Carilion IRB Application (Version 1.8)

1.0 General Information

***Please enter the full title of your study::**

A Comparison of the Effectiveness of Telepsychiatry with a Randomized Waitlist Control Utilizing Patient Reported Outcome Measures (PROMs)

***Please enter an abbreviated study title or key words you would like to use to reference the study:**

Telepsychiatry, PROMs, Waitlist
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add departments

2.1 Add the departments of all Key Study Personnel that will be involved with the design, conduct, or reporting on this project:

Is Primary?	Department Name
◉	**CC** - Department of Psychiatry and Behavioral Medicine
○	**CC** - External- Virginia Tech Blacksburg
○	**CC** - HEALTH ANALYTICS RESEARCH

3.0 ■ Assign key study personnel(KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

Name	Role	Training Record
O'brien, Virginia, MD	**Principal Investigator**	**View Training Record**

3.2 Please add the Research Staff, if applicable:

A) Additional Investigators

Name	Role	Training Record
Kablinger, Anita	**Sub-Investigator**	**View Training Record**
Mcnamara, Robert	**Sub-Investigator**	**View Training Record**
Sharp, Hunter	**Sub-Investigator**	**View Training Record**
Tenzer, Martha	**Sub-Investigator**	**View Training Record**

B) Research Support Staff

Name	Role	Training Record
Phenes, Ashlie, Master of Science	Other	View Training Record

3.3 *Please add a Study Contact:

Name	Role	Training Record
Kablinger, Anita	Study Contact	View Training Record
O'brien, Virginia, MD	Study Contact	View Training Record

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

4.0 Key Study Personnel (KSP) Info

4.1 Provide the following information below for each Carilion Clinic research team member: You will be asked to provide information about members of the research team that are outside Carilion at a later time.

Click "add another entry" to respond to this item.

CITI Training in Human Subjects Research Biomedical Researchers and GCP (for FDA-regulated and NIH-funded) will be verified for each team member before the application will be reviewed by the IRB. Detailed instructions for Carilion's CITI training requirements can be found at https://www.carilionclinic.org/irb/education . Please ask all team members to ensure their Carilion email address is added to their CITI account profile so that their CITI training is pulled into this system. This feed occurs on a nightly basis.

Entry 1

Research team member name:	Kablinger, Anita
Degree:	MD
Status:	Physician **If other, specify:**
Email address:	askablinger@carilionclinic.org
Phone number:	540-981-8582
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**
Research Duties (check all that apply):	☐ PI: Ultimately responsible for the study including conduct by all study team members ☑ Identification of potential subjects

- [x] Contacting potential subjects
- [x] Screening of subjects, including assessing eligibility criteria
- [x] Obtain Informed Consent
- [x] Randomization
- [x] Conduct of study procedures that result in research data
- [ ] Prepare or dispense study drug/device
- [x] Research specimen collection/shipping
- [x] Adverse Event documenting and reporting
- [x] Data entry
- [x] Data Analysis - Identifiable
- [x] Data Analysis - De-identified
- [x] Regulatory document maintenance
- [ ] Other (specify):

Entry 2

Research team member name:	O'brien, Virginia, MD
Degree:	MD
Status:	Physician **If other, specify:**
Email address:	vcobrien@carilionclinic.org
Phone number:	540-529-9063
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**

Research Duties (check all that apply):

- [x] PI: Ultimately responsible for the study including conduct by all study team members
- [x] Identification of potential subjects
- [x] Contacting potential subjects
- [x] Screening of subjects, including assessing eligibility criteria
- [x] Obtain Informed Consent
- [x] Randomization
- [x] Conduct of study procedures that result in research data
- [ ] Prepare or dispense study drug/device
- [x] Research specimen collection/shipping
- [x] Adverse Event documenting and reporting
- [ ] Data entry
- [x] Data Analysis - Identifiable
- [ ] Data Analysis - De-identified
- [ ] Regulatory document maintenance
- [ ] Other (specify):

Entry 3

Research team member name:	Mcnamara, Robert
Degree:	PhD
Status:	Carilion Staff/Employee **If other, specify:**
Email address:	rmcnamara@carilionclinic.org
Phone number:	540-512-1304
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**
Research Duties (check all that apply):	☐ PI: Ultimately responsible for the study including conduct by all study team members ☑ Identification of potential subjects ☐ Contacting potential subjects ☑ Screening of subjects, including assessing eligibility criteria ☑ Obtain Informed Consent ☐ Randomization ☑ Conduct of study procedures that result in research data ☐ Prepare or dispense study drug/device ☐ Research specimen collection/shipping ☐ Adverse Event documenting and reporting ☐ Data entry ☑ Data Analysis - Identifiable ☐ Data Analysis - De-identified ☐ Regulatory document maintenance ☐ Other (specify):

Entry 4

Research team member name:	Sharp, Hunter
Degree:	MS
Status:	Carilion Staff/Employee **If other, specify:**
Email address:	hdsharp@carilionclinic.org
Phone number:	

	540-510-4632
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**
Research Duties (check all that apply):	☐ PI: Ultimately responsible for the study including conduct by all study team members ☐ Identification of potential subjects ☐ Contacting potential subjects ☐ Screening of subjects, including assessing eligibility criteria ☐ Obtain Informed Consent ☐ Randomization ☐ Conduct of study procedures that result in research data ☐ Prepare or dispense study drug/device ☐ Research specimen collection/shipping ☐ Adverse Event documenting and reporting ☐ Data entry ☑ Data Analysis - Identifiable ☑ Data Analysis - De-identified ☐ Regulatory document maintenance ☐ Other (specify):

Entry 5

Research team member name:	Tenzer, Martha
Degree:	BS
Status:	Carilion Staff/Employee **If other, specify:**
Email address:	mmtenzer@carilionclinic.org
Phone number:	540-224-5192
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**
Research Duties (check all that apply):	☐ PI: Ultimately responsible for the study including conduct by all study team members ☐ Identification of potential subjects ☐ Contacting potential subjects ☐ Screening of subjects, including assessing eligibility criteria ☐ Obtain Informed Consent

- [ ] Randomization
- [ ] Conduct of study procedures that result in research data
- [ ] Prepare or dispense study drug/device
- [ ] Research specimen collection/shipping
- [ ] Adverse Event documenting and reporting
- [ ] Data entry
- [x] Data Analysis - Identifiable
- [x] Data Analysis - De-identified
- [ ] Regulatory document maintenance
- [ ] Other (specify):

Entry 6

Research team member name:	Phenes, Ashlie, Master of Science
Degree:	MS
Status:	Carilion Staff/Employee **If other, specify:**
Email address:	arphenes@carilionclinic.org
Phone number:	540-981-8025
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**
Research Duties (check all that apply):	- [ ] PI: Ultimately responsible for the study including conduct by all study team members - [x] Identification of potential subjects - [x] Contacting potential subjects - [x] Screening of subjects, including assessing eligibility criteria - [x] Obtain Informed Consent - [x] Randomization - [x] Conduct of study procedures that result in research data - [ ] Prepare or dispense study drug/device - [x] Research specimen collection/shipping - [ ] Adverse Event documenting and reporting - [x] Data entry - [x] Data Analysis - Identifiable - [ ] Data Analysis - De-identified - [ ] Regulatory document maintenance - [ ] Other (specify):

5.0 Application Type

5.1 Select the application type:

- (●) Human Subject Research Study
- ( ) Determination of Human Subjects Research (including QA/QI Determination)
- ( ) Establishing a prospective Data or Specimens Research Repository
- ( ) Humanitarian Use Device (non-research use)
- ( ) Expanded Access or Compassionate Use
- ( ) Single Patient Emergency Use
- ( ) Preparatory to Research Application
- ( ) IRB Grant Review ONLY for preliminary approval if required by funder
- ( ) Requesting Carilion Clinic RELY on another IRB of Record (WIRB, CIRB, VT, UVA, Advarra etc.)
- ( ) Conversion of a paper application due for Continuing Review or Annual Check-In

Please ensure the PI has completed and submitted the R&D Application Department Level Review Form (eCRAF), and that the PI's Department Chair or signatory has signed off on the R&D Department Level Review eCRAF Form BEFORE you proceed any further with this IRB application. Please read the below bullet points carefully and acknowledge your understanding.

- **The R&D Application Department Level Review eCRAF Form must be submitted by the PI and signed off by Department Chair or signatory through RedCap BEFORE you may proceed with this IRB application.**
- **The R&D Application Department Level Review eCRAF Form serves a major function for section and department level review and may result in this study not being permitted due to resources, scientific validity, or other reasons.**
- **You must submit a copy of the signed R&D Application Department Level Review eCRAF Form with this IRB application in the supplemental document section.**
- **Failure to complete the steps in the above order will result in a significant delay in the IRB's review of this study.**

(●) Acknowledged

6.0 Funding Information and Outside Services

6.1 Select the applicable funding source(s).

- [ ] None (no money, equipment, supplies, and/or services will be provided by external source)
- [ ] No monetary funding BUT equipment, supplies, and/or services will be provided
- [x] Federal Government
- [ ] Foundation or Non-profit
- [ ] Industry/Commercial Sponsor
- [ ] State or Local Government
- [ ] Investigator or Departmental/Unit Funds
- [ ] Carilion RAP Grant
- [ ] Other

Select all the Federal funding sources that apply:

- [x] National Institutes of Health (NIH)
- [ ] National Science Foundation (NSF)
- [ ] Department of Agriculture
- [ ] Department of Commerce
- [ ] Department of Defense

- [ ] Department of Education
- [ ] Department of Energy
- [ ] Department of Energy, Office of Science, STTR
- [ ] Department of Energy, Office of Science, SBIR
- [ ] Department of Health and Human Services
- [ ] Department of the Interior
- [ ] Department of Justice
- [ ] Department of Transportation
- [ ] Environmental Protection Agency
- [ ] National Institutes of Standards and Technology
- [ ] U.S. Air Force Office of Scientific Research (AFOSR)
- [ ] U.S. Army Research Office
- [ ] U.S. Navy Office of Naval Research
- [ ] Other

Please provide more detailed information about the funder, as applicable, including funder name or department (including name of NIH institute, center, or offices, name of NSF directorate, etc.).

iTHRIV award

Award / Contract Status:

awarded

Grant Title, if applicable:

A Comparison of the Effectiveness of Telepsychiatry with a Randomized Waitlist Control Utilizing Patient Reported Outcome Measures (PROMs)

6.2 Select services from all areas outside of the Research Team members' affiliations that are necessary to conduct the work.

