-in process. The handout that will be used is attached to Section 12 and is titled “EpxCogScreen Recruitment Flyer - Version 2.” If both the patient and caregiver are interested in participating, they may both choose to be consented in the clinic and then enrolled in the program by a study member. If they wish to be consented at a later time, a study member will call the caregiver and patient to provide
information and enroll them in the study.

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* * * Subject Population(h-k) * * *

4. Subject Population (continued)

Page numbers from a grant may be referenced in 4h.

h) Inclusion and Exclusion criteria.

Identify inclusion criteria.

Caregivers over the age of 18 can be recruited, but they must have a patient over the age of 65 in order to be involved in the study. In addition, caregivers must have access to a cell phone and be able to receive and send SMS text messages. Patients in the study must be over the age of 65 in order to participate in the study and must have been previously screened with the

age of 65 in order to participate in the study and must have been previously screened with the RCS in the clinic. Both patients with and without diagnoses of dementia will be included in the study.

In order to be included in the study, both patients and caregivers must speak English.

Identify exclusion criteria.

Patients under the age of 65 will be excluded from this study.

i) **Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.**

Patients will not receive compensation for their time.

j) **Describe who will cover study related costs. Explain any costs that will be charged to the subject.**

Epharmix has direct contracts with Verizon, T-mobile, Boost, Sprint, and AT&T so that no costs are transmitted to participants with these service providers. Other service providers may result in charges depending on the individual plan.

Epharmix will also be covering the cost of postage stamps for the patient and caregiver to send in their consent forms.

k) **Estimate the probable duration of the entire study, including data analysis and publication. In addition, estimate the total participant duration.**

The study will take approximately 18 months for the recruitment of patients, data collection and analysis, and publication. The total duration of patient participation in the study will be one month from the date of enrollment.

* * * Risks * * *

5. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk."

a) **Describe any physical, psychological, social, legal or other risks.**

Possible risks include a breach of confidentiality of PHI and annoyance due to repetition of messages.

b) **Describe the planned procedures for protecting against or minimizing potential risks, including potential risks to privacy, confidentiality, etc.**

Full effort will be placed to minimize the risk of breach of privacy. All patient information and study data will be password protected in computer files and all paper forms will be kept in a secure locked cabinet, controlled by the research coordinator. Additionally each patient will be assigned a code number to

minimize risk of exposure of patient information. This code number will be used to code all the data - 1,2,3,etc - assigned to each patient as they are included sequentially into the study. This number will be used for the electronic spreadsheet and placed on the paper documents and a code of the assigned numbers will be maintained in a password protected electronic spreadsheet also.

Communication via text are unsecured and potentially non-confidential. Additionally, the information stored on a patient's phone is outside the control of the study investigator. The patient is informed of these risks and is required to verbally consent to exchange potential Protected Health Information via these communication lines in order to receive this service. To prevent the accidental disclosure of PHI from pop-up phone notifications, the text message will read: "Confidential message" and the content will begin 3 lines later, which will not be seen on an automatic notification preview. Texts were specifically designed to exclude any PHI information.

The major side -effect of this intervention will be annoyance and disruption to patient lives. To reduce this, text messages will be reduced to the minimum possible to meet reminder or patient communication guidelines. In addition, efforts will be made to ensure that the text messages are kind, courteous, respectful, and quick so as to respect the patient's time and effort in participating. Caregivers will also be given the opportunity to opt out of the study at any time via texting a "STOP" message. In addition, both patients and caregiver can opt out of the study by contacting their physician or a member of the research team.

c) In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects. Include whether research is sensitive given cultural norms.

c1) State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.

c2) Will there be language barriers and if so, how will they be addressed?

Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.

NOTE: Export control laws include the transfer of technical information and data, as well as information and technology to foreign nationals. If this study has international components, contact the SLU Export Control Officer for direction on whether export control policies apply.

d) Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.

