Study Protocol

Shared Decision-Making: Implementing the AFib 2gether™ Mobile App

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INVESTIGATOR STUDY PLAN

1. TITLE
Shared Decision-Making: Implementing the AFib 2getherTM Mobile App

2. EXTERNAL IRB REVIEW HISTORY*
None.

3. PRIOR APPROVALS:
After review by the Conflict of Interest (COI) committee, it was confirmed that Dr. McManus could declare financial interest related to the research as he has consulted for pharmaceutical companies Bristol Myers Squibb and Pfizer.

4. OBJECTIVES*
Aim 1. Measure usability, perceived usefulness to patients and providers, and feasibility of the shared decision-making mobile app, AFib 2gether™, in 60 patients not on AC and their corresponding 20 providers (as many as 6 patients for each provider).
Aim 1a. Measure provider knowledge of and confidence in modern AF management and its association with usability and feasibility measured above.

5. BACKGROUND*
Atrial fibrillation (AF) occurs in epidemic proportions in older adults in the US.[1-5] Anticoagulation (AC) is the mainstay of therapy, but many patients are reluctant to start taking it. Even if they do start, patients become reluctant to resume after bleeding or other setback. Providers also struggle with balancing risk and benefit. Being able to determine the optimal decision for each patient is a valuable goal and has been recommended by the American Heart Association and other professional societies.[6] Determining the optimal decision for each patient presents several challenges. Providers do not always draw attention to the fact that there is a decision to be made and may make the decision for the patient without soliciting his or her preferences. Similarly, clinicians do not always inquire about the preferred approach of the patient to receive information to decide. In addition, providers may not be knowledgeable or confident managing AF patients with the most recent guidelines and the advent of direct oral anticoagulants (i.e. modern AF management). It is uncertain whether these provider barriers may limit shared decision-making. The AFib 2gether™ mobile app was developed to address the above challenges in obtaining a shared decision regarding AC for AF. The app provides a platform for a patient to confirm his or her risk of stroke and identify items for discussion at the next visit with his or her provider. The provider can then review these and help the patient to make a more informed decision. No one has tested the app with patients and providers for usability, perceived usefulness, and feasibility after actual clinical encounters. Similarly, it's not clear if provider knowledge of and confidence in modern AF management will affect usability and feasibility of the app.

6. INCLUSION AND EXCLUSION CRITERIA*
Study Population
The study population will be derived from cardiology providers within the University of Massachusetts (UMass) Memorial Healthcare System and their patients.

Providers

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Inclusion Criteria: Providers caring for at least 3 patients aged 18 years and older with ICD-10 diagnostic code consistent with AF or atrial flutter and CHA2DS2-VASc stroke risk score of 2 or more who are not on anticoagulation and have upcoming cardiology visits.

Exclusion Criteria: Providers who do not care for at least 3 patients aged 18 years and older with ICD-10 diagnostic code consistent with AF or atrial flutter and CHA2DS2-VASc stroke risk score of 2 or more who are not on anticoagulation and who have upcoming cardiology visits.

Vulnerable Populations

Children

Children will not be included in the study population.

Prisoners

Prisoners will not knowingly be included in the study population.

Pregnant Women

Pregnant women will not be included in the study population.

Adults Unable to Consent

Adults unable to consent will not be included in the study population.

Patients

Inclusion Criteria: Patients aged 18 years and older with ICD-10 diagnostic code consistent with AF or atrial flutter who had a visit with a cardiovascular medicine specialist in the previous one year with the diagnosis of AF present as an active diagnosis in the EHR and has an upcoming cardiology visit in the next 3 months. Patients must have a CHA2DS2-VASc score of 2 or higher and not currently be prescribed anticoagulation. In addition, patients must have a smartphone or be able to use a family member or friends smartphone to access the app.

Exclusion Criteria: Patients under the age of 18; patients without a ICD-10 diagnostic code consistent with AF or atrial flutter who had a visit a cardiovascular medicine specialist in the previous one year ; patients with a CHA2DS2-VASc score less than 2; patients currently prescribed an anticoagulant; and patients without an upcoming cardiology visit in the next 3 months. We will exclude patients with a WATCHMAN device or left atrial appendage closure surgery, patients on hospice or for whom life expectancy is less than six months and patients with bleeding episode or fall with injury in the last four weeks. Additionally, patients whose preferred language is other than English will be excluded since we are pilot testing a mobile app that is currently only available in English. Lastly, patients will also be excluded from this study if they are known to be pregnant or a prisoner.