Research and Development (R&D) will contact you to arrange a Feasibility Meeting based on your responses below. This will ensure roles, responsibilities, and costs associated with this project are understood by all parties. Final sign-off from leadership in the additional service areas, as well as contracts, may be required.

- [ ] Animals
- [ ] Basic Science Laboratory Services
- [ ] Center for Simulation, Research & Patient Safety (CSRPS)
- [ ] Department of Medicine
- [ ] Department of Pediatrics
- [ ] Department of Psychiatry
- [ ] Department of Surgery
- [ ] Emergency Department
- [ ] Hazardous Materials
- [x] Health Analytics Research Team (HART), including Epic Data Extraction, Statistics Services, Carilion RedCap, Epic Research Access
- [ ] Human Resources
- [ ] Jefferson College
- [ ] Nuclear Medicine
- [ ] Nursing
- [ ] Pathology
- [ ] Pharmacy
- [ ] Physical Therapy
- [ ] Radiology
- [ ] Recombinant DNA/RNA
- [ ] Respiratory
- [ ] Solstas Lab
- [ ] Technology Services Group (TSG)

☑ Other
☐ None

Please specify:

VT Psychology

6.3 You have selected that HART services are needed for this research. Specify the resources needed.

☑ Epic Data Extract
☑ Statistics Support (biostatisticians)
☑ Carilion REDCap (Data management)
☑ Epic Research Access for Chart Review
☐ TriNetX Identifiable Patient List/Data Set
☐ SPARC Carilion Secure Research Environment

Note: If you have not yet discussed this project with the HART team, please contact them at HART@carilionclinic.org before proceeding any further with this application. This will ensure that your request for this project is feasible.

7.0 Regulatory Compliance

7.1 How many studies is the PI currently responsible for?

2

7.2 Does the PI have protected or dedicated time available to conduct this research?

◉ Yes ○ No

7.3 Has any member of the research team ever received a FDA 483, "Warning Letter", Notice of Disqualification, or other warning or disciplinary action from an agency or licensing authority?

○ Yes ◉ No

7.4 Has this study been disapproved or terminated by another IRB?

○ Yes ◉ No

8.0 Conflict of Interest

8.1 A Conflict of Interest, per the Carilion Clinic Organizational Policy, is a situation in which an Investigator's and/or their Family Member's financial, professional, or other personal consideration may directly or indirectly affect, or reasonably appear to affect, the Investigator's professional judgement in performing their Institutional Responsibilities. A Conflict of Interest may be actual, apparent, or potential. Any research team member listed on the IRB application is considered to be an Investigator. It is the Principal Investigator' s responsibility to query all Carilion research team members on this study to ensure they have honestly completed their Annual COI Disclosure and that it is current. The Principal Investigator should be notified by the study team member if the study team member has disclosed any related interests. Carilion Clinic's Conflicts of Interest in Research Policy can be found here.

If this study has any external funding or support, have all Carilion research team members filed an Annual COI Disclosure through Carilion Clinic's Office of Organizational Integrity and Compliance via the COI-Smart online disclosure system?

◉ Yes
○ No
○ N/A - this study does not have any external funding or support

Do any Carilion research team members or their family members have a Conflict of Interest or related outside interest with the sponsor/funding agency of this study?

○ Yes ◉ No

It is the Principal Investigator and conflicted employee's responsibilities to ensure the conflict or any changes that result in a potential conflict are disclosed to the Office of Integrity and Compliance who will refer it to the Carilion Clinic's Research Conflict of Interest Commitee for appropriate management when necessary. Disclosure and management must occur before the conflicted employee is permitted to engage in any research activities. Any employee who violates the Conflict of Interest policy is subject to disciplinary actions, up to and including termination.

9.0 Collaboration

9.1 Is this research project a collaboration between Carilion Clinic and another institution (including, but not limited to Fralin Biomedical Research Institute at VTC, VTCSOM, VT, UVA)?

◉ Yes ○ No

9.2 Please provide the name(s) of the collaborating institution(s) and the name(s) and contact information of the lead PI(s) at that institution.

Lee Cooper, Ph.D., (Co-PI)
Clinical Associate Professor, Department of Psychology
Director, Psychological Services Center
Virginia Tech
ldcooper@vt.edu

9.3 Is Carilion acting as one site of a multicenter study?

◉ Yes ○ No

9.4 Will the multicenter protocol be followed as written or are there components or aspects of the research that this site will not participate in or that will be modified?

(E.x:, local site will not recruit into one of the cohorts or into a sub-study; the age range will be narrowed, a specific procedure or test isn't available locally so another will be performed, etc.)

◉ The protocol will be followed as written.
○ The protocol will be modified locally.

9.5 Is Carilion acting as the coordinating center for the multi-center study?

◉ Yes ○ No

9.7 Are any members of the research team listed on this IRB application under the jurisdiction of another institution's IRB?

◉ Yes ○ No

Please state specifically which external personnel are under the jurisdiction of another IRB, their role on this research study and the type of interaction they will have with the subjects, the name of the institution's IRB(s), and an explanation as to why they are listed on this IRB application.

Lee Cooper, Ph.D., (Co-PI)
Clinical Associate Professor, Department of Psychology
Director, Psychological Services Center
Virginia Tech
ldcooper@vt.edu
research design, data analysis (de-identified), scholarly products

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Hayoung Ko, M. A.
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research design, data management, data analysis (de-identified), scholarly products

Sydney Jones B.S.
Graduate Student, Clinical Science
Department of Psychology
Virginia Tech
sydneybj@vt.edu
research design, data management, data analysis (de-identified), scholarly products

9.8 Are you requesting that Carilion Clinic serve as the IRB of record for the other participating institutions or organizations?

For more information on IRB reliance requests, please visit the Carilion Clinic IRB website or contact the IRB Office.

(•) Yes ( ) No

List all the team members on the study at the collaborating site(s) and describe their role in the research, including if they will have access to identifiable data. Please also ensure all external team members have met the training requirements for their home institution. Failure to do so will delay the execution of the IRB Reliance.

Lee Cooper, Ph.D., (Co-PI)
Clinical Associate Professor, Department of Psychology
Director, Psychological Services Center
Virginia Tech
ldcooper@vt.edu
research design, data analysis (de-identified), scholarly products

Alyssa Gatto, M.S.
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Hayoung Ko, M. A.
Graduate Student, Clinical Science
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research design, data management, data analysis (de-identified), scholarly products

Sydney Jones B.S.
Graduate Student, Clinical Science
Department of Psychology
Virginia Tech
sydneybj@vt.edu

research design, data management, data analysis (de-identified), scholarly products

9.9 If this study has any external funding or support, do the external collaborators' institutions possess a PHS-Compliant FCOI policy?

- [x] Yes
- [ ] No
- [ ] N/A - study does not have external funding or support

9.11 Describe any plans for initial and ongoing training of the other sites on important aspects of the protocol.

We meet weekly to review study progress, data acquisition and trends with focus on maintaining protocol procedures without deviation

9.12 Describe the plan to manage communication of information at the other sites that is relevant to the conduct of the research and the protection of human subjects, such as reporting of unexpected problems, protocol modifications, and interim results for all sites to the Carilion Clinic IRB.

For FDA-regulated clinical trials, the plan must include the plan for reporting serious adverse events or serious adverse device effects, significant new risk information, and any other reports mandated by regulation or policy.

We meet weekly to review study progress, data acquisition and trends with focus on maintaining protocol procedures without deviation

The PI or other Carilion IRB-approved team member will report any unexpected problems, protocol modifications and interim results to the Carilion Clinic IRB

9.13 Describe the Carilion Clinic investigator's plan for oversight of research activities at other sites including verification of Institutional approvals, data safety monitoring, and ensuring data quality and integrity.

For FDA-regulated clinical trials, the plan must include the use of trained and qualified monitors to oversee the progress of the research.

The study team meets weekly to ensure approvals, monitoring and data quality and integrity are maintained

9.14 Will identifiable data or specimens be transferred, transmitted, or shared outside of Carilion?

For example, transfer of data or specimens from Carilion Clinic to an external collaborator (including VT, VTCRI, UVA, etc.).

- ○ Yes
- ◉ No

9.15 Provide information about the types of specimens and/or data, including specific datapoints, that will be shared and the methods of storage of the data at the collaborating site. Include a description of the process for shipping the specimens and/or transmitting the data to the collaborator, including the method of encryption if sharing data electronically.

Data collection will be entered into REDCap by Ashlie Phenes (Psychiatry Intake Coordinator) and reviewed by the PI or sub-investigator. Hayoung Ko, a VT Psychology graduate student, will be the data manager for the project. Thus, we request that she have access to REDCap data, without PHI access.

Data in REDCap that would be visible to Hayoung Ko at VT would be:

subject number
randomized group (no intervention or minimal intervention)
date of assessment by Ms. Phenes will be put as day 1 NOT a specific date of appointment
PHQ-9, GAD-7, BASE-6, USAUDIT, DAST-10 scores

Covid Event Checklist (positively checked answers with respect to COVID infection, prevention, negative mental health effects of Covid, SDOH and resiliency factors) - there are no dates or identifying information in this checklist, simply the check-marked items themselves
Adult Behavioral Health Screen (ABHS) (marked as completed or not)

The VT collaborator would not have access to any of the 18 HIPAA identifiers.

Data from REDCap will be exported to SPARC by HART and de-identified to allow other non-Carilion study members (LD, HK, AG and SJ) to analyze data that is de-identified.

10.0 Human Subjects Research Description

10.1 In the opinion of the Principal Investigator, does this research impart minimal risk or greater than minimal risk to subjects?

As defined by regulation, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please note that the IRB makes the final determination of risk level and may ask you to change this based on their decision.

If this is a Conversion of a Paper Application, select the risk level that has been determined already by the IRB at most recent review per the most recent approval letter (expedited review = minimal risk, full board review = greater than minimal risk).

- (•) Minimal Risk
- ( ) Greater than minimal

10.3 Select ALL the types of research activities that will be involved in your human subject research subject, or select None.