If a patient has a decrease in score of more than 3 points on the at home RCS, the a member of the patient's health care team will be notified that day. They will then call the patient and determine what further steps need to be taken (i.e. if the results were a false alarm or if the patient needs to be brought in to be evaluated)

e) Data Safety Monitoring

Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring board. Typically, data and safety monitoring is not required for minimal risk studies, nor

safety monitoring board. Typically, data and safety monitoring is not required for minimal risk studies, nor for the majority of behavioral and social sciences research. Please see the SLU Guidelines for Data and Safety Monitoring for more information.

e1) Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N

If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor and research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time, and g) conditions which would result in the stoppage of the study.

If no, please justify why not.

Minimal risk exists to the patient and the patient involvement involves completing a cognitive screen. Therefore, no plan is needed to monitor the data.

e2) Is there a Data Safety Monitoring Plan (DSMP)? N

Note, if all relevant plan information is included in DSMB question above, select 'Yes' and state "see above" in the answer box.

If yes, provide details (labeled a-d) including: a) what types of data or events are captured and how are they documented, b) who is monitoring data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, and d) conditions which would result in the stoppage of the study.

If no, please justify why not.

As stated, the risks to the patient are very minimal and involve administering an already clinically validated cognitive screen in a different setting.

* * * Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy * * *

6. Benefits/Alternatives

a) Benefits. Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.

A potential benefit to the participants of the study would be earlier detection of cognitive decline since the patients would be screened in between physician visits. Earlier detection could lead to earlier treatment and more time to plan for the future. However, there may be no direct benefit to patients.

If it is determined that the intervention is a valid screening tool to be administered by caregivers, any patient over the age of 65 would be eligible to be screened. Earlier detection of dementia and cognitive decline could lead to earlier treatment and better management of the disease.

decline could lead to earlier treatment and better management of the disease.

b) **Alternatives. Describe any alternatives available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.**

There are no alternatives available to the patient if they choose not to participate. The alternative is nonparticipation.

7. Procedures to Maintain Confidentiality and Privacy

Federal regulations require that research materials be kept for a minimum of three (3) years, and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated projects, the PI may be required to keep the data and documents for a longer time period.

Confidentiality

To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).

For the questions below, please use the following definitions:

**   Anonymous/De-identified: data contain no identifiers, including code numbers that investigators can link to   individual identities;**

**   Coded: data in which (1) identifying information, such as name or social security number, has been replaced   with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists   enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept   separately from coded data; AND/OR**

**   Identifiable: data that includes personal identifiers (e.g., name, social security number), such that   information could be readily connected to respective individuals.**

a) **Electronic (Computer) Data**

Click "Add" to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table.

Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Electronic Data

Type of Data	Storage Location	Data Transmission Outside of SLU	Supplemental information related to above items can be entered here or leave blank:
Identifiable	Epharmix	Posting of data directly to an external web portal using secure connection (i.e., HTTPS)	Patient responses to textmessages will be storedon the Epharmix cloudservers, which are hostedin a SOC1&2 andHITRUST certifiedhosting environment(Armor). The cloud setupallows for morerobustness andscalability. Connectionsto access data are allencrypted via SSL/TLS.Data stored will be placedin key-managed, role-based encryption vaultssecured via the AES256algorithm.
Coded	SLU ITS managed device (computer, tablet, etc.) with encryption	Not Applicable, I will not be sending/sharing electronic data outside of SLU	The Master DataCollection Sheet will be kept on a SLU ITS managed device in the SLUCare Geriatric Clinic. The device will be encrypted and the document will be encrypted. No data will be transferred from a SLUdevice to the Epharmixcloud.

1. **What type of electronic (computer) data does your study involve? Note: only one data type can be selected. Click on Add from the main page to enter information for additional data types once you've saved this information.**

   Anonymous/De-identified

   Coded

   X **Identifiable**

Protocol Title: EpxCogScreen

2.

Where are the data being kept/collected? (Check all that apply)
NOTE: THE ITEMS LISTED BELOW IN ITALICS CANNOT BE USED FOR DATA WHICH ARE (1) SENSITIVE AND CODED OR (2) IDENTIFIABLE unless an exception has been granted by the SLU Info Security Team (InfoSecurityTeam@slu.edu). Please attach proof of exception in section #12.