Vulnerable Populations

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Pregnant Women
Pregnant women will not knowingly be included in the study population.

Adults Unable to Consent
Adults unable to consent will not be included in the study population.

7. STUDY-WIDE NUMBER OF SUBJECTS*
We will include up to 20 cardiology providers (physicians and nurse practitioners) from the UMass Memorial Medical Group. We will also recruit up to 60 patients not on AC (as many as 6 patients for each provider)

8. STUDY-WIDE RECRUITMENT METHODS*
N/A. This is not a multi-site study.

9. STUDY TIMELINES*
The overall project timeline is described in the table below (Table 1):

Table 1. Project Timeline

	Year 1			
	Q1	Q2	Q3	Q4
IRB, hiring RA, training, recruitment of providers, provider survey				
Shared decision-making office encounters				
Analysis, chart review for anticoagulation switches, manuscript preparation, future grant preparation				

This study is planned to take place over the course of one year but will be extended if need be until all of the tasks and deliverables are completed. Primary analysis is expected to be complete by the end of year one.

Duration of an Individual Subject's Participation
Individual subjects are expected to participate for no more than one year in the study overall.

10. STUDY ENDPOINTS*
Primary Outcome Measure: Effective measure of usability, perceived usefulness to patients and providers, and feasibility of the shared decision-making mobile app, AFib 2gether™

Secondary Outcome Measure: Improvement in provider knowledge of and confidence in modern AF management and its association with usability and feasibility

Tertiary Outcome Measure: We will also review charts at six months from the time of the visit to see if patients switched to taking AC.

11. PROCEDURES INVOLVED*

METHODS

Population

We will include 20 cardiology providers (physicians and nurse practitioners) from the UMass Memorial Medical Group. Patients must be eligible for AC, have paroxysmal or permanent AF and have had a visit with a cardiology provider in the previous 12 months and have a follow up appointment with the provider in the next 3 months. We will exclude patients with a WATCHMAN device or left atrial appendage closure surgery, patients on hospice or for whom life expectancy is less than six months, patients with bleeding episode or fall with injury in the last four weeks, and patients whose preferred language is other than English.

Setting: The UMass Memorial Healthcare System, including the outpatient practices. Analysis of secure patient data will take place using secure medical school computers, in a secure office space. Audio recordings of patient appointments will take place in outpatient practices where patient visits occur and can be considered secure. Analysis of recordings will take place with headphones to minimize the potential for identifiable data to be overheard.

Procedure: Once 20 cardiology providers have been recruited and consented, we will email each a link to the secure REDCap-based survey tool to administer a modified version of Pfizer's survey entitled "Assessment of Provider Knowledge and Therapeutic Approaches for Reducing Stroke Risk in Patients with Nonvalvular Atrial Fibrillation." After completing the survey, we will ask them to download our mobile app to their phones. If study providers do not have a compatible device, or if they prefer not to use their own personal device, the study team will loan them a compatible device with the app loaded on it and bring the device to the clinic of the participating provider.

We will then identify eligible patients of each study provider with upcoming appointments in the next three months using the Epic Atrial Fibrillation registry. We will send providers their list of patients via secure, encrypted mail to review for accuracy of eligibility. We will then mail a letter signed by the patient's cardiology provider to the remaining patients explaining the purpose of the study two to three weeks before their scheduled appointment. For patients who have an appointment with the study provider within two weeks, we will mail one week before the scheduled appointment using expedited delivery. In the mailing, we will also include a fact sheet about the study, a letter from their provider, and the relevant HIPAA authorization form (coronavirus form while those restrictions are happening). Four to seven days after our letter mailing (or two to three days for letters mailed one week in advance of the cardiology visit), we will call each patient to request informed verbal consent.

After consenting a patient over the phone, we will orient the patient or his or her family member to download our mobile app. Once downloaded, we will instruct the patient to complete the questions prompted by the app (i.e. pre-visit questionnaire) in anticipation of the upcoming visit

with his/her cardiology provider. We will also collect information about the amount of time it took the patient to download and answer the initial survey questions in the app. After the patient completes the pre-visit questionnaire on the app, we will administer a separate usability scale based on the Mobile App Rating Scale (MARS) used widely in the medical literature.[7] We will then ask the patient to arrive at the cardiology provider's office 30 minutes prior to the scheduled appointment time and bring the signed HIPAA authorization form.