- [ ] Drugs, biologics or other FDA-regulated products (other than devices)
- [ ] Medical devices
- [x] Review of data/records (i.e. prospective clinical data collection from medical records, reviewing previously collected data)
- [ ] Biospecimen collection (i.e. blood, tissue, urine, saliva)
- [ ] Analysis of existing specimens from patients and/or bank or repository
- [ ] Human genetic analysis or Recombinant DNA, or Gene Therapy
- [ ] Invasive medical procedures (i.e. lumbar puncture, biopsy, endoscopy, surgery, etc.)
- [ ] Non-invasive medical procedures routinely employed in medical practice (i.e., physical measurements, EKG, EEG, moderate exercise, etc.)
- [ ] Imaging (i.e., x-ray, CT, DEXA, MRI, ultrasound, etc.), Use of Therapeutic or Diagnostic Radiation, Radioactive Drugs
- [ ] Task-based activities or games, or Psychometric Testing
- [x] Surveys, questionnaires, focus groups, or interviews
- [ ] Examination of educational practices, instructional techniques, curricula or classroom management
- [ ] Observations of public behavior
- [ ] Interventions or procedures involving deception
- [ ] Use of Internet
- [ ] Audio or Video recording
- [ ] International Research
- [ ] NONE OF THE ABOVE

10.4 Briefly describe the proposed research in language that can be understood by a non-scientist.

This description should summarize the objectives of the research and the procedures to be used, with an emphasis on what will happen to the subjects. If this is an application for the establishment of a research repository, summarize the objectives of the repository and how data/specimens will be used in the future.

The utilization of patient reported outcome measures (PROMs) during in-person care allows for on-going assessment of the severity of mental illness and patient outcomes across treatment (Lewis, et al., 2019; Douglas, et al., 2020). Additionally, it provides immediate feedback on the patient's psychiatric status to both the patient and practitioner (Lambert, et al., 2018). Carilion Clinic - Psychiatry & Behavioral Medicine (CC-P&BM) ambulatory clinic implemented PROMs prior to the start of the COVID-19 pandemic and continues to utilize them as part of patient care. All new patients are asked to complete an initial PROM bundle of assessments twenty-four hours before their initial appointment, including the Brief Adjustment Scale (BASE-6), Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder survey (GAD-7), US Alcohol Use Disorder Identification Test (USAUDIT), and Drug Assessment Screening Test (DAST-10). Automatic monthly reminders to complete the BASE-6, PHQ-9 and GAD-7 continue after the first visit with the clinician.

The COVID-19 pandemic necessitated a rapid transition nationally from in-person to telemedicine (Augusterfer, Mollica, & Lavelle, 2018; Torous & Wykes, 2020; Kalin, et al., 2020), a change that occurred in our clinic as well. Over the last 2 years, research members of Carilion Clinic Psychiatry and Virginia Tech Psychology departments have been actively using PROM data to assess psychiatric health outcomes before and after the outbreak of COVID-19 in the United States. Initial results indicate that patients who received care via telemedicine not only ***did not experience worsening symptoms, but showed improvements in depression, anxiety and psychological functioning***. How ever, without a control group of untreated patients to compare, the impact of telemedicine plus PROMs remains unclear. A wait-list control group design would allow us to compare patients receiving telemedicine and repeated completion of PROMs (current practice) to patients referred to psychiatry, but not receiving telemedicine treatment or completing PROMs during the same time period. We propose randomizing wait-list individuals to one of two groups to assess the influence of time alone awaiting initial psychiatric clinician assessment (no intervention) versus minimal intervention using repeated PROMs and microlearning patient education videos while awaiting initial psychiatric clinician assessment. This kind of design allows assessment for the influence of time and the type of health service contact that replicates the basics of measurement-based psychiatric services (measurement of symptomology and well-being), but with none of the benefits of psychiatric supports, interventions, and techniques.

10.5 Provide background information about the research question(s.) Explain why the research is needed and include the relevance of this research to the contribution of this field of study.

Please include the current state of knowledge about your project topic by summarizing and synthesizing the available research (including published data) to provide justification for the study. Include a reference list of literature cited to support the protocol statement, either in your response below or as a supplemental document as part of the application packet.

Patient-reported outcome measures are a component of Measurement-Based Care (MBC) that involves collaboration between patient and clinician using structured evaluations of patient symptoms to inform behavioral health treatment and clinical decisions (Lewis, et al., 2019). In clinical settings, MBC has been found to improve outcomes and decrease dropout (Lambert, et al., 2018). Since patient-reported outcome measures can be performed by patients or clinicians, in session or out of session, and in-person or via telemedicine, their application is particularly pertinent during or after a crisis (Augusterfer, Mollica, & Lavelle, 2018). The COVID-19 pandemic abruptly accelerated the transition to telehealth for many and necessitated alterations to traditional therapeutic means (Torous & Wykes, 2020; Kalin, et al., 2020). PROMs are a tool that can improve the telehealth experience by strengthening patient-clinician relationships strained by the use of telemedicine, and allows for tracking of patient symptoms, which can be discussed and intervened upon in session (Douglas, et al., 2020).

Over the last 2 years, research members of Carilion Clinic Psychiatry and Virginia Tech Psychology departments have been actively using PROM data to assess psychiatric health outcomes *before and after the outbreak of COVID-19* in the United States (IRB approved protocol 20-905). Initial results indicate that patients who received care via telepsychiatry not only ***did not experience worsening symptoms, but showed***

improvements in depression, anxiety and psychological functioning. However, without a control group of untreated patients to compare, the impact of telemedicine plus PROMs remains unclear. A wait-list control group design would allow us to compare patients receiving telemedicine and repeated completion of PROMs (current practice) to patients referred to psychiatry, but not receiving telemedicine treatment or completing PROMs during the same time period. We propose randomizing wait-list individuals to one of two groups to assess the influence of time alone awaiting initial psychiatric clinician assessment (no intervention) versus minimal intervention using repeated PROMs and reviewing microlearning patient education videos while awaiting initial psychiatric clinician assessment. This kind of design allows assessment for the influence of time and the type of health service contact that replicates the basics of measurement-based psychiatric services (measurement of symptomology and well-being), but with none of the benefits of psychiatric supports, interventions, and techniques.

As of July 2021, ***32 Carilion psychiatric clinicians*** are engaged in Owl Insights, an MBC vendor. Approximately ***500 unique individuals complete monthly PROMs*** through this system as part of routine clinical care. Our research group recently conducted analyses of nearly 900 ambulatory adult psychiatric patients in ambulatory psychiatry at Carilion Clinic (CC&PBM) engaging in PROMs via telepsychiatry and in-person modalities. PROM results of a patient cohort in clinical care prior to the onset of COVID-19 (November 2019) through March 2021 demonstrated that depression, anxiety and psychological functioning did not decline as hypothesized but statistically improved (Kablinger, et al., 2021). Data also show that the ***engagement rates range from 33 to 74% depending on demographic factors***, and completion rates were significantly different for diagnostic group and payor status of the patient (Kablinger, et. al, 2021). The standard goal for MBC utilization is 80%, while the department goal is to have ***all*** patients participate in PROM completion. Our research group has also completed focus groups of psychiatric clinicians and staff with regards to Owl Insights and PROMs within the past year, identifying barriers and facilitators to its use and plan training implementation for improved adherence and satisfaction (summary of focus group data and training outline- included in grant application, IRB approved protocol 20-1065). Since March 2020, CC-P&BM has been engaging with patients via telephone and several telehealth platforms. Currently, ambulatory psychiatry uses AmWell, a telehealth platform that provides secure telemedicine visits between clinician and patient. The department has documented between ***2100-2300 adult telemedicine sessions monthly*** **and** ***200-700 in-person visits per month*** between June 2020 and June 2021.

CC-P&BM currently has a wait-list of over 300 adults referred for mental health evaluation and treatment. Access to psychiatric clinicians remains insufficient despite increasing numbers of providers in our clinic and the mental health needs associated with the pandemic are rising. As a result, a clinical intake coordinator (Licensed Professional Counselor) began in the CC-P&BM ambulatory clinic September 2021. This coordinator will individually contact people on the wait-list for psychiatric care by phone as part of routine care, beginning with the referrals most remote in time. The coordinator will complete an intake assessment for each wait-list individual who wants a psychiatric referral. Prior to the initial intake assessment by the intake coordinator, wait-list individuals will receive a bundle of PROMs automatically (through Owl Insights) to complete. These measures include the PHQ-9, GAD-7, BASE-6, DAST-10, USAUDIT, Covid Event Checklist and the Adult Behavioral Health Screen (ABHS), all of which are currently used in routine ambulatory care. The intake coordinator will complete the intake assessment, noting the completion, and scores of, the PROMs. Scores of the PHQ-9, GAD-7 and BASE-6 will be utilized to triage the most severe referrals and move them up for a sooner appointment (the triage system of scores and Nurse-Practitioner vs Medical Doctor screening questions are attached to this application). Any concern about patient safety is also addressed immediately during this intake and is also noted in the materials attached to this application. **Up to this point, all intake coordinator/referral interaction are part of routine care.**

If eligible and capable of consent based on intake coordinator clinical judgement, individuals will then be randomized to participate to the no intervention group (completion of screening PROMs only during the intake coordinator assessment) or the minimal intervention group (intake coordinator assessment, including PROM screening and then prospective monthly PROM completion in addition to assigned microlearning

patient education videos). We will analyze changes in PROM scores for individuals engaged in both wait-list groups and compare results to their PROM scores at the initial provider telemedicine visit and over time (6 months post first provider assessment). Consent may be in-person with hard copy consent forms and signatures or through e-Consent either in-person using ipads or remotely using REDCap.

10.6 State the research hypothesis or the question that the research will answer.

List the research objectives and expected outcomes. A primary outcome or objective must be identified. After the statement of the primary objective, secondary objectives may be listed. Objectives should be simple and specific.

<u>Aim 1</u> will use PROMs to assess the symptomology and well-being of adult individuals on a wait-list group referred to CC-P&BM clinic from their initial referral to their initial psychiatric session.

In particular, we propose randomizing wait-list individuals to one of two groups to assess the influence of time alone awaiting initial psychiatric clinician assessment (no intervention) versus minimal intervention using prospective monthly repeated PROMs and viewing microlearning patient education videos while awaiting initial psychiatric clinician assessment.

<u>Aim 2</u> will use PROMs to determine whether there is a difference in clinical symptomology and well-being for patients during telemedicine treatment with their practitioner compared to wait-list individuals.

10.7 State how qualitative and/or quantitative data will be analyzed in order to answer the research questions.

Include an analysis from a statistician (or someone familiar with statistical methods) that either indicates the power calculation for the sample size necessary to meet the primary study outcome or objective OR a statement from the statistician indicating reasons why a power calculation is waived or not necessary for this study. Also include the statistical test(s) that will be used to analyze your primary study objective (t-test, chi-square, etc.). Secondary outcomes may be listed as descriptive.