- SLU ITS managed device (computer, tablet, etc.) with encryption
- SLU ITS managed device (computer, tablet, etc.) without encryption
- SLU ITS network storage (T: drive (shared drive), U: drive (personal drive))
- SLU ITS recognized document-level encryption
- SLU Google Drive/Documents (can only be shared with slu.edu addresses)
- Collection or Storage of data in SLU REDCap
- Collection or Storage of data in SLU Qualtrics
- Removable storage devices (flash drive, USB hard drive) with encryption
- Removable storage devices (flash drive, USB hard drive) without encryption
- Personally owned/non-SLU managed device (computers, tablets) with encryption
- Personally owned/non-SLU managed device (computers, tablets) without encryption
- Third party services such as Dropbox, Box, Evernote, SurveyMonkey, etc. (Please specify):
- Sponsor provided system or portal (Please specify):
- X Other (Please specify): Epharmix

3. If the data will be sent/shared outside of SLU, how are they being sent/shared? (Check all that apply)

- Not Applicable, I will not be sending/sharing electronic data outside of SLU
- SLU Email account with an encrypted file attachment
- X Posting of data directly to an external web portal using secure connection (i.e., HTTPS)
- Sending of data to a secure FTP site (e.g., SFTP, FTPS)
- Use of Virtual Private Network connection (VPN)
- Use of SLU REDCap account
- Use of an external Secure Web Mail account
- Physical delivery of encrypted files via CD/DVD or other medium (e.g., USPS, FedEx, Courier)
- Other (Please specify):

4. Supplemental information related to above items can be entered here or leave blank:

Patient responses to textmessages will be storedon the Epharmix cloudservers, which are hostedin a SOC1&2 andHITRUST certifiedhosting environment(Armor). The cloud setupallows for morerobustness andscalability. Connectionsto access data are allencrypted via SSL/TLS.Data stored will be placedin key-managed, role-based encryption vaultssecured via the AES256algorithm.

1. What type of electronic (computer) data does your study involve? Note: only one data type can be selected. Click on Add from the main page to enter information for additional data types once you've saved this information.

- Anonymous/De-identified
- X Coded
- Identifiable

2.

Where are the data being kept/collected? (Check all that apply)
NOTE: THE ITEMS LISTED BELOW IN ITALICS CANNOT BE USED FOR DATA WHICH ARE (1) SENSITIVE AND CODED OR (2) IDENTIFIABLE unless an exception has been granted by the SLU Info Security Team (InfoSecurityTeam@slu.edu). Please attach proof of exception in section #12.

- X SLU ITS managed device (computer, tablet, etc.) with encryption
- SLU ITS managed device (computer, tablet, etc.) without encryption
- SLU ITS network storage (T: drive (shared drive), U: drive (personal drive))
- SLU ITS recognized document-level encryption
- SLU Google Drive/Documents (can only be shared with slu.edu addresses)
- Collection or Storage of data in SLU REDCap
- Collection or Storage of data in SLU Qualtrics
- Removable storage devices (flash drive, USB hard drive) with encryption
- Removable storage devices (flash drive, USB hard drive) without encryption
- Personally owned/non-SLU managed device (computers, tablets) with encryption
- Personally owned/non-SLU managed device (computers, tablets) without encryption
- Third party services such as Dropbox, Box, Evernote, SurveyMonkey, etc. (Please specify):
- Sponsor provided system or portal (Please specify):
- Other (Please specify):

3. If the data will be sent/shared outside of SLU, how are they being sent/shared? (Check all that apply)

- X Not Applicable, I will not be sending/sharing electronic data outside of SLU
- SLU Email account with an encrypted file attachment
- Posting of data directly to an external web portal using secure connection (i.e., HTTPS)
- Sending of data to a secure FTP site (e.g., SFTP, FTPS)
- Use of Virtual Private Network connection (VPN)
- Use of SLU REDCap account
- Use of an external Secure Web Mail account
- Physical delivery of encrypted files via CD/DVD or other medium (e.g., USPS, FedEx, Courier)
- Other (Please specify):