The research assistant (RA) will join the study provider in anticipation of his/her visit with a study patient. If the patient did not bring the mailed HIPAA authorization form, we will have them sign an electronic version using a study device. Prior to beginning the visit, the RA will check whether the patient completed the patient portion of the pre-visit set of questions using the device of the patient or his/her family member. If the patient did not complete the pre-visit questionnaire or the MARS over the phone, the RA will provide the patient a study device with the app downloaded to fill out both surveys prior to beginning the visit. After completing the patient portion, the RA will then find the provider and complete the provider portion of the pre-visit task. Mainly, this involves checking patient responses for accuracy (i.e. did the patient correctly identify their risk for stroke and bleeding). It also includes reviewing items which the patient identified as important to discuss during the office visit.

Subsequently, the provider will conduct the visit with the RA in attendance but without any scripting. The visit will be audio recorded using an encrypted recorder that will be administered by the RA. The RA will not be present in the room during the appointment, however they will inform the patient and provider that an encrypted recorder will be left in the room. The recordings will be kept strictly confidential and only members of the study team who are not cardiologists will be involved in the recording and transcription of the tapes. At the end of the visit, the RA will collect usability information from the provider by administering the (MARS). The RA will also administer a select number of questions related to perceived usefulness of the app following the Technology Acceptance Model.[8] These will include items for the provider and separately for the patient. The RA will collect timing to understand the feasibility of implementing the shared decision-making app as well as for budgeting and planning purposes in the future. To assess the association of provider knowledge of and, separately, confidence in modern AF management, we will examine each item in the Pfizer survey for consistency using factor analysis as well as our own expertise.

We will submit the invite letter, patient fact sheet, and surveys for IRB approval prior to use in the study. We will also include the option of sending patient recruitment materials via the patient portal or having the provider send it through email or other process he / she uses for sending materials (including leaving at front desk of office, through portal , email) This will allow patients to have adequate time to review the material if their appointment is sooner than when we can mail the study materials to them. We are requesting this modification both during coronavirus restrictions but even after they have been lifted given that nearly 30% of visits are being rescheduled within the same week prohibiting a large sample of patients from benefiting from our intervention.

COVID-19 Modified Study Procedure

During coronavirus restrictions, we will use same provider letter but coronavirus specific fact sheet and HIPAA authorization. At the time of phone interview, we will review the coronavirus specific HIPAA authorization form in which we replace the wet signature that was originally obtained with a process of acknowledgment to disclose protected health information through the process of agreeing to participate in the study and phone interview.

Lastly, since appointments are now occurring remotely, the RA will not be present during those calls so we will not be audio recording. Once the visit is completed, the RA will contact the patient to complete their survey and mail them their $25.00 Amazon gift card.

Analysis:
For objective 1 regarding usability, we will calculate a composite score for both patients and providers. We will then norm this score to range from 0-100. If these norm scores fall along a normal distribution, we will calculate means and standard deviation for usability. Otherwise, we will group responses into categories and calculate frequencies. We will also calculate perceived usefulness for patients and providers and examine their distribution as we did for usability. In addition, we will record timing for each of the components of the shared decision making encounter. We will review the distribution of time required for each activity. If they fall along a normal distribution, we will calculate means; otherwise, we will group into categories and calculate frequencies. We will then examine for trends in the association between certain patient factors such as age, gender, race, and income with the mobile app rating scale

For objective 2, to assess the association of provider knowledge of and, separately, confidence in modern AF management, we will examine each item in the Pfizer survey for consistency using factor analysis as well as our own expertise. If there are 1 or 2 factors that can summarize these responses, we will measure the association between a one category shift in knowledge or confidence and mean provider usability, mean provider perceived usefulness, and time-based feasibility.

For objective 3, we will track study patients' switch to AC using the EHR. More specifically we will calculate the frequency of patients starting anticoagulation up to six months after the shared decision-making visit.

12. DATA AND SPECIMEN BANKING*
N/A

13. DATA ANALYSIS AND MANAGEMENT*

Given small sample size we don't anticipate being able to conduct extensive analyses and therefore are not attempting to achieve statistical power. Rather we will examine for trends in the association between certain patient factors and mobile app rating scale.

Data Security
All persons collecting or handling data will be trained in human subjects' procedures, confidentiality, and privacy protection. All investigators and project staff are required to receive, and complete Human Subjects and HIPAA training.

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All computerized data will be kept on secured computers or network servers, beyond University of Massachusetts firewalls or relying institutions' firewalls. These data will be accessible only to research staff with approved access, using confidential usernames and passwords. Any paper data will be kept in locked cabinets or a locked file room accessible only by research staff. Data downloaded from REDCap will be stored and secured according to these methods.