If this is a proof of concept or feasibility study that includes limited efficacy testing, please provide a description on how your design will determine if an intervention should be recommended for broader efficacy testing. If a study is meant to be solely descriptive, then the primary outcome or objective must be limited in scope. As such, the study results apply only to the sample being studied, and conclusions cannot be drawn about the larger population.

This is required for ALL studies, as this section helps the IRB confirm the data being collected are relevant to the study aims and planned analysis.

The primary outcome of interest is the change in total PROM score for each assessment required of patients enrolled in the study. Initial PROM scores will be acquired and assessed after referral into the CC-P&BM program. The potential to receive few records per patient is believed to be relatively high; therefore, the final PROMs completed for each assessment will be used to determine the change in total score. This change will be compared between patients receiving telemedicine and those of the control (wait-list) groups. A two-sample t-test or non-parametric equivalent of the mean change in total PROM will be performed to determine if the change is significantly different among treatment types. An alpha of 0.05 will be used to assess statistical significance. Univariate and multivariate analyses may occur to measure numeric variables by measures of central tendency and variation and categorical variables by frequencies and percentages. Trends of PROM scores will be evaluated between treatment types by the time in program.

10.8 Statistical Review

Name of statistician or person who prepared the statistical plan:	Department/Institution:	Date statistical review was conducted:

Hunter Sharp MS	HART	8.28.21

Note: The statistician or individual that prepared the statistical plan must also be included on the study team if they meet the definition of key research personnel (ex: significantly involved in the study design, conduct, or reporting of the research).

If a statistical review has not been submitted, explain why:

NA

10.9 Do you want to view the minimal risk exempt categories to determine if your research may qualify for exemption before completing the full application? Please note that determination of exemptions must be made by the IRB.

Your research may be Exempt from future IRB oversight if it only involves retrospective review of data (including Limited Data Sets), non-sensitive interviews or surveys, or falls into other minimal risk categories. If the research is determined to be exempt by the IRB, you will not be required to complete a full IRB application. If you complete the Exempt application and the IRB determines your research is not exempt, you will be required to complete the full IRB application.

○ Yes ◉ No

11.0 Subject Population

11.1 Please select the population(s) being targeted, or likely to be included in this research study. (select all that apply)

- ☐ Medical Chart Review of patients only (no in-person contact)
- ☐ Normal Adults/Healthy Volunteers
- ☐ In-Patient Population
- ☑ Out-Patient Population
- ☐ Patients in emergency situations
- ☐ Terminally ill patients
- ☐ Employees/Staff
- ☐ Students

- ☐ Children/Minors (anyone younger than 18 years of age in the state of Virginia. For research conducted outside of the state of Virginia, age of majority is dependent on state/local law)
- ☐ Prisoners
- ☑ Pregnant Women
- ☐ Fetuses
- ☐ Neonates of uncertain viability and/or nonviable neonates
- ☐ Adults with Impaired Decision-Making Capacity
- ☐ Persons with Limited-English proficiency (LEP) or Non-English Speakers
- ☐ Individuals of Childbearing Potential

11.2 Please indicate the total number of subjects anticipated to be enrolled at this site/by this investigator.

For the purposes of the IRB, a subject is enrolled once they have provided consent to participate, or for studies approved with a waiver of consent, once data has been collected on the subject.

200

11.3 If the research involves multiple subject groups or cohorts at this site, provide the anticipated number of subjects in each of group or cohort (e.g., control/experimental, adults/children, etc.).

wait-list (no intervention)- 100

wait-list (minimal intervention) - 100

11.4 Provide the age range for the proposed subject population (e.g., 0-5 years old):

18-99

11.5 Specify the inclusion criteria for each of the subject groups to be included in the research.

If there are multiple different groups being recruited with different eligibility criteria, instead add an Eligibility Criteria checklist for each group as a supplemental document after you complete this application. Please make note of this in the Inclusion Criteria below.

Order Number	Criteria
1	Although there are two wait-list conditions (no intervention vs minimal intervention), all potential subjects must be 18 years old or above and provide consent for randomization. Potential subjects must have the ability to complete PROMs either by cell phone or through email.
2	New adult ambulatory psychiatry patients seen in the psychiatry clinic between 11.1.21 and 4.5.22 assessed by the intake coordinator Ms. Ashlie Phenes.

11.6 Specify the exclusion criteria for each of the subject groups to be included in the research.

If there are multiple different groups being recruited with different eligibility criteria, instead add an Eligibility Criteria checklist for each group as a supplemental document after you complete this application. Please make note of this in the Exclusion Criteria below.

Order Number	Criteria
1	Patients who do not (or are unable to) provide consent for participation or do not have the ability to complete PROMs or watch microlearning videos remotely.
2	Intellectual disability or non-verbal
3	Patients with neurocognitive disorders who do not have the capacity to undergo informed consent and participate in the study

11.7 Is information being obtained about individuals other than the "target subjects" (such as a family member or colleague of the subject), making the other individuals "secondary subjects"?

○ Yes ◉ No

12.0 Pregnant Individuals, Individuals of Childbearing Potential, Breastfeeding Infants, Fetuses, or Neonates

12.2 Are there any additional risks to pregnant individuals by participating in this study?

If your research involves fetuses or neonates, please contact the IRB prior to submission.

○ Yes ◉ No

12.3 Are there any additional risks to individuals of childbearing potential, individuals who become pregnant, breastfeeding infant, or fetus or neonate by participating in this study?

○ Yes ◉ No

13.0 Informed Consent for Adult Subjects

13.1 How do you plan to obtain consent from ADULT subjects or their Legally Authorized Representative?

Check all that apply:

- ☑ Written consent document with signature (ie: obtaining signature from subject or Legally Authorized Representative)
- ☐ Waiver of written documentation of consent (ie: consent will be obtained through verbal confirmation from the subject or Legally Authorized Representative rather than through a signed document)
- ☑ Waiver of informed consent for minimal risk research (ie: typically appropriate only when the study does not involve any interaction or intervention with subjects)
- ☐ Waiver or alteration of the elements of informed consent (ie: research involving deception)
- ☐ Waiver of the informed consent document and process for PLANNED EMERGENCY RESEARCH. Contact the IRB before submission.
- ☐ No adults are being enrolled; this study is only enrolling children. (You will answer questions about the assent and parental permission process later.)

You must attach all consent forms, consent scripts, and information sheets in the Initial Submission Packet.

13.2 Is it expected that surrogate consent will need to be obtained from Legally Authorized Representatives (LARs) for some or all adult subjects?

○ Yes ◉ No

13.3 If the research includes more than one subject group or you have selected multiple responses above due to the inclusion of multiple subject groups, please specify the requested consent method for each group, or state N/A.

The requested data from normal standard of care PROM completions (11.1.21-4.5.22) does not include consent as it is part of our clinical care with all ambulatory patients.
The signed informed consent was obtained for all participants in the study from 4.6.22 to present today.

13.4 How will written consent be documented?

Click the Help bubble to the right for more information about requirements for eConsent before selecting this option.

- ☑ Traditional signed written consent form on paper document
- ☑ eConsent: signed via an REDCap or other electronic or web-based form
- ☐ Short Form Method (for non-English speaking subjects only)
- ☐ Other

13.5 Describe the process of obtaining consent and documenting the process, including the following:

- **Circumstances under which consent will be obtained, including how the potential participant will first be approached;**

- **Where the consent process will take place (ex: in person in a private clinic room, over the phone, through WebEx, etc.);**
- **When the consent process will take place and how long participants will be given to decide;**
- **If eConsent is being utilized, describe how you will first contact the potential participants and provide the consent form to them to review;**
- **Steps that will be taken to ensure voluntary participant and to minimize the possibility of coercion or undue influence;**
- **Any cultural considerations (ex: tribal or group permission requirements, age of majority, technological implications, etc.);**
- **If any participants do not speak English, whether a translator with witness will be used, whether translated materials will be used, whether the consent process changes based on the language;**
- **If multiple participant groups or consent procedures are to be included, these need to be clearly delineated;**
- **how participants will be provided with a copy of their signed consent;**
- **Describe the method you will use to document the consent PROCESS within each participants' research record /medical record (state which). This should include a process note or checklist that will document all the components listed above, the start and end time of the discussion, and is in addition to the signed and dated consent form (if applicable).**

For example, describe it consent will take place in the research office, in a private conference room, in the doctor's office, in a group setting, over the phone, etc.

The psychiatry intake coordinator contacts patients referred to the CC-P&BM ambulatory clinic over the phone, starting with the most remote referral.

Confirmation of patient identity using two identifiers will occur and the coordinator will ensure the patient has privacy to discuss referral, complete intake information, including PROM scores and then offer study participation. Emphasis is placed on psychiatric care which will occur even if the patient does not want to participate in the study and that there is no negative consequences if they do not want to participate. This assessment is preferred to occur by video (Amwell) and utilize remote e-consent procedures.

Alternatively, patients may be seen in the ambulatory psychiatry clinic in a private office with the coordinator or other IRB-approved team members while maintaining all COVID-19 precautions to discuss study participation and complete hard-copy or e-consent processes. ***The participant will also be required to answer multiple choice questions to demonstrate their understanding of the study before they sign the document.***

Guidelines for the intake coordinator assessment, including introduction and discussion of the wait-list study are attached to this application (Triage Program Working Details 10.22.21).

Econsent: The consent document will be created using a REDCap-based electronic consent form. The IRB-approved consent form will be developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users.

The IRB approved research team member (intake coordinator, LPC) will reach out to the participant to schedule time to talk over the phone or through Amwell. The study team will request verbal permission to send the eConsent via email or text so that the participant will be able to review before the call. The email/text will not include PHI. The investigator will first state:

"Carilion Clinic cannot control the security of email or text messages once we send them, therefore we need your permission to text or email you the link to the e-Consent form for the study we discussed. Please be aware that while the email title will not include your disease status or symptoms, the body of the email will contain the link to the study. Someone else accessing your email/text messages could click on the link and read the consent, and therefore learn about your disease status or symptoms, which you may consider to be of a private or sensitive nature. Do you still wish to receive the link to the e-Consent via email/text?"

The permission to send the consent form via text or email will be documented in the individual's research record.