4. Supplemental information related to above items can be entered here or leave blank:

The Master DataCollection Sheet will be kept on a SLU ITS managed device in the SLUCare Geriatric Clinic. The device will be encrypted and the document will be encrypted. No data will be transferred from a SLUdevice to the Epharmixcloud.

b) Hardcopy (Paper) Data

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data
Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Hardcopy Data

Type of Data	Storage Location	Transported Data Security	Supplemental information related to above items can be entered here or leave blank:
Identifiable	SLU Locked Cabinet; SLU Locked Room/Office; SLU Locked Suite	Locked container; Personnel Supervision	Hard copy data includes patient consent and assent forms.

1. What type of hardcopy (paper) data does your study involve? Note: only one data type can be selected. Click on Add from the main page to enter information for additional data types once you've saved this information.
   - Anonymous/De-identified
   - Coded
   - X Identifiable
2. Where are hardcopy materials being kept? (Check all that apply)
   - X SLU Locked Cabinet
   - X SLU Locked Room/Office
   - X SLU Locked Suite
   - SLU Long Term Storage Facility
   - Non-SLU Location (Please specify):
   - Other (Please specify):
3. If hardcopy materials are transported at any time in the study (e.g., from data collection site to storage site, shared with co-investigators), how are they secured?
   - X Locked container
   - X Personnel Supervision
   - Physical delivery (e.g., USPS, FedEx, Courier)
   - Fax Machine
   - SLU Email account with an encrypted file attachment
   - Non-SLU Email account with an encrypted file attachment
   - Other (Please specify):
4. Supplemental information related to above items can be entered here or leave blank:

   Hard copy data includes patient consent and assent forms.

c) **If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.**

Electronic records (computer files, electronic databases, etc.) -
Data will be entered into a secure T drive on a SLU computer in the SLUCare Geriatric Clinic that will be maintained on a secure server and will be password protected. Data will be coded, and a separate encrypted spreadsheet will be kept linking patient name only to subject study identification number. Patients will be coded 001, 002, 003, etc. in chronological order.
The electronic intervention system being evaluated as the intervention in this study collects the participant's name and contact phone number, and is maintained on both the Saint Louis University School of Medicine computer servers and Epharmix servers for the duration of the study. These servers and the data stored herein will be maintained as HIPAA compliant to the best of our ability. All data will be coded. The master key with names corresponding to codes with dual authentication will be stored separately from the data with codes, on a password-protected excel spreadsheet on a password protected computer. This data will be kept by Epharmix indefinitely after the conclusion of the study unless otherwise requested by Saint Louis University School of Medicine. The HIPAA documents will be kept for 6 years.

In addition to storing information on SLU servers, Epharmix servers will have patient's first name, last name and telephone number. The code that is used will be the same as above, with patients coded as 001, 002, 003, etc. in chronological order. The assigned code will be the same for the patient on both servers.

d) **If data or specimens are being shared outside of the research team, indicate who will receive the material, specifically what they will receive (data or specimens), and if an agreement has been signed to cover the transfer. Note: unless covered under a Clinical Trial or other agreement, the transfer of data or specimens to an external entity will require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) is used; for the transfer of data, a Data Use or Data Transfer Agreement is used. Please contact the Research Innovation Group at 314-925-3027 for assistance.**

Patient's first name, last name, and phone number will be shared with Epharmix. Patient's response via text messages are stored in Epharmix's secure, encrypted database. Epharmix's technical staff will have access to the data (for maintenance and debugging purposes should issues arise), but will not access the data for other purposes. Epharmix technical staff consists of three developers which have accounts with access to these data. No other Epharmix employee or staff member can access the data.

e) **If samples or data will be provided to SLU from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected. Note: unless covered under another agreement (e.g., Clinical Trial Agreement or subcontract), the transfer of data or specimens from an external entity to SLU may require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) may be required; for the transfer of data, a Data Use or Data Transfer Agreement may be required. Please contact the Research Innovation Group at 314-925-3027 for assistance.**

N/A

f) **If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).**

g) **Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc.** N

If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.