We will retain study identifiers including medical record number in the research data set in order to facilitate chart reviews, which are necessary for validation of electronic capture of anticoagulation status. Once the study is complete, we will strip our research data of all identifiers and only maintain the limited database for any subsequent analyses that may become necessary to respond to reviewers of manuscripts we publish or future inquiries from other scientists requesting us to run analyses.

Analyses will be performed using only limited datasets, and only aggregate data will be reported. All data will be used for research purposes only; published data will not contain any individual identifiers and will be reported in the aggregate.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*
The proposed study involves no more than minimal risk to participants.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*
N/A

16. RISKS TO SUBJECTS*

Potential Loss of Confidentiality
There are potential risks associated with data collection and information management. These include inadvertent disclosure of research variables collected. Every effort will be made to inform the subject of this potential and minimize the risks.

Protection Against Risks
Minimizing Risks: All efforts will be made to minimize risks. All data collected, whether in the form of paper surveys and online surveys will be stored in locked cabinets or secure servers in the office of the research team. Data will be brought to the research offices on a daily basis for safe storage. Participation in the study will be kept strictly confidential. Data entered into the study database will be stored on a secure server using a study participant identification code that does not identify patients or healthcare providers by name. Only the investigators and research staff will have access to study information. All standards mandated by HIPAA for research will be met.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*
The potential benefits to subjects from study participation include increased knowledge of AF and AC to improve rates of adherence to AC guidelines.

Benefits to patients include having their providers availed of the most recent evidence regarding anticoagulation for patients with AF. This may in turn prevent strokes or limit bleeding that would otherwise have occurred without the benefit of this provider support.

18. VULNERABLE POPULATIONS*

Children
Children will not be included in this study.

Pregnant Women
Pregnant women will not be included in this study.

Prisoners
Prisoners will not be included in the study.

Adults Unable to Consent
Adults unable to consent will not be included in the study.

Employees
Individuals who are recruiting subjects are not in position of authority over the participants in this study. We will also obtain confirmation prior to deploying our intervention from clinical chiefs that they will not seek access to identifiable information regarding providers collected as part of the research.

19. MULTI-SITE RESEARCH*
N/A

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
N/A

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*
Results of the overall study will be emailed to participating providers after publication. All results shared in published research will be in aggregate or summary format, and will not include identifiable information about participants.

22. SETTING

The lead site for this study is the UMass Memorial Health Care System and affiliated practices. Data review and analysis will be conducted in the study staff offices on secure computers.

23. RESOURCES AVAILABLE
All study personnel will read the study protocol, receive the appropriate supervision and possess the appropriate experience (both higher education and related work experience) needed to fulfill their roles and complete their responsibilities for this study. All investigators and project staff are required to receive and complete Human Subjects and HIPAA training. All research personnel will hold a current Human Subjects Training Certificate. All study staff have adequate time budgeted to fulfill their responsibilities in the study, and will meet periodically to ensure that

they are adequately informed about the protocol, the research procedures, and their duties and functions. The Principal Investigator will oversee all personnel and all research activities conducted within this study.

The Principal Investigator will also have responsibility for the overall conduct of the project at the study site. S/he will have primary oversight of all study personnel. S/he will participate in the design and the execution of the respective study analyses and will be responsible for the reporting of study results. S/he will participate in recruitment and informed consent procedures.

The Co-Investigators will assist the Principal Investigator in research design and development, as well as analytic aspects of the study. They will participate in recruitment and informed consent procedures.

The Biostatistician will assist in the design and performance of analyses relevant to the project and will assist in the development of study deliverables.

The Programmer/Analyst will perform a range of programming and data management activities essential to conduct of the project. S/he will assist in the development of study databases, data cleaning and validation activities, algorithms based on study data, and the performance of analyses under the direction of the investigators.

The Project Manager will assist the Principal Investigator and the Co-Investigators in implementing all aspects of the project. Under the direction of the investigators, the Project Manager will be responsible for day-to-day oversight of the project, including: developing timelines, work allocation, workflow plans, monitoring project progress and task completion, monitoring spending and effort allocation, and managing correspondence and administrative tasks. S/he will monitor/manage ethics and regulatory approvals (IRB, HIPAA/DUA). The Project Manager will attend and plan for all project-related meetings as needed. S/he will work under the direction of the Principal Investigator to assist with all study activities, preparing IRB submissions and reports, and developing study materials, such as development of data collection instruments and intervention-related tools. S/he will assist in supervising the research assistant and initial set up of recruitment. S/he will be responsible for maintaining communications with all parties participating in the project.