Once the investigator is on the phone or Amwell call with the potential participant, the investigator will ask the individual to verify their identity by using a combination of questions, including name, date of birth, and their specialist provider name. A passcode will be created from the first 3 letters of the subject's last name and their provider's last name. The link to the eConsent form will sent to the participant and will be accessed on the potential subject's personal

electronic devices (e.g., computers, portable tablets, smart telephones). The investigator will enter the passcode in REDCap and the potential participant will enter the passcode in order to access the consent. The investigator and potential participant will discuss the study and review the consent form page by page. If there is another study team member available, or the participant has a family member nearby, they will be asked to observe as a witness. The investigator will encourage the participants to follow along in the document and ask questions. The investigator will give the potential participant as much time as they would like either on the phone or after the call before the signing the consent. The participant will be told they can call the investigator with any follow-up questions. The investigator will document on the form by signing their name that they reviewed the consent with the participant and will document the date of this discussion.

The participant will also be required to answer multiple choice questions to demonstrate their understanding of the study before they sign the document. *The questions will include: 1. Please describe the purpose of the study. 2. Please describe your responsibilities in the study 3. Please describe what you should do if you think you are injured by your participation in the study 4. Please describe what you should do if you wish to stop being in the study. The questions must be answered correctly before the participant may proceed to the next page. The investigator will ensure the code is accurate when reviewing the participant's signature. When the individual is ready to provide consent, they will type their name and then sign their name using their finger or stylus and will also be required to type the date of signature. They will be asked to provide their passcode number. They will then be asked how they would like to receive a copy of their signed consent. Once the consent form is signed and submitted, subjects will be able to receive a print-out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form. If the participant selected that they wish to receive an email copy of the signed consent, they should be presented with the following statement and confirm by providing their email address that they wish to receive via email.*

"Carilion Clinic cannot control the security of email messages once we send them, therefore we need your permission to email you the copy of your signed consent. Please be aware that while the email title will not include your [disease status], the attachment to the email will contain the study consent you have signed. Someone else accessing your email messages could click on the attachment and read the consent, and therefore learn about your disease status or symptoms, which you may consider to be of a private or sensitive nature. By providing your email address, you are authorizing Carilion Clinic to email you a copy of your signed form.

The process of obtaining consent will be documented within a process note by the person obtaining consent in the research record. This process note will include statements about:

- *the process of verifying the individual's identity over the phone and then with the eConsent signature;*
- *the method that was used to discuss the study with the potential subject (discussion happened over the phone, Amwell, etc.);*
- *the questions that the potential subject asked;*
- *whether a witness was required and present, and who the witness is;*
- *the time the potential subject was given to make their decision;*
- *how long the conversation lasted;*
- *how the participant received a copy of their signed document.*

We are now requesting access to the baseline retrospective data that exists prior to the study. No recruitment or consenting were completed during this SOC.

13.6 How will you ensure that subjects or LARs have sufficient opportunity to consider whether or not to participate?

Check all that apply:

- ☐ Subjects will be provided the consent form to take home for consideration prior to signing.
- ☑ Subjects will be allowed a waiting period to consider their decision.
- ☐ Other

Please specify waiting period:

48 hours-one week

13.7 How will the subjects' or LARs understanding of the consent information presented be assessed?

Check all that apply:

- ☐ Subjects will be asked to "Teach-Back" the study to the researchers
- ☑ Subjects will be asked open-ended questions about the research (purpose, procedures, risks, alternatives, voluntary nature)
- ☐ A tool or post-consent assessment will be used
- ☐ Other

Specify the "teach back" questions or open-ended questions that the subject will be asked to describe in their own words in order to assess their understanding.

Check for Understanding

1.I want to make sure that we have the same understanding about this research. Could you

please tell me what this project is about in your own words?

2.Would you please walk me through what will happen if you agree to be in this study?

Randomized (like a flip of a coin) to either complete psychiatric intake assessment with an intake coordinator, including completion of PROMs OR complete psychiatric intake assessment with an intake coordinator, including completion of PROMs initially and monthly until provider appointment, AND be encouraged to watch videos about symptoms the patient is experiencing to learn about emotional illness and treatment approaches

3.What do you understand as the benefits and risks of this study, if you join?

Benefits: assessment of your symptoms to better pair you with a provider and assure timely provider assessment and treatment initiation; you may help determine ways to triage referrals to psychiatry that will be more helpful to patients in the future

Risks: Completing measures of your symptoms may make you feel poorer emotionally as you complete them but the intake coordinator will be available to answer any questions or concerns and ensure you get timely provider assessment and treatment initiation

4.What will happen to you and your information if you decline to be a part of this study at any point?

You may withdraw at any point and your information will be destroyed. Your care at Carilion will not be affected.

5.Who will be able to see the information that you share with us?

Research Study Team and Carilion Clinic Institutional Review Board (IRB)

6.If you have any questions or concerns about the study, who will you contact?

Dr. Anita Kablinger

Answers to these questions are required to ascertain understanding prior to signing consent document.

13.8 Utilizing eConsent has additional requirements. Please describe the following:

- **The method to verify the identity of the individual providing consent;**
- **How participants will sign the eConsent (ex: type their name, use stylus or finger to sign);**
- **If potential participants will sign the consent while having a virtual conversation or if they will have additional time to consider their participation;**
- **If use of LAR is being requested, how you will ensure this individual is an appropropriate LAR per Virginia requirements and verify their identity.**

Verifying identification through two identifiers (name, DOB, address, contact info) over the phone, on Amwell or in-person

Sign econsent by typing their name

Sign the consent after virtual or in-person consultation either at the end of the initial discussion or up to one week for consideration of study involvement

LAR or witness NA for this study

13.9 If the enrollment of subjects who cannot read the consent form, due to visual impairment, literacy, or other issues, is anticipated, how will consent be obtained and documented?

Refer to 45 CFR 46.117(b)(2) or 21 CFR 50.27(b)(2) for information regarding when the use of a short form is appropriate. A witness to the consent process is needed.

- [x] N/A
- [ ] Short form
- [ ] Other mechanism
- [ ] Consent form read to participant with witness present

13.10 How will you ensure research participants remain informed about the study and continue to agree to participate in the research study after their initial informed consent has been obtained?

- [x] N/A

14.0 Request for Waiver, Alteration, or Waiver of Documentation of Consent for Adult Participants

14.1 Select the type of Waiver of Informed Consent or Alteration of Informed Consent being requested.

- ○ Full Waiver – Informed Consent will not be sought from any subjects or for any research activities
- ◉ Partial Waiver – Informed Consent will not be sought for some subjects (such as a historical cohort) or for some activities (such as for recruitment or screening)

14.2 General (46.116(d))
In order to waive the requirement for informed consent, the research must not be FDA-regulated and ALL of the following criteria must be met. If the waiver is only for recruitment or screening, justify the criteria for the waiver usage you are requesting.

☑	The research involves no more than minimal risk*. *Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	Please explain: request is to access clinical data of patients seen in ambulatory psychiatry for baseline research purposes; confidentiality regulations will be maintained
☑	The waiver or alteration will not adversely affect the rights and welfare of the subjects.	Please explain: as above
	The research could not practicably be carried out without the requested waiver.	Please explain:

☑	If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	as above - accounts for all ambulatory psychiatry patient data used for clinical purposes; # is impractical without waiver
☑	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	Please explain: post iTHRIV data results will be shared as part of the grant requirements

15.0 Privacy and Confidentiality

15.1 Does the research include interaction with or observation of subjects?

◉ Yes ○ No

15.3 Select the data points that will be reviewed, collected, recorded, or created for research purposes, including screening or recruitment.

Check all that apply:

- ☑ name
- ☑ 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:
- ☑ an element of a date, except year, for dates related to an individual, including birth date, admission date, discharge date and date of death; and all ages over 89 and all elements of such ages may be aggregated into a category of age 90 or older
- ☑ telephone numbers
- ☐ fax numbers
- ☑ electronic mail address
- ☐ social security number
- ☑ medical record number/ master patient index (MPI)
- ☐ health plan beneficiary numbers
- ☐ account numbers
- ☐ hospital account receivable (HAR)/contact serial number (CSN)
- ☐ certificate/license numbers
- ☐ vehicle identifiers, including license plate number
- ☐ device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ biometric identifiers, including finger and voice prints
- ☐ full face photographic images and any comparable image
- ☐ any other unique identifying number, characteristic, code
- ☐ None of the above

15.4 Will any of the above data points be reviewed, collected, recorded, or created from the medical record (or other healthcare records)?

◉ Yes ○ No

Since you plan to access or use PHI from the Medical Record, you must contact the HART Team at Carilion Clinic immediately to ensure the data you will need is accessible and to discuss data management and storage. Do not proceed with the submission of this application until you have done so.

15.5 Is the private information being requested the minimum necessary to meet the research goals?

(•) Yes ( ) No

15.6 Under the HIPAA Privacy Rule, when accessing or using PHI, a HIPAA Authorization of the subject must be obtained, or the IRB must grant a waiver.

Indicate which of the following apply (more than one may be selected):

- [x] The HIPAA Authorization is embedded in the research consent document.
- [x] A partial waiver of the requirement for HIPAA Authorization is requested (e.g., for screening or for some subjects, such as a retrospective cohort)
- [x] A full waiver of the requirement for HIPAA Authorization is requested
- [ ] The HIPAA Authorization will be sought but one or more required elements will be eliminated or altered
- [ ] The PHI accessed or used for this research is a Limited Data Set (LDS) and a Data Use Agreement (DUA) is or will be in place prior to accessing or obtaining the LDS.
- [ ] HIPAA Authorization will be obtained as a separate document (only permitted if required by sponsor)
- [ ] Other

15.7 Will educational records protected under the Family Educational Rights and Privacy Act (FERPA) be accessed or used for the research?

( ) Yes (•) No

15.8 Does the research involve the administration or use of surveys, interviews, or other evaluations or examinations protected under the Protection of Pupil Rights Amendment (PPRA)?

( ) Yes (•) No

15.9 Will the research records (other than the consent form) and/or specimens contain data that is identifiable, coded, or de-identified?

- [ ] Identifiable (includes direct identifiers or information such that subject identities could be ascertained)
- [x] Coded or linked (identifying information that would enable the investigator or collaborator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, etc., and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens)
- [ ] De-identified or unlinked (specimens/data cannot be linked to specific individuals by anyone, including the Carilion investigator, either directly or indirectly through coding systems)

15.10 Where will research data be stored during the period the research is active? Describe the security controls in place, including physical safeguards for paper records and technical safeguards for electronic records

Storage options other than those listed below are NOT currently permitted, including the use of Carilion provided or personal laptops, flash drives or other portable devices, non-Carilion cloud or other hosted environment. Any exceptions to the list above must be approved by the Carilion Privacy and Information Security Officer and documentation provided to the IRB.