Privacy

Privacy refers to persons having control over the sharing of oneself with others.

h) Please indicate how participant privacy will be protected in this study (select all that apply):

X Discussion of health related and/or personal information in a private room/area

X Research interactions/interventions are conducted in a private room/area

Use of drapes or other privacy measures

X Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

X Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

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* * * Potential Conflict of Interest * * *

8. Potential Conflict of Interest

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

1) X No equity interest and/or Financial Interest less than or equal to $5K
2) Any equity interest and/or Financial Interest exceeding $5K but not exceeding $25K in the past year or expected in the current year
3) Financial Interest exceeding $25K in the past year or expected in the current year

Check all those that apply:

Consulting
Speaking Fees or Honoraria
Gifts
Licensing agreement or royalty income
Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors
Other fees/compensation

If you have marked #2 or #3, please contact coi@slu.edu to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan
   has been approved for all investigators for this study
   is pending
   has not been initiated

2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:

Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

1. **Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.**

   . This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated

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Disclosure Form to the COIRC.

2. **You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact coi@slu.edu.**

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* * * Informed Consent * * *

9. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) **How is consent being obtained? When and where will the discussion take place? If the study involves a Non-English Speaking participant/population, please include details about plans for translated consent materials and interpreters to be used (see <a href=https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc target=_blank>SLU Guidelines for Involving Non-English Speaking Subjects for more details).**

All caregivers of patients will receive information from a health care provider or medical student at the Saint Louis University Geriatric Clinic. If a patient and caregiver are interested in participating in the study, both parties will need to consent. If they are interested in participating, the parties may be consented in clinic or at a later time depending on the preference of the patient and caregiver.

If a later time is preferred, the subject will receive two copies of the consent and HIPAA documents sent to their preferred mailing address. They will be contacted by a research team member to deliver the informed consent language, in full, over the phone. He/she will ensure that subjects consent to receive and send Protected Health Information by phone or text message. The patient's consenting capacity will be assessed through three true/false questions. These questions are attached in section 12.

Even if participants receive information about the study over the phone, consent will be documented by patient and caregiver signature on the consent forms sent via mail. The participants will sign two copies of the consent form, one to keep for personal reference, and another one which will be mailed to Dr. Berg-Weger's office using pre-addressed and stamped envelopes provided with the consent forms. The envelopes will be provided by the SLU Geriatric Clinic and postage costs will be covered by Epharmix.

Subjects will be informed that these communication lines are unsecured and may be non-confidential. They will have the opportunity to ask questions directly and consent or decline to participate. After enrollment, subjects will then be sent an initial message with information about the trial electronically according to their registered phone number, including the ability to opt -out at any point. Standard data and messaging charges may apply.

2) **If the study involves adults unable to consent for themselves (whether diminished capacity to consent is temporary, permanent, progressive or fluctuating), please address the following: a) how is capacity to provide consent being assessed (initially and throughout study, if applicable); b) if unable to provide consent, how is LAR being determined (See <a href=https://www.slu.edu/Documents/research/IRB/LAR_Guidelines.docx target=_blank>SLU LAR Guidelines); c) if unable to provide consent, will assent be obtained and if not, why not?; d) if unable to provide assent, will dissent be honored and if not, why not? Note: participants initially unable to provide consent for themselves are expected to be given an opportunity to provide consent once capacity is gained. See <a href=https://www.slu.edu/Documents/research/IRB/Adults_Unable_to_Provide_Consent.docx target=_blank>SLU Guidelines for Adults Unable to Provide Consent for additional detail.**

All patients and caregivers will be consented, unless they have a legally authorized representative (LAR) who will provide consent for him/her. A patient will also not be able to provide consent if a qualified practitioner's documents that the patient lacks decision-making capacity or if an individual has been ruled incompetent by a court of law. However, if neither of these apply, the patient's understanding of the research will be assessed through three true/false questions. These questions are attached in section 12.

b) If it is determined that the participant is unable to consent, an LAR may sign the consent form for the patient. LAR guidelines and documentation for the use of a LAR are attached. The LAR will be chosen in the following order:
a.[Attorney in Fact/Power of Attorney]
b.Spouse, unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
c.Adult child;
d.Parent;
e.Brother or sister;
f.Relative by blood or marriage.

c, d) Both assent and dissent will be honored and obtained verbally. The attached assent script and form will be used in cases where the participant does not have consenting capacity.