The Research Assistant will be responsible for organizing study documentation and IRB application submissions, really and performing other general project coordination activities. S/he will coordinate all meetings related to the study, record meeting minutes, and send agendas and reminders prior to each meeting. S/he will distribute the clinician profiles for Aim 1.

24. LOCAL RECRUITMENT METHODS

Recruitment of providers. We will invite cardiology providers to participate in our study. Initially, we will send a group email followed by subsequent individualized emails and telephone calls. For their participation, cardiology providers will receive a stipend of $200 gift certificates redeemable through Amazon.com.

Recruitment of patients. We will identify eligible patients from our previously constructed Epic-based AF registry which relies on ICD-10 codes and pharmacy records. After identifying eligible patients, we will forward this list to participating providers to review for accuracy of eligibility. We will then mail a letter signed by the patient's cardiology provider to the remaining patients two to three weeks before their scheduled appointment, explaining the purpose of the study. For eligible patients who have an appointment with the study provider within two weeks, we will mail one week before the scheduled appointment using expedited delivery. In the mailing, we will also include a fact sheet about the terms of participation in our study, which include voluntary basis of participation and right to withdraw at any time. Four to seven business days after our letter mailing, we will call each patient to explain the study in further detail and request informed verbal consent. We will allow four to seven days to elapse before calling in order to ensure that the letter and fact sheet have been delivered and the patient has sufficient time to review the documents. We will wait two to three days to call patients to whom letters are mailed one week in advance of their cardiology visit. We will provide patients a stipend of $25 of Amazon gift certificates for their participation.

Local Recruitment Methods During COVID-19:
Recruitment of patients will be slightly modified given the setbacks of COVID-19. Modified study material will be mailed to patients during the same timeframe however, we will also enable the option of sending study materials via the patient portal and electronic provider transmission. For mailed letters, we will call patients during the same timeframe as our original protocol however for materials sent via the patient portal, we will call two to three days after. Once we contact the patient over the phone, we will conduct our baseline interview and review the modified HIPAA authorization form for their consent. Patients who agree to participate and complete their appointment and surveys will then be mailed a $25 Amazon gift card.

25. LOCAL NUMBER OF SUBJECTS

We will include up to 20 cardiology providers (physicians and nurse practitioners) from the UMass Memorial Medical Group. We will also recruit up to 60 patients not on AC (as many as 6 patients for each provider)

26. CONFIDENTIALITY

Only a limited dataset will be kept for analysis by the study team at the University of Massachusetts Medical School. Results of the analyses will be presented in the aggregate.

Personal identifiers will be kept in a separate data file from the research dataset and will be retained during assembly of the databases, in order to allow accurate linkage of participant health information across multiple source files, and to support medical chart review for validation and supplemental data collection. This linkage data file (containing a link between the Study ID and personal identifiers) will only be accessed by authorized study personnel who require such information to implement the academic detailing intervention and conduct the medical record reviews. This linkage data file will be destroyed at the earliest possible date, once data collection is complete and data accuracy are verified. The completed database will be retained in secure fashion for future IRB approved research. Information from the audio recording's will be transferred immediately after recordings to a secure UMass Medical School network drive. Once transferred, recordings will be destroyed from the recording device. Data collected will be held

onto for three years and then properly destroyed.

See also #13, *Data Analysis and Management***.**

Protection for Risks Associated with Potential Loss of Confidentiality
The organization proposing this study has systems, oversight, experienced personnel, and an organizational culture that supports the appropriate use, access and storage of confidential information. All persons collecting or handling data will be trained in human subjects' procedures, confidentiality and privacy protection. All investigators and project staff are required to receive and complete Human Subjects and HIPAA training. All research personnel will hold a current Human Subjects Training Certificate.

See also #13, *Data Analysis and Management***.**

Data Collected via REDCap
Study data will be captured via REDCap. The REDCap Consortium is comprised of hundreds of active institutional partners from CTSA and other institutions, and it supports a secure web application (REDCap) designed exclusively to support data capture for research studies (http://www.project-redcap.org). University of Massachusetts Medical School is a REDCap Consortium site.

REDCap is used to build and manage online surveys and databases. The front end of REDCap is written in PHP, which is widely used, robust, open source scripting language. Web servers, database servers, and security of communication between servers occur locally at each Consortium site where data capture is stored. Thus, all study data is stored and hosted at the local institution, and no project data is ever transmitted at any time by REDCap from that institution to another institution or organization.