- [ ]

Hardcopy data in a locked office in a locked cabinet

- [x] Electronic data on a password protected, secure drive on a Carilion server (contact mmtenzer@carilionclinic.org to set up a shared drive)
- [x] REDCap (contact mmtenzer@carilionclinic.org to discuss use of REDCap)
- [ ] Sponsor's electronic data capture system
- [ ] SPARC Carilion Secure Research Environment (contact mmtenzer@carilionclinic.org to discuss)

15.11 Provide any additional information pertaining to the storage and management of the research data.

Best research pratice is to have data management plan which will help you manage and protect your data, meet funder requirements, and help others use and protect your data, if shared. A well structured project can help protect the confidentiality of patient and participant data. Carefully planned data management also allows for a better use of your time and resources. For guidance on data management pratices, please review the Harvard Catalyst document and upload your data management plan into the Supplemental documents.

Intake coordinator will maintain a data collection sheet in a share drive for this purpose; all data and consents will be completed and stored in REDCap.

15.12 How long will research records, data, and specimens be retained following completion of the study? Where will study records will be retained when the study has been closed (long-term storage)?

Describe when and how the identifiers, if applicable, will be destroyed. If specimens will be retained, describe where.

Please note that any data involving PHI must be maintained for a minimum of 6 years, and data that does not contain PHI must be maintained for a minimum of 3 years. In many cases, identifiers will need to be retained after the research is completed (e.g., for publication or data verification purposes or because of contractual requirements or grant terms).

Please click the Help bubble to the right for more information on minimum storage requirements.

Records will be retained for 6 years post study

REDCap study data will be destroyed as per guidelines

Data in secure share-drive will be destroyed as per guidelines

15.13 Describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.) and indicate whether a linking file (key) will be created and, if so, how it will be protected.

sequential number plus EMPI - placed in REDCap build and on protected share drive

see data collection sheet attached to this application

15.15 Who will have access to identifiers?

Only IRB-approved Carilion team members

15.16 How will access to the identifiers be protected?

Password protected for REDCap

Secure access to share-drive for Carilion team members

15.17 Describe whether data will be aggregated/summarized in publications or presentation, or whether individual participant results will be published/presented.

Aggregated and summarized; no individual data will be presented or published

15.18 Will research records include information that subjects or others might consider to be sensitive in nature?

E.g.,communicable disease status, substance abuse, mental health information, illegal behaviors, etc.

(•) Yes ( ) No

Explain what sensitive information is included, why it is needed, and any additional safeguards that will be taken to protect it:

Patient-rated outcome measurements focus on psychiatric symptoms, substance use:

PHQ-9
GAD-7
BASE-6
USAUDIT
DAST-10

Owl Insights is a cloud-based platform for measurement based care (MBC) that enables patients to complete scales remotely for use in clinical care on a routine basis, by setting up a secure login and password.

The intake coordinator will assess symptom severity and safety risk at each step (initial assessment by phone, Amwell video or in-person and monthly scale measurements if randomized to minimal intervention group). An alert is automatically sent to the clinical team if the patient answers PHQ-9 question 9 (suicidality) with anything other than zero (0). Procedures for handling a patient at risk is outlined in the Triage Program details attached to this application and is identical to any clinical intervention done currently.

15.19 Do you plan to obtain a Certificate of Confidentiality (CoC) from NIH for this research or is one already in place (ex: for NIH-funded research) that covers this site and any recipient site or organization?

Per Section 2012 of the **21st Century Cures Act** as implemented in the **2017 NIH Certificates of Confidentiality Policy**, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC. Please note that for research that is not NIH-funded, the IRB may require you to obtain a CoC if it deems the data to be sensitive.

(•) Yes ( ) No

Please do not apply for the CoC until your study receives full IRB approval. Please reference the approval letter for instructions on completing this process. This should be done before enrolling subjects in the study.

16.0 Request for Partial Waiver, Full Waiver, or Alteration of HIPAA Authorization

16.1 Describe how the use of PHI in this study poses no greater than minimal risk to participants' privacy.

There is no recruitment for this data but currently exists in our OWL database.

PHI including name, EMPI # and DOB are part of the patient database in OWL - we request to download data from OWL between 11.1.21-4.5.22

16.2 Describe why the research could not practicably be carried out without the use of PHI.

This is retrospective data in our OWL database and does not involve recruitment.

16.3 Describe why the research could not be practicably carried out without the waiver or alteration.

The psychiatry ambulatory clinic sees approx 250-300 patients per week - the PROMs are completed as part of clinical care. This is retrospective data in our OWL database and does not involve recruitment.

16.4 Do you assure that any data identifying subjects used in this study will not be disclosed to anyone other than the research team, sponsor, and oversight groups?

(•) Yes ( ) No

16.5 Do you assure that you will not reuse or disclose this data for any other research unless you first receive IRB approval?

(•) Yes ( ) No

16.6 Describe how you will utilize PHI for purposes of recruitment and describe how the use of PHI in this study poses no greater than minimal risk to participants' privacy.

There is no recruitment for this data but currently exists in our OWL database.

PHI including name, EMPI # and DOB are part of the patient database in OWL - we request to download data from OWL between 11.1.21-4.5.22

16.7 Describe why the research could not practicably be carried out without the use of PHI for recruitment.

This is retrospective data in our OWL database and does not involve recruitment.

16.8 Describe why the research could not be practicably carried out without the partial waiver for recruitment.

The psychiatry ambulatory clinic sees approx 250-300 patients per week - the PROMs are completed as part of clinical care. This is retrospective data in our OWL database and does not involve recruitment.

16.9 Do you assure that any data identifying subjects used in this study will not be disclosed to anyone other than the research team, sponsor, and oversight groups?

(•) Yes ( ) No

16.10 Do you assure that you will not re use or disclose this data for any other research unless you receive IRB approval?

(•) Yes ( ) No

17.0 Research Settings/Performance Sites

17.1 Indicate the sites where research activities will occur, or from which subject data or specimens will be obtained, and a brief summary of the activities that will occur at each.

☐ N/A (Select this option if this research is a Medical/Chart Review ONLY)

	Site	Summary
☐	CRMH	
☐	CRCH	
	CNRVMC	

☐		
☐	CFMH	
☐	JCHS	
☑	CRMH Rehab	Patients seen in, or referred to, ambulatory psychiatry clinic
☐	Riverside	
☐	Crystal Spring Medical Office Building	
☐	Other Carilion Clinic Physician's Office	
☐	Blue Ridge Cancer Care (BRCC) / US Oncology	
☐	Fralin Biomedical Research Institute at VTC	
☑	VT Blacksburg Campus	VT colleagues are involved in data management and analysis but no patients or patient care occurs at this location
☐	Assisted Living Facility or Nursing home	
☐	Other Locations (specify):	

18.0 Applicable Regulations for ClinicalTrials.gov Registration

18.1 Is this study FDA-regulated?

○ Yes ◉ No

18.2 Is this research funded wholly or in part by NIH?

◉ Yes ○ No

18.3 Is this study a Clinical Trial, as defined by FDA or NIH, and therefore needing registration on ClinicalTrials.gov? Click the help button to the right to learn more about the definition of a clinical trial.

(•) Yes ( ) No

18.5 Is the clinical trial already registered in ClinicalTrials.gov?

(•) Not yet, but clinical trial will be registered prior to enrolling any subjects
( ) Yes
( ) No, this clinical trial will not be registered

ClinicalTrials.gov #:

Note: The following statement must be included verbatim in the consent form for trials that are/will be registered on ClinicalTrials.gov:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

18.6 Who is responsible for registering this trial in ClinicalTrials.gov and ensuring information is updated, as necessary? Please provide a name if the person is at Carilion or listed on the research team, or state the sponsor or lead site if the sponsor or lead site will register the trial.

The responsible party for an applicable clinical trial (ACT) must register the trial and submit results information. The responsible party is defined as:

- ***The sponsor of the clinical trial, as defined in 21 CFR 50.3; or***
- ***The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information***

The responsible party for an ACT must submit the required clinical trial information **no later than 21 days** after enrollment of the first participant, but registration is highly recommended before enrollment begins due to some journal requirements.

Anita Kablinger MD, CPI

19.0 Study Procedures

19.1 Provide a step-by-step description of the research procedures and/or and interactions with human subjects.

Provide a study schedule and list all activities or procedures that will be performed and describe the frequency and duration of research procedures, diagnostic and research tests, questionnaires or surveys, specimen collection, and experiments, including screening, intervention, follow-up etc in step-by-step chronological order. State the length of time subjects will be in the study and the expected amount of time required for each study visit or activity. Describe how, when and where research activities will be administered and analyzed. If the research includes blinding, indicate whether researchers or subjects will be "unblinded" to study assignment and describe when and how this will be done.

See Triage Program Working Details attached to this application for detailed description. Each survey is also included as attachments to this application.

Steps include:
The study will be introduced after the patient has completed the intake. At the end of the intake /assessment, the intake coordinator (team member) will describe the study to the potential participant and participant is able to confirm understanding about the study using the questions detailed in section 12.7. Consent is obtained either remotely or in-person, and a copy will be given to the patient in-person or emailed/mailed if remote. Introduction of the study will be, "We are researching if these measurements are helpful to people waiting for a psychiatric evaluation. Participation in the research is voluntary and you will be assigned randomly to either wait until your first appointment with your provider to complete these measurements again or complete these measurements every month until your first appointment with your provider." (The three measures they complete each month are the PHQ-9 depression, GAD-7 anxiety, and BASE-6 daily functioning). "Participation in this study is not linked to your psychiatric care – that is, it won't affect the wait-time to getting your initial appointment with your provider either way. Are you interested in participating in this study?"

1. If patient says yes, proceed to REDCap and complete consent process – you will need to set up a new participant record in RedCap and enter demographic information.
    1. Depending on which group the patient is assigned you will need to change the OWL Insights to not automatically send the inventories monthly if they are only in the 1x at onset group (no intervention).
2. Randomly assign patient into group (REDCap will do this when you start a new patient record); inform patient of the group they have been randomly assigned into to provide further instructions.
3. Provide all patients with CONNECT phone number at termination of the call.