Note: Any assent documents which will be used per the Adults Unable to Provide Consent guidance, should be appropriately named and uploaded using the Add button and the Consent drop down menu selection.

Informed Consent

Title	Consent Type	Attached Date
Approved_Assent Script and Form Version 2	Consent	04/10/2018
Approved_Consent Form- Version 6	Consent	04/10/2018

Title	Approved_Assent Script and Form Version 2
Consent Type	Consent
Upload Consent Document	X Attachment Approved_Assent Script_2

Upload your informed consent document. Use the SLU Informed Consent Template to create your consent document. If more than one consent will be used (e.g., adult consent, parental consent, etc.), label the consent documents with these headings to help distinguish them from one another.

Upload any assent documents which will be used for adults who are unable to provide consent here and not in the assent section.

Title	Approved_Consent Form- Version 6
Consent Type	Consent
Upload Consent Document	X Attachment Approved_consent version 6

Upload your informed consent document. Use the SLU Informed Consent Template to create your consent document. If more than one consent will be used (e.g., adult consent, parental consent, etc.), label the consent documents with these headings to help distinguish them from one another.

Upload any assent documents which will be used for adults who are unable to provide consent here and not in the assent section.

*** * * Assent * * ***

10. Assent

Complete this section if your study includes minors. The Assent Form Template provides guidelines for writing assent documents.

1. Will minors be asked to give assent, then consent once they reach adulthood? If not, please justify. If not capable to provide assent initially, please address whether assent will be obtained as the minor gains capacity. Note: children who reach the age of adulthood during participation should be given the opportunity to provide consent as parent/guardian consent no longer applies. If obtaining consent would be impracticable (e.g., this is a registry with data/specimen obtained long ago), a waiver of consent should be added for IRB review. See <a href=https://www.slu.edu/Documents/research/IRB/Minors_in_Research.doc target=_blank>SLU Guidelines for Research Involving Minors for additional detail.

2. If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.

3. How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition). If capacity is fluctuating, please explain how capacity will be assessed throughout the study.

be assessed throughout the study.

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

* * * HIPAA * * *

11. HIPAA

Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information visit the IRB HIPAA page or refer to the SLU IRB HIPAA Guidance.

1. **Will health information be accessed, received or collected?**

No health information. HIPAA does not apply.

X Yes (continue to question 2).

2. **Which personal identifiers will be received or collected/recorded?**

No identifiers. I certify that no identifiers from the list below will be received or collected andlinked to health information. (Skip remainder of page).

Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

City/State/Zip codes

Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

Age (if subjects are 90+ years)

X At least one direct identifier will be received or collected/recorded.

X Names

Social Security numbers

X Telephone numbers

Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

X All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

X All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Fax numbers
Electronic mail addresses
X Medical record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locations (URLs)
Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice prints
Full face photographic images and any comparable images

If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.

3. Sources of Protected Health Information:

Hospital/medical records for in or out patients
X Physician/clinic records
Laboratory, pathology and/or radiology results
Biological samples
X Interviews or questionnaires/health histories
Mental health records
Data previously collected for research purposes
Billing records
Other
Please describe:

4. If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.

Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.

X With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5. HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.

HIPAA Documents

HIPAA Documents	Title	Attached Date
HIPAA Authorization	Approved_HIPAA Version 5	04/10/2018

Title	Approved_HIPAA Version 5
HIPAA Documents	HIPAA Authorization
HIPAA Form	Approved_HIPAA version 5
HIPAA Authorization Template	