Some additional security features include: a) specification of "user access": by account, by project, or by User Access group; b) system Log-in: assigned username and user-identified password required, automatic inactivity logout, password specificity requirements, passwords must be changed every 30 days, restrictions on use of previous password; c) system lock-out: following succession of unsuccessful login attempts, or if no login to the system within 30 days.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS
HIPAA Waiver Request
We are requesting a HIPAA authorization waiver to access medical record (EHR) data; these data will be used for the purposes of study recruitment. Once enrolled, study patients will be asked to sign a HIPAA authorization form for the authorization to audio record their visit and access and use medical record/healthcare data for study purposes (track switch in AC status). (See attached HIPAA authorization form).

Protection for Risks Associated with Participating in Research Interviews
All participants will be told that participation is voluntary, that they are free to not respond or to terminate involvement at any time, with no adverse consequences.

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Protection for Risks Associated with Data Handling
All data collected for this project at the UMass site will be stored and will remain on UMMS servers. Data containing PHI will not be downloaded to data systems outside of UMMS or to personal networks. Research team members will work with study data within the data regulated, HIPAA compliant environments.

Chart abstraction data and survey data will be stored in REDCap. This data will be exported into Excel files, which will be stored on a UMMS network drive that is password-protected and secured.

28. COMPENSATION FOR RESEARCH-RELATED INJURY
None; there are no resources available. We do not anticipate any research-related injuries. We believe the research poses no more than minimal risk to subjects.

29. ECONOMIC BURDEN TO SUBJECTS
N/A. There are no anticipated costs to participate in the study.

30. CONSENT PROCESS
Cardiology providers will be consented either in-person or electronically. For in-person, members of the research team will meet with the providers to describe the study to them and will review the informed consent with them. For the in-person consent process, we will follow *HRP-800 INVESTIGATOR GUIDANCE: Informed Consent*. For electronic consent, we will email the providers a link to the online consent form in REDCap. If providers consent electronically, we will print and retain their signed form, however, it will not contain the UMMS IRB stamp and/or watermark.

For patients recruited with our initial target of three patients per provider, we will readminister consent to get permission to recruit up to six patients.

Consent forms are attached with this submission.

We will obtain verbal consent from patients over the telephone after explaining the study and answering questions.

We will also ask patients to sign a paper copy of the HIPAA authorization form which will be mailed to them in order to access and use their medical record/healthcare data for study purposes (see attached HIPAA authorization form).

During COVID-19 restrictions, since we will not be meeting the participants in person to obtain their HIPAA authorization signature, we will instead send them a coronavirus specific HIPAA authorization form. This form will be extensively reviewed with the patient over the phone to obtain their acknowledgment to disclose protected health information.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

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We will request written informed consent from all providers participating in the study. If electronic consent is obtained, we will print a copy of each signed consent form.

Signed informed consent forms will be retained for a minimum of six years after completion of this study.

We will also obtain verbal informed consent from all patients participating in the study. The date and time of consent will be recorded. To maximize study enrollment and to reduce burden for the study team and participant, we are requesting a waiver of documentation of written consent for subjects. We attest that the following statements are all true:

1. The research involves no more than minimal risk to the subjects.
2. The research involves no procedures for which written consent is normally required outside of the research context, and all study activities are conducted by telephone.
3. Subjects will be provided a written statement including the elements of consent (described on the Fact Sheet).

Due to the COVID-19 restrictions we will use a separate fact sheet that does not include information about the audio recording during the patient visit as we will not be able to audio record
See also #30 *Consent Process*.

32. DRUGS OR DEVICES

This research is testing a mobile medical app that facilitates shared decision-making with respect to anticoagulation therapy by providing a platform for a patient to confirm his or her risk of stroke and to identify items for discussion at their next appointment with aprovider. The testing takes place in real world clinical encounters in which patients and providers will be asked to judge not just the usability, but whether the app improves aspects of their patient care. The FDA has indicated that it will exercise enforcement discretion of MMAs that help patients/users self-manage their disease or condition without providing specific treatment suggestions or that help patients document, show or communicate potential medical conditions to health care providers.

To protect patient information, participants will be given a unique study ID within the app. Information shared with the provider will only be viewed during the appointment. The provider will view their patients information in person since the participant will directly show their provider their answers within the app on their phone. If the patient answered the questions using the study device, then the provider will review the answers from the study device.

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