Initial consenting process occurs after routine clinical psychiatry intake assessment by intake coordinator (if intake coordinator assesses that patient has capacity to pursue study discussion): 30-45 min consent process through REDCap or hard copy in-person. REDCap will be utilized to perform randomization. There is no blinding due to the nature of the wait-list control groups; both patients and investigators will be aware of study group assignment.

No intervention group randomization: no additional time/study procedures occur after consent; **SOC monthly PROMs DO NOT begin until after initial psychiatric provider evaluation for 6 additional months.**

Minimal intervention randomization: each month PROMs including PHQ-9, GAD-7 and BASE-6 are sent automatically for subject to complete via email or cell phone before initial psychiatric provider appointment - takes approximately 15 minutes to complete; watching microlearning videos about illness/symptoms takes approximately 15-30 minutes to watch depending on # videos recommended. Current wait-time for patients to see MD provider is 3-4 months; therefore, subjects in the minimal intervention group will participate in the study for up to 6 months before beginning regular treatment with provider.

PROM data from both groups will continue at initial psychiatric provider evaluation and monthly as is current clinical practice. Therefore, an additional 6 months of PROM data for each group will be followed to assess the research question of whether a no intervention or minimal intervention group may provide benefits to patients waiting to be seen and followed by psychiatric providers.

Total study participation time = 6-12 months depending on length of wait time before first psychiatric provider appointment

You must attach surveys, instruments, interview questions, focus group questions, etc. in the Initial Submission Packet and label them clearly.

19.2 Specify which procedures, tests, visits, etc. described above are part of usual standard of care at Carilion Clinic and which are being performed solely for research purposes. If procedures, tests, visits are routinely performed for clinical care, but are providing data for this research study, state this as well.

All surveys and microlearning education videos are part of routine clinical care in ambulatory psychiatry. The study focuses on how often the surveys are completed and how this may affect outcomes in ambulatory psychiatry visits and care.

Microlearning videos: Mytonomy
URL: **https://carilionclinic.org\learn**
Username: **carilion@mytonomy.com**

Password: Healthy2021

19.3 Describe the data collection methods and how data be compiled and collected for assessment. State whether the data/specimens to be utilized in the repository are already in existence (retrospective) or if the data will be generated in the future (prospective).

- **"Retrospective data" is data that is already in existence at the time of application receipt by the IRB. Retrospective is in reference to the date the data was GENERATED, not the date the data is COLLECTED. If all data is retrospective, please provide the start date from which data will be collected and the end date, and note that ALL data must be in existence at time of submission of this application.**
  - **Example: This IRB application is being submitted on 12/1/21 and is collecting data on a standard of care surgery and looking at patient outcomes. All surgeries for this retrospective studies will be completed between 11/31/2018 and 11/31/2021 (the day before the study is submitted to the IRB). This study will likely qualify for a waiver of consent.**
- **"Prospective data" includes any data (including data from the medical record) that are not currently in existence at the time of receipt of the application by the IRB, even if the data is being collected solely for Standard of Care. Prospective data collection typically requires informed consent from the participant to be able to use their clinical data or specimens for research purposes. If all data is prospective, please state date range from which data will be generated.**
  - **Example: This IRB application is being submitted on 12/1/21 and the study is collecting data on a standard of care surgery and looking at patient outcomes. All surgeries for this prospective studies will be completed between 1/1/2022 and 1/1/2025. This study will require informed consent UNLESS a waiver of consent is requested and justified.**

Attach a copy of your data collection tool or spreadsheet listing exactly what data is to be gathered during this research study.

The intake assessments beginning 10/25/21 are Standard of Care (SOC). This data would not be included in this proposed study/consent because only NEW patients being referred/assessed by the intake coordinator are part of the study. If patients have already been assessed and are waiting for a provider appointment they are not part of any study. This data between 10/25/21 and date of IRB approval for this study would be requested in an amendment should the investigators want to include this preliminary SOC data.

Data collection sheet source document attached to this application.

Psychiatry intake assessments began October 25, 2021.

This study, with randomization to wait-list control groups (no intervention vs minimal intervention), will begin once IRB approval and REDCap build has been completed - estimate by end of January 2022.

Retrospective data involving initial psychiatric intake and intake PROM completion scores beginning October 25, 2021 may be requested as a future amendment after approval of this study.

19.4 Describe how long individual participants will be actively in the study. If there will be a period of time after the active component of the study where participants will still be in the study (ex: participants outcomes are being extracted from the medical record at 1 year, but the last research study visit was at 3 months), state this as well.

Participants will be active in the study for 6-12 months - monthly PROMs will be collected for 6 months after initial psychiatric provider assessment in addition to wait-time prior to first appointment.

19.5 Describe how long the entire study is expected to last, including data analysis.

The entire study including data analysis will be two years (estimate 12.1.21-11.30.23 estimate based on date of IRB approval) - iTHRIV funding is approved for 2.1.22 to 1.31.23.

19.6 Describe the qualifications of study personnel conducting the research procedures. This could include medical training specific to conducting the interventional procedures in this research, phlebotomy training for those drawing blood, study protocol specific training to be provided by the sponsor, or any other training to demonstrate that the research personnel

are appropriately quailified to conduct the study.

Ashlie Phenes is an LPC with psychiatric care experience

Drs. O'Brien, Kablinger, McNamara are physicians in psychiatry with experience in psychiatric care and research using PROMs

Mattie Tenzer and Hunter Sharp are part of HART and have experience with study design and analysis of PROMS from Owl Insights

Lee Cooper, Alyssa Gatto, Sydney Jones and Hayoung Ko (external collaborators) are psychology providers and educators who, not only utilize PROMs in their own practice - though none of their patient population is included in this study - and have been part of our MBC research team for the past 2 years

19.7 Please describe appropriate alternatives to the study procedures or course of treatment.

(For example: not to participate, standard of care treatment, other research study, same treatment offered off study)

Alternatives are not to participate in the randomized study. PROMs, however, are utilized in routine patient care and would continue to be assigned to, and completed by, ambulatory patients in the psychiatric clinic.

20.0 Research Review of Data/Records

20.1 What types of records will be reviewed for this research study?

- [x] Medical record/medical chart
- [ ] Films/x-rays
- [x] Data in a database
- [ ] Hospital administrative/billing records
- [ ] Quality improvement records
- [ ] Publically available database
- [ ] Other

Provide a detailed description about your selection above, including if the records are already in existence at the time of this submission or if you will be accessing future records, and special permissions that may be needed to access the data/records:

EMR review for initial psychiatric intake assessment (part of routine care) with PHI elements put into REDCap for research purposes. Owl Insights is a cloud-based system that provides PROMs and is a database of PROM measures for the past 2.5 years in our ambulatory clinic. Over 100,000 individual PROMs have been completed to date by patients in ambulatory psychiatry.

20.2 What is the original purpose of the data being reviewed?

- [x] Clinical Care
- [ ] Collected as part of routine business activities
- [ ] Research Study
- [ ] Collected under Repository Protocol
- [ ] Other

20.3 If collected as part of a previous research study or repository protocol, enter the IRB number for the study.

20.4 Is the data identifiable private information or Protected Health Information (PHI)?

- (•) Yes
- ( ) No

21.0 Incidental Findings

21.1 Does this study involve any imaging procedures (x-rays, CT, MRI, PET, ultrasound, etc.) specifically for research purposes?

○ Yes ◉ No

21.2 Does the research include any of the following?

- ☐ Exams, blood tests, genetic tests or markers, or other tests or procedures that may generate incidental or secondary findings, including disease or conditions other than the one under study, or familial relationships including paternity and ancestry.
- ☐ Testing for communicable diseases
- ☑ None

22.0 Identification/Recruitment of Subjects

22.1 How do you plan to identify potential subjects?

To "identify" a potential subject refers to procedures to determine which individuals may qualify to participate in the study in order to decide which individuals to contact about taking part.

Check all that apply:

☑	Existing Record Review, including Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review.	Select all that apply: ☑ Patients' records reviewed will be those from research team's own patient population ☑ Patients' records will be those from other physicians or medical practices' patient population ** You must request Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of HIPAA Authorization for recruitment purposes.*
☐	Researchers who ARE NOT treating clinicians of potential subjects will ask treating clinicians for referrals of eligible patients interested in the study.	Select all that apply: ☐ Treating clinicians will identify potentially eligible patients and obtain patient permission before providing researchers with patient contact information. ☐ Treating clinician will provide documentation of patient permission in a email/letter to researcher, and researcher must

		document permission in research record. **You must request a Waiver of Informed Consent/HIPAA Authorization for recruitment purposes.*
☐	Potential subjects will not be directly identified by the researchers from existing records. The potential subject will obtain IRB-approved information about the study from an advertisement, flyer, brochure, website, grand rounds presentation, department meeting, etc. In most cases, the potential subject will contact the researcher if interested.	Comments:
☐	Review of Registry/Database in which individuals have previously signed a consent giving their permission to be contacted for future studies.	Comments:
☐	Student Records	Comments:
☐	Other	Please specify other:

22.2 Please describe the identification process.

List all information you plan to collect and record during the identification process PRIOR to contacting potential subjects. This includes the inclusion/exclusion criteria and demographics to determine if a person qualifies for a study before contacting that person to be a potential subject.

No information will be collected specifically for the study prior to contacting the person.

The psychiatry intake coordinator will call all people referred to adult ambulatory psychiatry and complete an intake assessment. Once the assessment is completed, patients will be asked if they would like to participate in the wait-list study and be randomized to either a no intervention group (no further interaction between intake and first clinician appointment) or to minimal intervention group (patients will receive monthly reminders to complete PHQ-9, GAD-7 and BASE-6 and be assigned micro-learning videos to view during the wait-time for their first clinician appointment).

A waiver of informed consent/HIPAA authorization is requested for recruitment purposes only.

22.3 Through what methods will potential subjects be contacted or recruited?

Check all that apply. To "recruit" a potential subject refers to the initial contact method you plan to use to convey information to a potential subject to determine if he or she would be interested in taking part in your study.

- ☑ Direct in-person contact
- ☑ Telephone call
- ☐ Letter

- [ ] E-mail
- [ ] Brochure
- [ ] Radio/Television script
- [ ] Newspaper Ad
- [ ] Online advertisement (including Facebook, Twitter, Craigslist, other websites, etc.)
- [ ] Flyer/Poster
- [ ] Snowball sampling
- [ ] Clinical trial website posting
- [ ] Other
- [ ] None (there will be no interaction or intervention with potential participants in this study)

22.4 Please provide any additional details about how potential subjects will initially be contacted, who will contact them, or how they will be introduced to the research.

- ***If recruitment material is being mailed, emailed, or otherwise distributed, describe where/how the distribution list will be obtained.***
- ***If potential subjects will be recruited by telephone, describe how many times the research team will attempt to call / leave a voice message.***
- ***When subjects respond to recruitment material, describe the information that will be provided to them about the study and the information that will be collected from subjects (e.g. name, telephone number, etc.). Describe also, how many times you will attempt to respond to call the subject back / leave a voice message.***

Please see section 17.1 and the Triage Program Working Details 12.1.21 document attached to this application.

22.5 After potential subjects are identified, describe the pre-screening process that will take place prior to obtaining informed consent.

This could include asking questions to a potential subject to determine whether he or she meets eligibility criteria, for example: patients will answer questions about their medical history, be expected to come to the first screening visit after fasting, stop taking medications, change diet, etc. To comply with HIPAA regulations, only the minimum necessary protected health information may be collected at this time. This means only questions relating to the inclusion and exclusion criteria may be asked.

- [ ] No prescreening will take place

The psychiatric intake coordinator will call all adult psychiatry referrals to perform a psychiatric intake and triage prior to an initial psychiatric provider appointment. At the end of the intake, and in the clinical judgment of the intake coordinator, patients capable of consenting to this study will be offered participation and undergo an informed consent process either over the phone, through Amwell or in-person. Consenting may be completed via econsent or hard copy consent. Patients unable to complete PROMs via cell phone or email (or have no internet access) are not eligible to participate in the study.

22.6 Indicate whether pre-screening information will be retained on persons who do not ultimately participate in the study and what specific information, including identifiers, will be retained.

Pre-screening information will be kept to ascertain the percentage of people who are unable to participate due to lack of ability to complete PROMs or who do not have the capacity for informed consent.
Demographics of these individuals (including age, gender, reason for not participating) will be maintained to compare to the groups of individuals who do participate and assess differences.

Attach all recruitment materials, letters, phone scripts, flyers, etc. in the Supplemental Documents section after you complete the IRB application.

23.0 Risks and Risk Minimization and Benefits

23.1 List the possible risks, discomforts, or harms to subjects associated with the research.

If the risks differ based on group assignment, describe for each group. Estimate the (1) probability of occurrence, (2) the seriousness, and (3) the duration of each risk. If this information is captured in the protocol or investigators brochure (IB) or other materials, indicate the document and page numbers where the information can be located.

Possible risks or discomforts to subjects include a minimal risk of security/data breach of mental health information and change in emotional symptoms and functioning from completing surveys or watching education videos.

Outside collaborator (Hayoung Ko from VT) is requested to have REDCap access - to minimize risk of security breach, training in maintaining security measures will be implemented. As a psychology graduate student, Hayoung is aware of the importance of maintaining confidentiality for those with mental illness. However, to decrease the risk of breach, REDCap access for Hayoung will be to collected data that DOES NOT include PHI.

The most severe risk of change in emotional symptoms is to have suicidal ideation. Alerts for any answer > 0 on question 9 of the PHQ-9 will be immediately emailed/texted to the intake coordinator or the primary provider (if the subject has begun treatment with the psychiatric provider). Crisis intervention for safety concerns is a part of the intake coordinator's training and specific step-by-step interventions are included in the Triage Program Working Details 12.1.21 attached to this application.

23.2 Define adverse events (AEs), serious adverse events (SAEs), and unanticipated problems (UAPs) for the study. Describe the protocol-specific reporting procedures, including who will be responsible for each step (e.g., PI), timeframes for reporting, how reports will be distributed, and follow-up that will occur.

Ensure that the reporting procedures meet the reporting requirements of Carilion Clinic IRB, the FDA, NIH, OHRP, sponsor, study leadership and any other regulatory body that applies to the study, as applicable. Please note that all Carilion Privacy breaches must also be reported to the Privacy office by the PI. Noncompliance must be reported to the IRB as well as Office of Integrity and Compliance.

Unanticipated problems are security/data breach of mental health information. Safeguards to access data will be put in place as above.

AEs include suicidal ideation - see previous section for how safety concerns are addressed by intake coordinator. All alerts will be assessed and handled by the intake coordinator and communicated with Drs. O'Brien or Kablinger. In addition, all contacted patients have the phone number for CONNECT to address urgent needs 24/7.

The study team will notify the IRB and Privacy Office of any breaches of confidentiality within 48 hours of identification.

23.3 Describe the actions that will be taken to minimize the risks associated with participation in this research.

If this research includes risks that might require immediate or prompt medical management, describe access to/availability of emergency medical equipment and trained personnel at each setting where procedures that impart physical/health risks will take place. If this information is available in the study protocol indicate the page numbers where the information can be located.

Please see section 20.1 and 20.2

23.4 For studies involving drugs, devices, biologics, or imaging, describe the type of pregnancy testing that will occur and how frequently it will be conducted on women of reproductive potential.

Include:

- ***If pregnancy testing will not be conducted, provide the reason.***
- ***State the types of birth control methods women of reproductive potential will be instructed to use.***
- ***If women will not be instructed about acceptable methods of birth control, provide the reasoning.***
- ***Describe the birth control methods men of reproductive potential will be instructed to use. If men will not be instructed about acceptable methods of birth control, provide the reasoning.***

NA

23.5 Does the research include screening tools, questionnaires, or procedures that may indicate the presence of serious depression and/or suicidal ideation?

(•) Yes ( ) No

Describe the criteria that will be used in the screening tools/questionnaires to determine if the participant is considered to be at risk. Describe or upload the plan to refer or intervene in the event that potential serious depression and/or suicidal ideation are identified.

Tiered Levels of Severity of PROMs:
Tier 1: (severe) PHQ-9 = 21-27, or GAD-7 =17-21, or Suicidal Ideation (Q9 >0)
Tier 2: (moderate) PHQ-9 = 16-20, or GAD-7 = 11-15
Tier 3: (mild) PHQ-9 =11-15 or GAD-7 = 6-10
PHQ-9 <11, GAD < 6 (normal to minimally ill)

Tier 1 severe - patient will be put at the top of the referral list for sooner appointment time (if currently safe), otherwise crisis intervention occurs as below.

If patient answers "yes" to question 9 (ie >0) on the PHQ-9, or reports suicidal ideation, ask follow-up questions regarding this: provide number to CONNECT, offer number to the National Suicide Hotline, complete a wellness check if necessary.

1. National Suicide Hotline: 1-800-273-8255
2. CONNECT: (540) 981-8181
3. Roanoke County Wellness Check: (540) 562-3265
4. Roanoke City Wellness Check: (540) 853-2212
5. Emergency/Actively Suicidal: 911

23.6 Describe the Data Safety Monitoring Plan or Data Safety Monitoring Board, or indicate the page(s) of the protocol or name of the document where this information can be located. While a robust Data Safety Monitoring Plan is REQUIRED for greater than minimal risk studies, a plan should also be in place for studies that are minimal risk. Please click on the Help circle to the right for information on writing a DSM plan based in risk levels of the research.

Include:

- ***The data that will be reviewed, including safety data, untoward events, and efficacy data;***
- ***Who is responsible for reviewing the data;***
- ***How the safety information will be obtained and documented (e.g., case report forms, by telephone calls with participants, printouts of laboratory results, etc.);***
- ***The frequency or periodicity of review of cumulative data;***
- ***The statistical tests for analyzing the safety data to determine whether harm is occurring;***
- ***Any conditions that trigger an immediate suspension of the research or other action for the research.***

Patient data related to the wait-list and triage program (including study participants) - the intake coordinator will review weekly with Dr. O'Brien as ambulatory psychiatry director.

A data safety monitoring plan includes assessment of PROM trends and any apparent safety /efficacy concerns. Drs. O'Brien and Kablinger will review accumulated data and communicate and address any untoward events.

23.7 Describe the plans and rationale for conducting an interim analysis.

○ Yes ◉ No

23.8 Have stopping rules been established for the study, including for reasons of futility?

○ Yes ◉ No

23.9 Are there defined criteria (ex: rates of adverse events) for when study interventions should be discontinued?

○ Yes ◉ No

23.10 Are there exams or procedures that the subject will be asked to have done or follow to safely withdraw from the study?

○ Yes ◉ No

23.11 Will subjects who withdraw from the interventional component of the study be asked for their permission to continue to gather information about them through follow up visits, phone calls, records review, or other methods?

○ Yes
○ No
◉ N/A

23.12 Describe the potential benefits to science and/or society expected from this research.

Evaluating PROMs in patients seen in a psychiatric outpatient clinic wait-list will provide important information about abilities to provide intervention while waiting for psychiatric provider appointments.

Results can inform wait-list groups for pending psychiatric care around the country in different systems.

23.13 Are individual subjects expected to directly benefit from participating in this research?

Note: Compensation is not considered a benefit.

◉ Yes ○ No

Please explain:

Intake with a coordinator to triage appointment needs in conjunction with completion of PROMs may show direct benefit to subjects by ensuring timely evaluations and safety assessments with those referred and interested in psychiatric care.

24.0 Costs and Compensation

24.1 Will the subject, or the subject's insurance, be responsible for any medical costs incurred as a result of participation in the research?

Take into account medical costs associated with study procedures, drugs, or devices.

○ Yes ◉ No

24.3 Will subjects be reimbursed for any expenses related to their research participation, including medical costs, travel, parking, or transportation?

○ Yes ◉ No

24.4 Will subjects receive any monetary compensation (cash, check, or giftcard) or non-monetary gifts, incentives, or tokens of appreciation for participating in this research?

Note: Reimbursement for costs is not considered compensation. Use of raffles or lotteries are discouraged at Carilion Clinic since the compensation is not being equitably dispersed to participants. Raffles and lotteries may be permitted on a case-by-case basis with appropriate justification.

○ Yes ◉ No

25.0 Application Questions Complete

25.1 You have now completed the IRB Application. Please click Save & Continue to proceed to the Initial Submission Packet.

Date Completing Form:

03/16/2023

The Initial Submission Packet is a short form filled out after the IRB application has been completed and is where you will attach protocol-related documents, such as consent forms and recruitment materials. You will also be able to conduct a final review of the IRB application.

The PI will be required to sign off on the final Initial Submission Packet. The study may then proceed to the Department Signoff, if necessary based on the application type selected, and may require COI review before proceeding to the IRB.

You can view the Submission History of the study at any time to determine the status.